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Acknowledgement Letter

05/03/2023

Robert Steurer, Consultant
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Dear Robert Steurer:

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AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram : Part IV: The ST Segment, T and U Waves, and the QT Interval. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society

Pentti M. Rautaharju, MD, PhD; Borys Surawicz, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC

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AHA/ACCF/HRS Scientific Statement

AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram

Part IV: The ST Segment, T and U Waves, and the QT Interval

A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society

Endorsed by the International Society for Computerized Electrocardiology

Pentti M. Rautaharju, MD, PhD; Borys Surawicz, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC

The present article is the fourth in a series of 6 documents focused on providing current guidelines for the standardization and interpretation of the electrocardiogram (ECG). The project was initiated by the Council on Clinical Cardiology of the American Heart Association. The rationale for this project and the process for its implementation were described earlier.[1]

Abnormalities in the ST segment, T wave, and duration of the QT interval reflect abnormalities in ventricular repolarization. These abnormalities are common and often difficult to interpret. The U wave most likely represents an electric-mechanical phenomenon that occurs after repolarization is completed. However, it is frequently included in discussions of repolarization and is discussed in this section.

The ST segment corresponds to the plateau phase of the ventricular transmembrane action potential. Under normal conditions, the transmembrane voltage changes slowly during this phase and remains at approximately the same level in all ventricular myocardial cells. As a result, only small voltage gradients are present. This absence of pronounced voltage gradients is similar to that which occurs during electric diastole, ie, from the end of repolarization to the onset of the next depolarization, when ventricular myocardial cells are at their resting transmembrane potential of approximately −85 mV. This corresponds to the TP segment on the ECG. The absence of significant voltage gradients in ventricular myocardial cells during these 2 phases of the cardiac cycle explains why the ST and TP segments are normally nearly flat and at approximately the same level; that is, they are isoelectric.

The T wave corresponds to the phase of rapid ventricular repolarization (phase 3) of the ventricular action potential.

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The American Heart Association, the American College of Cardiology, and the Heart Rhythm Society make every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

Parts I and II of this series, "Recommendations for the Standardization and Interpretation of the Electrocardiogram," were published in the March 13, 2007, issue of *Circulation* (*Circulation.* 2007;115:1306–1324 and 1325–1332). They are available online at http://circ.ahajournals.org/content/vol115/issue10/

Parts III, IV, V, and VI of this series are available online at http://circ.ahajournals.org/content/vol119/issue10/ (*Circulation.* 2009;119:e235–e240; e241–e250; e251–e261; and e262–e270). They also published ahead of print February 19, 2009.

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During this phase, the transmembrane action potential repolarizes from its plateau voltage of approximately 10 to −10 mV to its resting level of approximately −85 mV. The interventricular and intraventricular voltage gradients created as the cells undergo rapid sequential repolarization generate the T wave on the body surface ECG. The configuration of the T wave is determined by the spatial-temporal characteristics of ventricular repolarization, particularly the asynchrony of phase 3 of the ventricular action potentials. Our knowledge of these characteristics is still incomplete. In general, repolarization proceeds from epicardium to endocardium, that is, opposite to the direction of ventricular depolarization,[2,3] and probably, like during excitation, a significant fraction of simultaneous repolarization wave fronts are mutually canceled. The difference in the spatial sequence of depolarization and repolarization in the left ventricular free wall reflects the observation that there tends to be an inverse relationship between activation time and action potential duration.[4] The action potential duration of epicardial cells is shorter than that of the endocardial and midmyocardial cells.[5] In addition, it is known that inhomogeneities of repolarization occur over relatively short distances on the surface of the ventricles and most probably also within the ventricular wall.[5,6] It is probable that some of these inherent action potential differences are the result of electrotonic interactions during repolarization.[7]

Abnormalities in the ST segment and T wave are caused by abnormal voltage gradients during the plateau and rapid repolarization phases of the action potential and by changes in the sequence of repolarization that may occur both with and without abnormal voltage gradients. These abnormalities are often associated with a variety of well-defined anatomic, pathological, physiological, and pharmacological events.

In this section, we address several issues relative to the measurement, description, and interpretation of ST segment, T and U waves, and QT interval. They include the distinction between primary and secondary repolarization abnormalities, appropriate descriptive and interpretive terminology, and measurement of the QT interval and its adjustment for rate, gender, and QRS duration.

Distinction Between Primary and Secondary Repolarization Abnormalities

Abnormalities in the ST segment and T wave, which are the result of changes in the shape and/or duration of the repolarization phases of the transmembrane action potential and occur in the absence of changes in depolarization, are referred to as primary repolarization abnormalities. They may be localized or diffuse and may be caused by a variety of events, including ischemia, myocarditis, drugs, toxins, and electrolyte abnormalities, particularly abnormalities of serum calcium and potassium. An abrupt change in heart rate, hyperventilation, changes in body position, catecholamines, sympathetic stimulation or ablation of the stellate ganglion, and temperature changes also can cause primary repolarization abnormalities.[8,9]

Abnormalities in the ST segment and T wave that occur as the direct result of changes in the sequence and/or duration of ventricular depolarization, manifested electrocardiographically as changes in QRS shape and/or duration, are referred to as secondary repolarization abnormalities. These changes do not require changes in the shape or duration of phase 2 and phase 3 of ventricular action potential of individual cells. Rather, they may be due to voltage gradients that are normally largely canceled but become manifest when the changes in the sequence of depolarization alter the repolarization sequence. The ST- and T-wave changes that occur in association with bundle-branch blocks, ventricular preexcitation, and ectopic and paced ventricular complexes are examples of secondary repolarization abnormalities.

The classic ventricular gradient concept introduced by Wilson et al[10] in 1931 is of some theoretical interest concerning primary versus secondary repolarization abnormalities. Ventricular gradient in a single ECG lead is the net time integral of the ECG voltage from the beginning of the P wave to the end of the U wave. Its spatial counterpart is the ventricular gradient vector determined from the orthogonal XYZ leads. The practical utility of the ventricular gradient in differentiating primary from secondary repolarization abnormalities has not been demonstrated.[11] When the direction of the QRS axis is normal, an abnormal direction of the T-wave axis is generally an indication of primary repolarization abnormalities.

Recognition of secondary repolarization abnormalities is usually not difficult. In left bundle-branch block, the ST-segment and T-wave vectors are generally directed opposite to the mean QRS vector. In right bundle-branch block, they are directed opposite to the slow terminal component of the QRS complex. In ventricular preexcitation, ST-T changes are directed opposite to the delta wave of the QRS complex. The magnitude of the ST-T change is dependent on the magnitude of the QRS-waveform changes when the excitation pathways change.

The secondary ST- and T-wave changes associated with transiently altered ventricular conduction such as those that occur with ectopic ventricular complexes or transient bundle-branch blocks usually revert promptly to the pattern that existed before the ventricular conduction changes developed. However, some secondary repolarization changes take longer (hours or days) to develop and to dissipate. The repolarization changes associated with prolonged ventricular pacing are examples of this phenomenon.[12]

Primary and secondary repolarization abnormalities may occur concurrently. For example, ventricular hypertrophy is associated with changes in the shape and duration of the ventricular action potential of isolated ventricular cells, particularly on the endocardial surface.[13] These changes may contribute to ST- and T-wave changes and are independent of the changes that are secondary to QRS-amplitude changes and prolongation of the QRS complex. A combination of primary and secondary repolarization abnormalities should also be considered when T-wave polarity does not change as anticipated by the changes in the QRS complex.

Recommendation

The distinction between primary and secondary repolarization abnormalities is clinically relevant because primary abnormalities indicate changes in the repolarization charac-

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teristics of ventricular myocytes whereas secondary changes do not. The designation of the ST- and T-wave abnormalities as primary or secondary is appropriate, and it is recommended that automated interpretative algorithms be programmed to identify them.

ST-Segment Abnormalities

ST- and T-wave amplitudes are referenced against the TP or PR segments of the ECG. When low-frequency filtering is done in ECG acquisition to remove baseline drift, the actual DC voltage levels of various ECG waves or segments cannot be determined. Thus, elevation of the ST segment may reflect PR/TP depression, true ST elevation, or both; conversely, ST depression may reflect PR/TP elevation, true ST depression, or both.[14–16] When considering deviations of the ST segment, one should bear in mind total QRS amplitude because this variable also affects the amplitude of ST-segment abnormalities. Displacement of the ST segment is usually measured at its junction with the end of the QRS complex, the "J point," and, in some settings such as exercise testing, 40 and up to 80 ms after the J point. The ST segment can be described as elevated, depressed, upsloping, horizontal, or downsloping. In addition, the magnitude of abnormal deviations and the leads showing them should be identified. A depressed ST segment may be further characterized as horizontal, downsloping, or upsloping (rapidly or slowly).

Elevation of the ST segment in leads V_1, V_2, and V_3 should be referenced against the elevation that occurs normally in these leads and is greater in young and middle-aged males than in females[17–21] and greater in blacks than in whites.[21] ST elevation is usually most pronounced in chest lead V_2. The upper normal limit for J-point elevation in V_2 varies to a certain degree in various reference sources, probably largely as a result of differing selection criteria for the normal group. One reference source[20] reports the upper 98th percentile normal limit as approximately 0.3 mV in white men less than 40 years of age (up to 0.33 mV in the 24- to 29-year age group) and approximately 0.25 mV in white men 40 years old and older. The corresponding limits for white women remained relatively unchanged with age, staying at approximately 0.15 mV.

Another reference source[21] lists normal limits for J-point and ST_{60} (ST at 60 ms past the J point) amplitudes for white and black men and women 40 years old and older in 2 age groups. The upper normal limit (98th percentile) for J-point amplitude in V_2 was approximately 0.15 mV in white men and 0.20 mV in black men. The corresponding limits were approximately 0.10 mV for white women and 0.15 mV for black women. The upper normal limits for ST_{60} in V_2 were approximately 0.3 mV in white men and approximately 0.35 mV in black men. The corresponding limits were approximately 0.2 mV in white women and approximately 0.25 mV in black women.

Evaluation of ST elevation is of particular concern in connection with myocardial ischemia in acute myocardial infarction, as discussed in detail in part 6 of this series of recommendations (Acute Ischemia/Infarction). The threshold value for abnormal J-point elevation in V_2 and V_3 recommended in that part is 0.2 mV for men 40 years of age and older and 0.25 mV for men less than 40 years of age. The recommended threshold value for adult women in V_2 and V_3 is 0.15 mV. The threshold recommended for abnormal J-point elevation for men and women in all other standard leads is 0.1 mV. These threshold values appear to be an appropriate compromise for practical clinical use in the evaluation of ST elevation.

In the evaluation of ST elevation, it is important to consider ST-segment waveform in addition to the normal limits for ST amplitudes. The ST segment in normal J-point elevation in V_2 and particularly V_1 is generally sloping down steeply. Normal ST elevation at 60 ms past the J point is combined with an upsloping ST segment rather than with the more horizontal ST segment present in myocardial ischemia.

The reference values established in adequately large population-based normal groups stratified by age, gender, and race should be incorporated into computer-ECG ST-segment classification algorithms to avoid the inappropriate diagnosis of injury currents associated with myocardial ischemia, myocardial infarction, or pericarditis.

ST-segment elevation can most often be attributed to 3 specific causes: (1) a normal variant, frequently referred to as *early repolarization*, commonly characterized by J-point elevation and rapidly upsloping or normal ST segment; (2) injury currents associated with acute ischemia or ventricular dyskinesis; and (3) injury currents usually associated with pericarditis. Criteria exist to differentiate these causes[22–24] and should be incorporated into the descriptive and diagnostic algorithms of the various computer-ECG algorithms. However, it is important to recognize that in practice it is often difficult to differentiate between them. In addition, a variety of other conditions may be associated with ST-segment elevation.

ST depression may be caused by various physiological, pathological, and pharmacological interventions that change the plateau phase of the ventricular action potential. Examples include the effects of ischemia, hypokalemia, and a variety of cardiac and noncardiac drugs. These are primary ST-segment changes. Depression of the ST-segment also may occur concurrently with T-wave changes. Examples include the ST-segment depression associated with hypertrophy and, as secondary repolarization abnormalities, in ventricular conduction disturbances.

The ST-segment changes on the standard ECG that are associated with acute ischemia or infarction are due to the flow of current across the boundary between the ischemic and nonischemic zones referred to as *injury current*. ST-segment elevation generally occurs with reciprocal ST depression in ECG leads in which the axis is opposite in direction from those with ST elevation. These ST-segment abnormalities are discussed in part VI (Acute Ischemia/Infarction),[66] which gives −0.05 as the recommended threshold value for abnormal J- point depression in leads V_2 and V_3 in men and women and −0.1 mV in all other leads.

Consideration of ST-segment changes as a response to exercise stress testing is outside the scope of the present working group.

Recommendation

Although it may be difficult to differentiate various causes of ST-segment abnormalities, the ECG interpretative report

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should include a qualitative description of the ST segment with due consideration of the age and gender of the patient, including a note if ST depression is 0.1 mV or more pronounced. One or more of the possible causes, depending on the presence of other ECG abnormalities and the knowledge of any pertinent clinical information, also may be included. For evaluation of ST elevation, reference values established in adequately large population-based normal groups stratified by age, gender, and race should be incorporated into computer-ECG ST-segment classification algorithms to avoid the inappropriate diagnosis of injury currents associated with myocardial ischemia/infarction or pericarditis.

T-Wave Abnormalities

Just as ST-segment segment abnormalities can occur with or without T-wave abnormalities, T-wave abnormalities can occur in the presence or absence of ST-segment segment abnormalities. The T-wave amplitude in limb leads is influenced by the frontal-plane T axis, which in turn is influenced by the QRS axis.

In children older than 1 month, the T wave is often inverted in leads V_1, V_2, and V_3. In adolescents 12 years old and older and in young adults less than 20 years of age, the T wave may be slightly inverted in aVF and inverted in lead V_2. In adults 20 years old and older, the normal T wave is inverted in aVR; upright or inverted in leads aVL, III, and V_1; and upright in leads I and II and in chest leads V_3 through V_6.

In evaluations of T-wave abnormalities, T-wave negativity in lateral chest leads V_5 and V_6 is clinically particularly important. In these leads, the T wave is slightly negative (less than 0.1 mV) in 2% of white men and women 60 years of age and older and in 2% of black men and women 40 years of age and older; it is negative by 0.1 mV or more in 5% of black men and women 60 years of age and older.[21]

In normal adults, the T-wave amplitude is most positive in lead V_2 or V_3. The reported normal standards for the T wave in various reports from community-based populations vary to some extent by age, gender, and race.[20,21] T-wave amplitudes for V_2 from 1.0 to 1.4 mV have been listed as upper normal thresholds in men (up to 1.6 mV in the 18- to 29-year age group) and from 0.7 up to 1.0 mV in women.

A number of terms such as *peaked*, *symmetrical*, *biphasic*, *flat*, and *inverted* are being used as appropriate qualitative T-wave descriptors. As more quantitative descriptors, it is proposed that the T wave in leads I, II, aVL, and V_2 to V_6 be reported as *inverted* when the T-wave amplitude is from -0.1 to -0.5 mV, as *deep negative* when the amplitude is from -0.5 to -1.0 mV, and as *giant negative* when the amplitude is less than -1.0 mV.[25] In addition, the T wave may be called *low* when its amplitude is less than 10% of the R-wave amplitude in the same lead and as *flat* when the peak T-wave amplitude is between 0.1 and -0.1 mV in leads I, II, aVL (with an R wave taller than 0.3 mV), and V_4 to V_6.

Interpreting isolated T-wave abnormalities is difficult and often the source of ambiguous and inaccurate statements. The inappropriate diagnoses of myocardial ischemia and infarction are common errors. As indicated above, ST- and T-wave abnormalities that are secondary to abnormalities in ventricular conduction should be labeled as such. ST- and T-wave changes associated with hypertrophy, hypokalemia, and drugs can be attributed to one of these factors. Giant T-wave inversion is usually limited to one of several entities, including hypertrophic cardiomyopathies, non–ST-segment elevation myocardial infarctions, and neurological events, particularly intracranial hemorrhage. The interpretation of such T-wave changes should be descriptive, and a statement listing the most common causes is appropriate.

It is virtually impossible to develop a cause-specific classification for minor T-wave abnormalities. For these, classification as *slight* or *indeterminate* T-wave abnormality is appropriate. The overreader can then apply analysis of other features, and the clinical condition if available, to provide a more likely list of diagnostic possibilities. In these situations, comparison with prior ECGs (if available) is often helpful.

Notching of the T wave may be difficult to discriminate from a U wave that is superimposed on the downslope of an upright T wave. It is important to recognize that the T wave is rarely notched in all 12 leads and that the interval between the 2 summits of a notched T wave is usually less than the interval between the peak of a monophasic T wave and the U wave, which usually exceeds 150 ms at heart rates of 50 to 100 bpm.[26]

Recommendation

The ECG report should include a description of T-wave abnormalities, identification of associated ST-segment changes if present, and a statement as to whether the changes are indeterminate or more likely to be associated with a specific cause.

T-Wave Alternans

T-wave alternans signifies T-wave amplitude variations that alternate every second beat. These amplitude variations are quantified with various modifications of moving-average analysis or as the variance of specific frequency components in spectral analysis. T-wave alternans is typically observed as microvolt-level variation (microvolt T-wave alternans) and, at times, as more pronounced variations in alternating complexes or as slower components outside the range of the proper T-wave alternans, generally most prominent in phase with respiration.

T-wave alternans indicates latent instability of repolarization predictive of malignant arrhythmias. It is generally not present at the resting state even in high-risk patients, and a stress test (exercise or pharmacological stress or pacing), requiring special equipment and analysis software, is needed to provoke it. These procedures are outside the scope of the present document. It is sufficient to state that although the role of T-wave alternans regarding its clinical utility has not been fully defined, it holds substantial potential in identifying patients at high risk of serious arrhythmic events.

The U Wave

The U wave is a mechanoelectric phenomenon[26] that results in a low-amplitude, low-frequency deflection that occurs after the T wave. It is frequently absent in the limb leads and is

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most evident in leads V_2 and V_3, where its amplitude has been suggested to be approximately 0.33 mV or 11% of the T wave.[27] Its presence is heart-rate dependent; it is rarely present at rates greater than 95 bpm. Bradycardia enhances the U-wave amplitude and is present in 90% of cases at heart rates less than 65 complexes per minute.[28]

It has long been held that an increase in U-wave amplitude, usually in association with depression of the ST segment and a decrease in T-wave amplitude, may be caused by a variety of cardioactive drugs with quinidine-like effects and by hypokalemia and that with more advanced hypokalemia, that is, K less than 2.7 mmol/L, the U-wave amplitude may exceed the T-wave amplitude in the same lead. However, more recent information suggests that this may be due to fusion of the U wave with the T wave rather than to an increase in U-wave amplitude per se.

Fusion of the U wave with the T wave also occurs in association with an increase in sympathetic tone[29] and in the presence of a markedly prolonged QT interval such as that which occurs in congenital and acquired long-QT syndromes (LQTS).

An inverted U wave in leads V_2 through V_5 is abnormal.[30] It may appear transiently during acute ischemia or in the presence of hypertension.[31,32] An abnormal U wave is often quite subtle and is rarely an isolated ECG abnormality. Thus, its presence is often not recognized or is overlooked by ECG readers and automated systems. For these reasons, no specific descriptive or diagnostic statements are recommended for inclusion in the automated list of terms. It remains the responsibility of the overreader to recognize abnormal U waves and to determine their clinical relevance.

Recommendation

Statements concerning the U wave should be included in the ECG interpretation when the U wave is inverted, when it is merged with the T wave, or when its amplitude is greater than that of the T wave.

The QT Interval

Measurement of the QT interval and its adjustment for rate, gender, and QRS prolongation represent 2 of the major challenges in electrocardiography. They are matters of great importance to physicians, drug manufacturers, and regulatory agencies because of the relationship between prolongation of the QT interval and potentially lethal ventricular arrhythmias. The document released in October 2005 by the Food and Drug Administration (FDA) provides guidance for the design, conduct, analysis, and interpretation of clinical studies for evaluation of QT-interval prolongation.[33]

QT and ST-T patterns vary a great deal in various genotypes of the LQTS. Zhang et al[34] described 10 different ST-T patterns in first 3 genotypes of the syndrome (4 in LQT1, 4 in LQT2, and 2 in LQT3), and these patterns were present in the majority of genotyped LQTS patients.

The QT interval is defined as the interval from the onset of the QRS complex, that is, the earliest indication of ventricular depolarization, to the end of the T wave, that is, the latest indication of ventricular repolarization. The problems associated with this measurement include the following: (1) recognizing the onset of the QRS complex and the end of the T wave, (2) determining the appropriate lead(s) in which to measure the QT interval, and (3) adjusting the QT interval for increases in QRS duration, gender, and rate.

When the majority of ECGs were recorded on single-channel analog machines, various leads were recorded sequentially, and the QT interval was measured manually in the individual leads. Determination of the end of the T wave was often difficult and sometimes impossible, and the onset of the QRS complex and the end of the T wave varied in different leads, appearing shorter when the axis of an individual lead was more perpendicular to the spatial vector of the onset of the QRS complex or the end of the T wave. The onset of the QRS complex tends to occur up to 20 ms earlier in V_2 and V_3 than in the limb leads.[35] Some regard differences of up to 50 ms in QT intervals measured in the various leads in normal subjects as being normal[36]; others have suggested that differences of up to 65 ms were still within the limit of normal.[37] This value is reported to be less in women than in men.[38]

When the QT interval is measured in individual leads, the lead showing the longest QT should be used.[39] This is usually V_2 or V_3. However, if this measurement differs by more than 40 ms from that in other leads, the measurement may be in error, and measurements from adjacent leads should be considered. If the T wave and U wave are superimposed or cannot be separated, it is recommended that the QT be measured in the leads not showing U waves, often aVR and aVL,[39] or that the downslope of the T wave be extended by drawing a tangent to the steepest proportion of the downslope until it crosses the TP segment. It should be recognized that defining the end of the T wave in these ways might underestimate the QT interval.

As detailed in the section on ECG technology,[1] most currently used automated digital machines record all leads simultaneously. This technique permits their temporal alignment and superimposition, which facilitates a more accurate assessment of the beginning of the QRS complex, the end of the T wave, and the separation of the U wave from the T wave. As a result, the automatically measured QT interval is often longer than the QT interval as measured in any individual lead, and the values currently regarded as normal, which were established with single-channel sequential recordings, may no longer be valid. Most automated systems do not routinely display the superimposed tracings or the points used to derive the QT interval.

In view of the clinical importance of the QT-interval prolongation, it is essential to visually validate QT-interval prolongation reported by a computer algorithm.

In addition to administration of QT-prolonging cardioactive drugs, a number of conditions can induce QT prolongation. It is often possible to identify a specific cause of QT prolongation when appropriate clinical information is available; for instance, both hypokalemia and hypocalcemia can prolong phase 2 and phase 3 of the action potential and prolong the QT interval. It is not feasible here to compile a comprehensive list of all possible causes of QT prolongation. It is sufficient to emphasize that its presence in an ECG report should call for a careful clinical evaluation of possible causes.

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Recommendation

It is recommended that selective subsets of temporally aligned superimposed ECG leads be made available as an optional display to facilitate QT measurement and to validate the onset and end points of the QT interval. In view of the clinical importance of QT-interval prolongation, it is essential to visually validate QT-interval prolongation reported by a computer algorithm.

QT Correction for Rate

Many formulas have been proposed to adjust the QT interval for rate.[40,41] The most widely used is the formula derived by Bazett[42] in 1920 from a graphic plot of measured QT intervals in 39 young subjects. This adjustment procedure divides the measured QT by the square root of the RR interval to derive the rate-adjusted value. The formula introduced by Fridericia,[43] also in 1920, uses the cube root of RR. Bazett's formula leaves a strong positive residual correlation ($r=0.32$) and Fridericia's formula leaves a negative correlation ($r=-0.26$ to -0.32) with heart rate,[44,45] and the adjusted QT values may be substantially in error, particularly when the heart rate is high. More recently introduced formulas for QT adjustment as a linear or power function of RR or heart rate for adults[44,45–48] and for children[49] effectively remove the rate dependence of the adjusted QT, and they are clearly preferable to both Bazett's and Fridericia's formulas. Some investigators have introduced separate normal limits or rate correction factors for each heart rate subinterval using the so-called "bin method."[46,50]

Recommendation

It is recommended that linear regression functions rather than the Bazett's formula be used for QT-rate correction and that the method used for rate correction be identified in ECG analysis reports. In addition, rate correction of the QT interval should not be attempted when RR interval variability is large, as often occurs with atrial fibrillation, or when identification of the end of the T wave is unreliable.

QT Correction for Gender and the Limits for Prolonged and Short QT Interval

Although Bazett's and Fridericia's formulas make no adjustment for gender, many studies have demonstrated that the QT interval is longer in young and middle-aged females than in males. The gender difference is potentially important because women are generally considered to be more prone to malignant arrhythmias in LQTS than men. The gender difference appears during adolescence,[51] when the rate-adjusted QT shortens in boys, possibly as a testosterone effect, but undergoes little change in girls.

The reported gender difference in various studies varies from 6 to 10 ms in older age groups and from 12 to 15 ms in younger adults. Overall, the gender difference in rate-adjusted QT interval becomes small after 40 years of age and practically disappears in older men and women. Separate gender- and age-specific QT-adjustment formulas have been proposed to accommodate these differences.[21,44,46,47] Normal limits proposed in different studies vary to a certain extent, depending on the characteristics of the study population and particularly on the type of QT-adjustment function used. It is important to recognize that normal limits established using the upper and lower limits of actual percentile distributions of the rate-adjusted QT are preferable to those as mean values $\pm 2\times$SD because these distributions are strongly skewed.[44]

Normal standards for thresholds for abnormal QT from large subgroups of community-based populations are available.[21,44–48] These limits are relatively uniform in reports that have appropriately used linear regression functions with QT-rate adjustment as a linear or power function of RR or heart rate.[21,44,46–48] The following normal limits are suggested as a practical compromise for the evaluation of QT-interval prolongation and shortening in adult men and women: prolonged QT: women, 460 ms or longer; men, longer than 450 ms; and short QT: women and men, 390 ms or shorter.

FDA guidelines for industry recommend that 3 severity levels for rate-corrected QT be reported when considering possible QT-prolonging effects of drugs: longer than 350 ms, longer than 480 ms, and longer than 500 ms.[32]

Although the upper normal limits for QT adjusted for rate as a linear function of RR in small groups of children stratified by age, gender, and heart rate have been published,[52] the limits for prolonged and short QT established in reasonably large groups of children have been reported only for Bazett's formula.[53] In that report, the 98th percentile limit for rate-adjusted QT was approximately 450 ms in children younger than 12 years of age. The gender difference of 8 ms appeared in the 12- to 16-year age group. It should be noted that QT adjusted by Bazett's formula may produce false QT prolongations.[45]

Recommendation

It is recommended that, in addition to rate, an adjustment for gender and age be incorporated into QT adjustment. As practical clinical limits for considering the QT interval as abnormal, it is recommended that the adjusted QT of 460 ms or longer in women and 450 ms or longer in men be considered a prolonged QT interval and that QT 390 ms and shorter be considered a short QT interval.

Correction for QRS Duration

The QT interval prolongs in ventricular conduction defects, and an adjustment for QRS duration becomes necessary.[54–56] This can be accomplished best by incorporating QRS duration and RR interval as covariates into the QT-adjustment formula or by using the JT interval (QT duration–QRS duration).[55] If the JT interval is chosen, normal standards established specifically for the JT interval should be used.[55]

Recommendation

QT- and JT-adjustment formulas have recently been introduced for use in the setting of prolonged ventricular conduction. With confirmation, they may be incorporated into automated algorithms to provide appropriate correction factors.

Evaluation of QT Intervals in Sequential Tracings

Evaluation of QT intervals from sequential ECG recordings is essential for identification of QT prolongation induced by

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pharmacological agents in drug studies. It is also helpful as an adjunct to ST analysis in determining the presence of active ischemia in patients suspected of having myocardial infarction.

When sequential tracings from patients recorded at different times of day and at different locations are compared, it is important to recognize that the time of day can influence the QT interval,[57,58] that differences may exist between the different recording systems and between the programs used for QT measurement, and that different formulas for QT-rate adjustment may have been used. Moreover, there is a significant interreader variability in the measurement of QT interval.[59] Rigorous standardization of the recording and evaluation procedures should be followed when serial comparison of QT intervals is undertaken.

The FDA guide for industry suggests that in the evaluation of possible QT prolongation induced by drugs, 2 levels of change in serial ECGs in the rate-corrected QT from the baseline be reported: an increase of greater than 30 ms and an increase of greater than 60 ms.[33]

Recommendation

It is recommended that for serial comparisons ECG recorders meet specific performance standards and, if possible, be of the same type; that uniform, carefully standardized ECG acquisition and QT-measurement procedures be used; and that, whenever possible, a single reader be responsible for overreading sequential tracings of an individual patient or research subject.

QT Dispersion

Increased heterogeneity of myocardial repolarization may predispose patients to the development of malignant ventricular arrhythmias.[60] As indicated above, significant differences exist in the duration of the QT interval when measured in the individual leads. Visualization of these differences is facilitated by the display of a suitable subset of temporally aligned simultaneous leads with a slight separation on the amplitude scale.

The difference between the longest and shortest QT intervals is referred to as QT dispersion. This concept was introduced in 1990 for risk identification in patients with LQTS.[61] Since its introduction, QT dispersion has been one of the most popular topics in ECG research. In November 2006, a PubMed search cited 670 publications with QT dispersion in the title, and a Google search under "QT dispersion measurement" revealed 171 000 communications.

The QT-dispersion concept has led to the expectation that QT dispersion is a measure of regional or localized heterogeneity of myocardial repolarization. Numerous studies have suggested an increased risk of morbidity and mortality for an increase in QT dispersion. However, substantial methodological problems with the QT-dispersion measurement have been identified that have raised fundamental questions about the validity of the concept.[62–65] In principle, the expectation that QT dispersion is a measure of the regional or localized heterogeneity of myocardial repolarization implies that the leads with the shortest and longest QT contain signal information at the terminal part of the T wave that is not present in the first 3 orthogonal components of the 12-lead ECG (or the composite global T wave).[65]

Until adequately validated data in specific clinical conditions are presented showing that QT dispersion on the body surface ECG is the counterpart of localized dispersion of myocardial repolarization and conveys adequately strong nondipolar signal information that cannot be extracted from the X,Y,Z components, it seems unwise to include it as a part of the routine ECG report.

Recommendation

It is recommended that QT dispersion not be included in routine ECG reports. However, because of the fundamental importance of the heterogeneity of myocardial repolarization in the genesis of malignant ventricular arrhythmias, continued research into the identification of markers of increased dispersion of myocardial repolarization on the body surface ECG is encouraged.

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Cleveland Clinic Center for Continuing Education

Atrial Fibrillation

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Contents

Definition

Atrial fibrillation (AF) is a common heart rhythm disorder caused by degeneration of the electrical impulses in the upper cardiac chambers (atria) resulting in a change from an organized heart rhythm to a rapid, chaotic rhythm. The resulting arrhythmia is often rapid and irregular with no discernible pattern (known as irregularly irregular). The disrupted rhythm occurs because of the unpredictable conduction of disordered impulses across the electrical bridge, called the atrioventricular (AV) node, to the lower cardiac chambers (ventricles). The arrhythmia also results in ineffectual atrial contractions affecting cardiac output and vulnerability to blood clot (thrombus) formation that can result in stroke events.

According to the 2014 American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Rhythm Society (HRS) clinical practice guidelines, AF can be classified based on the duration of episodes. Paroxysmal AF refers to AF that begins suddenly and ends spontaneously within 7 days of onset.[1] Persistent AF refers AF that occurs for longer than 7 days and ends spontaneously or with treatment. Long-standing persistent AF refers to patients who have uninterrupted AF for more than a year. Permanent AF refers to AF that persists despite treatment to restore normal sinus rhythm or that is not treated.

These AF classifications are not mutually exclusive and it is common for patients with one type of AF to exhibit overlapping features of another type. These classifications are relevant clinically with respect to outcomes and prognosis with rhythm-controlling treatment strategies. Atrial fibrillation is commonly associated with other supraventricular arrhythmias, namely atrial flutter and focal atrial tachycardia.

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Prevalence

Atrial fibrillation is the most common sustained cardiac tachyarrhythmia encountered by clinicians worldwide. An estimated 2.7 to 6.1 million people in the United States have Atrial fibrillation with projections to reach nearly 12.1 million in 2030.[1,2]

The prevalence of A fib increases with age, afflicting about 10% of the population by 80 years of age.[3] The growing prevalence of AF may be influenced by extended survival outcomes for patients with congestive heart failure (CHF), valvular heart disease, and coronary artery disease as AF is common among patients with other forms of structural heart disease.

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Pathophysiology

Atrial fibrillation may be acutely associated with physiologic stressors such as surgical procedures, pulmonary embolism, chronic lung diseases, hyperthyroidism, and alcohol ingestion. Disease states commonly associated

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with AF include hypertension, valvular heart disease, CHF, coronary artery disease, Wolff-Parkinson-White syndrome, pericarditis, obstructive sleep apnea, and cardiomyopathy. Considerable research has been devoted to the mechanisms and pathogenesis of AF. Genetic studies have identified specific associations, particularly in the cases of familial AF [4] Achieving a complete understanding of AF is limited by the complexity of this disorder and the heterogeneous patient population it affects.

The pathogenesis of AF can be broadly divided into the categories of triggers, substrate, and sustaining mechanisms. Since the late 1990s, it has been recognized that the initiation of AF can occur because of premature atrial contractions triggered by beats that arise from the pulmonary veins (PVs), usually from muscular tissue sleeves near the junction with the left atrium.[5] These triggers may also fire repetitively and contribute to the maintenance of AF, essentially becoming drivers of AF. Focal triggers outside the PV including posterior left atrial, ligament of Marshall, coronary sinus, venae cavae, septum, and left atrial appendage contribute to the disease process. Focal triggers, especially the PVs, are felt to be very important early in the disease process and, in particular, among patients with paroxysmal AF. Over time, myocardial fibrosis develops within the atrial tissue in association with AF to support its maintenance by shortening affected tissue refractory periods. Myocardial fibrosis of the atrium seems to be the common feature of the progression of AF disease state. This has led to the adage that *AF begets AF*. Once AF is initiated by focal triggers, several theories have been postulated to explain the maintenance of AF. They include the multiple wavelet model, AF rotors and the role of the autonomic nervous system. The multiple wavelet model has suggested that AF is sustained by multiple simultaneous wavelets meandering throughout the atria. Atrial tissue with abnormal electrical propagation recorded by mapping catheters has been referred to as complex fractionated electrograms. Expression of specific connecting protein channels at the cellular level are also felt to be important contributors to the disease substrate and sustaining mechanisms. Contemporary understanding of the AF substrate and sustaining mechanisms now also includes the role of the autonomic nervous system and, more recently, the discovery and evaluation of the concept of AF rotors.[6,7]

Cardiac ganglionic plexuses clustered posteriorly and superiorly to the left atrium are known to play an important role in the initiation and maintenance of AF. Both parasympathetic and sympathetic limbs can provoke atrial arrhythmias. Evidence supportive of this concept includes therapeutic benefit derived from destruction of cardiac ganglionic plexuses and also noncardiac plexuses including the stellate ganglion and perinephric ganglia associated with the renal arteries.[8] In addition, completely vagally denervated hearts as in heart transplantation are known to have a very low incidence of AF.[9]

Atrial fibrillation rotors represent an emerging concept as a sustaining mechanism for AF involving spiral waves detected by spectral analysis of dominant frequencies recorded by intracardiac mapping catheters. Such spiral waves can be conceptualized as wavelets of consistent electrical activation around a central localized source that could be either structural (ie, scar-related) or purely functional (ie, conduction heterogeneity involving certain cellular sodium and potassium channels). The focal impulse and rotor modulation computational mapping system is used to identify AF rotors.[10]

Atrial fibrillation may have hemodynamic consequences. It can decrease cardiac output due to ineffectual atrial systole and increase pulmonary venous pressure resulting in heart failure. Deleterious hemodynamic effects also include nonphysiologic tachycardia, increased valvular regurgitation, and irregularity in ventricular systole.

AF is associated with morbidity and even mortality. AF can produce bothersome symptoms that affect quality of life, but patients with AF also have a substantial risk of thromboembolic stroke, AF is associated with a fivefold increased risk of stroke, threefold risk of heart failure. and twofold risk of dementia and mortality.[1] Some data demonstrate an association of AF with reduced overall survival.[11]

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Signs and Symptoms

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The clinical manifestations of AF are variable, although fatigue is the most common symptom. Often, the symptoms are attributable to the rapid ventricular response. However, even when the ventricular response is controlled, symptoms can occur from loss of AV synchrony or atrial systole This is particularly important for patients with left ventricular dysfunction (CHF) and impaired diastolic filling (mitral stenosis , hypertrophic and restrictive cardiomyopathy) .That said, some patients with AF are genuinely asymptomatic, even at rapid heart rates for unclear reasons. More often, however, patients report nonspecific symptoms such as fatigue, dyspnea, dizziness, and diaphoresis. Palpitations are a common feature. Occasionally, patients present with extreme manifestations of hemodynamic compromise, such as chest pain, pulmonary edema, or syncope. Atrial fibrillation is present in 10% to 40% of patients with a new thromboembolic stroke.[12]

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Diagnosis

The clinician must realize that an irregular pulse detected by physical examination or an irregular ventricular rhythm seen on the electrocardiogram (ECG) is not always AF. It is necessary to consider and exclude other types of irregular rhythm disturbances, including atrial or ventricular ectopy, atrial tachycardia, or atrial flutter (Figure 1) with variable AV conduction, multifocal atrial tachycardia (Figure 2), and wandering atrial pacemaker. Conversely, a regular pulse or rhythm does not exclude AF. For example, AF can manifest with a regular ventricular response in the presence of AV block or with a ventricular paced rhythm.

A 12-lead ECG is best to establish the diagnosis of AF. Electrocardiographic findings in AF include the absence of P waves and the presence of low-amplitude, high-frequency atrial fibrillary waves (F waves). The atrial rate varies in the range of 300 to 700 beats per minute. In the absence of drug therapy, a patient with normal AV conduction has an irregularly irregular ventricular rhythm and often has a ventricular rate in the range of 120 to 180 beats per minute.[13] The baseline on the ECG strip often is undulating and occasionally has coarse irregular activity (Figure 3). This activity may resemble atrial flutter, but it is not as uniform wave to wave as atrial flutter.

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Treatment

Most patients presenting with AF are not critically ill. However, in some cases, the presence of AF may cause life-threatening hemodynamic compromise. It should be emphasized that for any unstable patient presenting with AF—for example, a patient with chest pain, pulmonary edema, or hypotension—the recommended therapy is rapid electrical cardioversion, according to the Advance Cardiovascular Life Support guidelines.[14]

Atrial fibrillation has particular importance in the setting of the Wolff-Parkinson-White syndrome. Patients with Wolff-Parkinson-White syndrome may be vulnerable to ventricular fibrillation and sudden death because of the development of AF, which can result in extremely rapid conduction over the accessory pathway (Figure 4). Prompt electrical cardioversion is of utmost importance for these patients. Treatment with AV node-blocking medications such as verapamil or digoxin can facilitate rapid conduction over the accessory pathway and result in ventricular fibrillation. When intravenous pharmacologic therapy is required, the drug of choice is procainamide or amiodarone.

There are 3 goals in the management of AF: control of the ventricular rate, minimization of thromboembolism risk (particularly stroke), and restoration and maintenance of sinus rhythm. The first 2 goals are essential for most patients, but the third goal may not be necessary in all patients. The AHA/ACC/HRS guidelines provide a more detailed review of the management of patients with AF treated purely with a rate-controlling approach and those patients treated to restore and maintain normal sinus rhythm (ie, a rhythm controlling strategy).[1]

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Control of the Ventricular Rate

Rate control in patients with AF is essential to reduce symptoms and improve quality of life. The optimal heart rate goal has not been fully defined and may be patient specific. In the RACE II clinical trial, patients were randomly assigned to strict (less than 80 bpm) vs lenient (less than 110 bpm) rate control strategies.[15] Lenient rate control was not inferior to strict rate control in terms of cardiovascular morbidity and mortality. Based on this study, the European Society of Cardiology guidelines incorporated the lenient rate control strategy as the first-line approach to asymptomatic patients with preserved cardiac function.[16] However, the guidelines from AHA/ACC/HRS society favor a more stringent rate control strategy (class II A recommendation).

Guideline statements only address goals in patients with preserved cardiac function. The optimal rate in patients with heart failure has not been fully defined. For example, some studies show that in patients with heart failure, slow ventricular rates are associated with higher mortality and higher ventricular rates may be needed to improve exercise tolerance.[17,18] However, patients with heart failure can easily become decompensated when ventricular rates are uncontrolled. Hence, most clinicians use a patient-specific window of optimal rate control that avoids the consequences of both extreme bradycardia and tachycardia.[19]

Ventricular slowing is accomplished with medications affecting the AV node (Table 1). The most commonly used drug classes are beta blockers and calcium channel blockers. Most patients with persistent atrial fibrillation receive daily suppressive therapy. However, a pill-in-the-pocket, rate-control strategy has been proposed in patients with a low burden of self-terminating AF, though no studies have investigated this strategy.[19]

If these medications are ineffective or if excessive bradycardia occurs, other measures may need to be considered. One option suitable for some patients is catheter ablation of the AV node and pacemaker implantation (ablate and pace). Meta-analysis of the ablate-and-pace approach has demonstrated improvements in a number of clinical parameters, including symptoms, quality of life, exercise function, cardiac performance, and longevity in patients with CHF receiving a biventricular pacemaker.[20]

However, this approach usually results in pacemaker dependence and carries the associated risks and complications of indwelling pacemaker leads. Pacemaker implantation without AV nodal ablation should be considered if the problem is simply excessive bradycardia that prohibits the effectiveness of rate-controlling medication, and the rapid ventricular rates are well controlled by medication. For patients with abnormal LV systolic function, a biventricular pacemaker (ie, cardiac resynchronization therapy) should be considered in conjunction with AV nodal ablation based on the results of the BLOCK HF trial.[21]

Table 1: Drugs for Atrial Fibrillation That Slow Conduction Through the Atrioventricular Node

Beta Blockers
• Advantages: Intravenous administration produces a rapid onset of effect; heart rate control at rest and with activity; oral forms available.
• Disadvantages: May worsen heart failure in decompensated patient. May exacerbate reactive airway diseases; cause fatigue, depression, and impotence. Abrupt withdrawal may cause rebound tachycardia, hypertension and myocardial ischemia.

Drug	Dose	Onset of Action	Duration of effect
Propranolol			
Intravenous	1 mg bolus, repeat every 5 minutes as needed to achieve goal	5 minutes	1 to 4 hours
Oral immediate release	10 to 30 mg every 6 or 8 hours daily	1 to 2 hours	6 to 24 hours depending on

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			form
Oral extended release	80 to 160 mg daily	1 to 2 hours	6 to 24 hours depending on form
Metoprolol			
Intravenous	2.5 to 5 mg every 2 to 3 minutes as need to achieve goal	5 minutes	1 to 3 hours
Oral immediate release	12.5 to 100 mg every 6 to 8 hours	1 to 2 hours	3 to 24 hours depending on form
Oral extended release	50 to 400 mg once daily	1 to 2 hours	3 to 24 hours depending on form
Esmolol			
Intravenous	500 µg/kg over 1 minute, then maintenance dose of 25 to 300 µg/kg/min; titrate by 25 to 50 µg/kg/min every 5 to 10 minutes to achieve goal	2 to 10 minutes	9 minute half-life
Nadolol			
Oral (avoid in patients with renal dysfunction)	10 to 240 mg daily for rate control	1 to 2 hours	17 to 24 hours

Calcium Channel Blockers

• Advantages: Intravenous administration produces a rapid onset of effect; heart rate control at rest and with activity; oral forms available.

• Disadvantages: May worsen heart failure in decompensated patient; may cause fatigue, edema and constipation.

Drug	Dose	Onset of Action	Duration of effect
Diltiazem			
Intravenous	0.25 mg/kg over 2 minutes, then 5 to 15 mg/hour; may repeat bolus of 0.35 mg/kg if goal heartrate not achieved	5 minutes	1 to 10 hours
Oral immediate release	30 to 120 mg every 6 to 8 hours (typical maximum of 360 mg daily)	1 hour	5 to 24 depending on form
Oral extended release	120 to 360 mg once daily	1 hour	5 to 24 depending on form
Verapamil			
Intravenous	Initial bolus: 0.075 to 0.15 mg/kg (usual dose: 5 to 10 mg) over at least	3 to 5 minutes	0.5 to 6 hours

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	2 minutes; if no response, may give an additional 10 mg bolus after 15 to 30 minutes		
Oral immediate release	80 to 120 mg every 8 to 12 hours to a maximum of 480 mg daily	1 to 2 hours	6 to 8 hours
Oral extended release	180 to 480 mg once daily	1 to 2 hours	6 to 8 hours

Other

• Advantages: Can be used in patients with heart failure. Useful in combination with other atrioventricular nodal agents.

• Disadvantages: Slow onset of action; poor control of heart rate with activity; narrow therapeutic margin; long duration of effect.

Not recommended as monotherapy under practice guidelines.

Drug	Dose	Onset of Action	Duration of effect
Digoxin			
Intravenous	Loading dose of up to 1 mg in first 24 hours, with bolus of 0.25 to 0.5 mg; then remainder in divided doses 6 to 8 hours	5 to 60 minutes	3 to 4 days
Oral	0.125 to 0.25 mg daily)	1 to 2 hours	

Includes data from January et al[1] and Van Gelder et al.[19]

Special Situations in AF Rate Control

In patients with an implantable cardioverter defibrillator, great care is needed in both the device programming and pharmacologic rate control in order to avoid the risk of inappropriate shocks associated with rapid ventricular rates. In patients with a cardiac resynchronization therapy device, the goal is to achieve 100 % biventricular pacing.[22] If the presence of atrial fibrillation prevents achievement of this goal, further consideration to rhythm controlling strategies or AV nodal ablation is recommended.

Preventing Thromboembolism and Stroke Risk

Atrial fibrillation carries a considerable risk for thromboembolism and stroke. The Framingham study has shown that during a follow up period of 30 years, patients with nonvalvular AF had a more than fivefold risk of stroke and the risk of stroke attributed to stroke increased with age.[12] Ischemic stroke can be the first manifestation of occult AF, which is also referred to as subclinical AF. Ischemic strokes related to AF tend to be associated with greater morbidity and mortality than from other causes of stroke.[23] As the CRYSTAL AF and EMBRACE trials have demonstrated, AF is frequently detected in patients during post stroke cardiac rhythm monitoring in patients with cryptogenic stroke.[24,25] Some data suggests that such asymptomatic AF can carry a worse prognosis ostensibly related to the stroke risk incurred without the presence of symptoms to provide a warning.[26]

The annual risk of stroke may be even higher in patients with AF who have 1 or more of the following risk factors: older than 65 years, female, diabetes mellitus, hypertension, heart failure, coronary artery disease, previous stroke, or transient ischemic attack. Individual stroke risk stratification can now be calculated for patients on the basis of the presence or absence of such risk factors (ie, CHADS2 and CHADS2 VA2S2C risk

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scores).[27] Several strategies including antithrombotic therapy with vitamin K antagonists (VKA), direct oral anticoagulation (DOAC), and antiplatelet therapy with aspirin, dipyridamole, and clopidogrel. DOAC drugs include Factor Xa inhibitors (eg, apixaban, rivaroxaban, edoxban) and direct thrombin inhibitors (eg, dabigatran).

In meta-analysis, VKAs reduced stroke or systemic thromboembolism by 64% and all-cause mortality by 26% compared with placebo.[23,28,29] DOACs offers an additional risk reduction of 19% for stroke or systemic thromboembolism primarily driven by reduction in hemorrhagic stroke and 10% for mortality relative to warfarin.[29] The combination of warfarin with aspirin increases the bleeding risk. Warfarin is superior to aspirin and also the combination of aspirin and clopidogrel in stroke prevention.[29] Aspirin and clopidogrel is superior to aspirin alone in stroke protection among patients that are warfarin ineligible, but is associated with greater bleeding risk.[30]

Practice guidelines include recommendations regarding the form of antithrombotic therapy for patients with AF.[1] The AHA/ACC/HRS guidelines recommend the CHA2DS2-VASc score to identify patients with AF at low, moderate, or high risk for thromboembolism. A score of 0 is considered low risk and does not require not antithrombotic therapy. A score of 2 or greater is considered high risk and antithrombotic therapy with VKAs or NOACs should be considered. A score of 1 is considered moderate risk for which antithrombotic therapy or aspirin may be considered. The goal of warfarin therapy for preventing stroke and thromboembolism from AF generally is an international normalized ratio between 2.0 and 3.0. The DOAC classes of medications do not require monitoring. Safety and efficacy have been evaluated in administrative datasets in addition to clinical trials leading to U.S. Food and Drug Administration (FDA) approval. Each DOAC drug has unique properties with respect to half-life, renal clearance, and availability of pharmacologic reversal agents.

For patients who have been in AF for more than 48 hours and are not adequately anticoagulated, electrical or pharmacologic cardioversion should be delayed until appropriate measures are taken to reduce the thromboembolic risk. There are two approaches to reduce thromboembolic risk in these patients. The conventional approach is to administer oral anticoagulation for at least 3 weeks before electrical or pharmacologic cardioversion. The second approach is transesophageal echocardiography (TEE)-guided electrical cardioversion method when cardioversion cannot be postponed or an expedited approach is preferred. In such cases, once a therapeutic level of anticoagulation has been achieved with an oral agent, intravenous heparin, or subcutaneous enoxaparin, a TEE may be performed to exclude the presence of an intracardiac thrombus. If no thrombus is seen, cardioversion may be performed. TEE can detect the presence of a thrombus in the left atrium, particularly in the left atrial appendage, which is poorly visualized on transthoracic echocardiography. The TEE-guided approach has been validated in several small multicenter trials as well as in a large, randomized, multicenter trial known as the Assessment of Cardioversion Using Transesophageal Echocardiography (ACUTE) trial.[31]

Oral anticoagulation should be continued after cardioversion until sinus rhythm has been maintained for at least 4 weeks to allow the atrial transport mechanism to recover. If the cardioversion was performed using the TEE-guided approach with intravenous heparin as the method of anticoagulation, it is advisable to continue intravenous heparin until therapeutic oral anticoagulation is achieved. The decision to initiate and continue anticoagulation for AF shorter than a duration of 48 hours should be based on the presence of other risk factors for thromboembolism. Subgroup analyses from RELY, ROCKET AF, and ARISTOTLE support the use of DOACs at cardioversion in addition to one nonproprietary study.[32]

On account of the left atrial appendage accounting for the source of most thrombi in patients with nonvalvular AF, several interventions gave been designed for left atrial appendage closure and thus stroke reduction. The Watchman device, a closure device deployed percutaneously that blocks the left atrial appendage has been approved by the FDA for stroke prevention in patients with non valvular AF who are at an increased risk of stroke and who have no contra indication to short term anti coagulation.[33,34]

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The Lariat device is another percutaneous system for left atrial appendage exclusion, however, its labelling is not specific for stroke prevention.[35]

Restoration and Maintenance of Sinus Rhythm

The restoration and maintenance of sinus rhythm can be beneficial for patients with bothersome symptoms. However, management of patients with asymptomatic or minimally symptomatic AF has been controversial for many years. Selecting appropriate patients for a rhythm-controlling strategy are well articulated by clinical practice guidelines.[1] In addition to improving symptoms, the potential benefits of restoring and maintaining sinus rhythm include avoidance of the development of atrial cardiomyopathy from ongoing AF, improvement in heart failure, and improved overall quality of life. A rhythm-control strategy often requires the use of antiarrhythmic drugs that may have significant and even life-threatening side effects, and procedures that carry uncommon, but potentially life-threatening or disabling complications. Some nonrandomized trials have reported an increase in mortality among patients who were on long-term antiarrhythmic therapy for AF, presumably from the proarrhythmic effects of the drugs.[36] In addition, several randomized studies have compared the treatment strategies of ventricular rate control or rhythm control with restoration and maintenance of sinus rhythm, albeit in older patients (mean age, 65 to 70 years) with minimal or no symptoms during AF.[37,40]

The Atrial Fibrillation Follow-up Investigation of Rhythm Management (AFFIRM) trial, was a large, multicenter randomized study that compared rate control with rhythm control in patients with AF.[37] Both treatment strategies used appropriate anticoagulation strategies according to established guidelines. This study demonstrated that a rhythm-control strategy is no better than a ventricular rate control strategy with regard to quality of life, incidence of stroke, or mortality at a follow-up of approximately 5 years. A meta-analysis of 5 randomized controlled trials comparing rate-control with rhythm-control strategies included more than 5,000 patients and demonstrated that a rate-control strategy is not inferior to a rhythm-control strategy.[41] Studies comparing catheter ablation with antiarrhythmic drug therapy as an initial approach to AF control have yielded some promising results.[42,43] Ongoing, large, multicenter randomized trials like the Catheter Ablation Versus Anti-arrhythmic Drug Therapy for Atrial Fibrillation (CABANA) Trial (https://clinicaltrials.gov/ct2/show/NCT00911508) and Early Treatment of Atrial Fibrillation for Stroke Prevention Trial (EAST) (https://clinicaltrials.gov/ct2/show/NCT01288352) should provide more insight regarding catheter ablation vs antiarrhythmic drug therapy. Acutely, restoration of sinus rhythm may be achieved with either pharmacologic or electrical cardioversion. It is important to remember that electrical and pharmacologic cardioversion are no different with regard to the risk of thromboembolic stroke. Therefore, the requirements for anticoagulation apply equally to either treatment strategy and are largely dictated by the patient-specific thromboembolic risk profile discussed previously.

Direct-Current Electrical Cardioversion

Electrical cardioversion is more effective than pharmacologic cardioversion. The success rate direct-current electrical cardioversion with a biphasic shock is approximately 95%.[44] Electrical cardioversion should be administered with the patient under deep sedation, with cardiac and hemodynamic monitoring, and in the presence of personnel skilled in airway management. The administration of an antiarrhythmic drug may promote more successful direct current cardioversion and subsequent maintenance of sinus rhythm. Similarly, it is reasonable to add an antiarrhythmic drug for any patient who develops an early AF recurrence after direct-current electrical cardioversion and to consider a repeat attempt after the drug has been initiated and reaches steady-state blood levels.

Pharmacologic Cardioversion

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Rates of successful immediate cardioversion by pharmacologic means have ranged from 40% to 90%, with success more likely to come for patients with AF of shorter duration.[45] Unlike electrical cardioversion, pharmacologic cardioversion does not require sedation. Contemporary use of pharmacologic cardioversion in the US occurs in nonelective scenarios in the emergency department or intensive care unit, and also in stable outpatients treated with a unique type of rhythm control strategy referred to as a pill-in-the-pocket approach. Elective pharmacologic cardioversion is uncommon in the U.S given the superiority of a planned electrical cardioversion under sedation with appropriate airway management personnel on hand.

The intravenous agents approved in the US for immediate pharmacologic cardioversion of AF are procainamide, amiodarone, and ibutilide(Table 2). Amiodarone is the most commonly used drug in emergency department and intensive care unit settings. Pharmacologic conversion of AF can be achieved with oral drugs. The pill-in-the-pocket approach is sometimes used with class Ic drugs like flecainide or propafenone and may be useful for select outpatients in order to quickly abort AF episodes shortly after onset. This approach has the potential to reduce emergency department visits and hospitalizations, but must be carefully initiated and supervised. It is recommended that the first such application of this strategy is done in a monitored environment, such as an emergency department, in order to establish patient-specific safety.

Table 2: Agents for Immediate Pharmacologic Cardioversion of Atrial Fibrillation

Drug	Dosing	Notes
Procainamide		
Intravenous	20 to 50 mg/minute or 100 mg every 5 minutes (until arrhythmia controlled, hypotension occurs, QRS complex widens by 50% or total of 17 mg/kg is given); maintenance 1 to 4 mg/minute	• Can achieve therapeutic levels quickly. • Half-life elimination: 2 to 5 hours (procainamide); 6 to 8 hours (procainamide metabolite N-acetyl procainamide [NAPA]) • Blood levels of both procainamide and NAPA need to be followed to prevent toxicity, especially in the setting of renal or hepatic insufficiency, or both • Rapid administration may cause hypotension • Up to 10% of patients with congestive heart failure may experience worsened heart failure • Procainamide is rarely used as there is no longer an oral product
Amiodarone		
Intravenous	150 to 300 mg given over 10 to 120 minutes, depending on tolerance of blood pressure; maintenance infusion at 0.5 to 1 mg/minute	• Can be used in patients with severe left ventricular dysfunction • Half-life elimination: 25 to 120 days • Drug interactions are common with amiodarone; careful profile review is essential • Long-term use associated with many side effectsIncidence of torsades de pointes higher than with procainamide or amiodarone
Oral	600 to 800 mg daily in divided doses until 10 g total; maintenance dose 200 mg daily	
Ibutilide		
Intravenous	1 mg bolus; can repeat after 10 minutes if no effect; use lower doses in patients weighing < 60 kg	• Avoid use in patients with baseline prolongation of QT interval • Few extra cardiac side effects • Incidence of torsades de pointes higher than with procainamide or amiodarone • Patients must be observed for a minimum of 4 hours post dose or until QT(c) returns to baseline

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Includes information from January et al.[1]

Antiarrhythmic Drug Therapy for Maintenance of Sinus Rhythm

Many oral agents are available for long-term maintenance of sinus rhythm in patients with AF (Table 3). Class Ia antiarrhythmic drugs (quinidine, procainamide, and disopyramide) have become less commonly prescribed than in the past because of their side effect profiles. The class Ic agents, namely flecainide and propafenone, have more favorable side effect profiles and are more commonly utilized. However, the use of these medications does have some degree of risk. The Cardiac Arrhythmia Suppression Trial (CAST) has shown that flecainide and encainide are associated with an increase in mortality when used for the suppression of ventricular arrhythmias in patients who have had a myocardial infarction with ventricular dysfunction.[46] As a result, there is much concern about the use of the class Ic antiarrhythmics in patients who have any type of underlying coronary artery or structural heart disease. Flecainide and propafenone are usually well tolerated and are appropriate first-line options for the treatment of AF in patients without structural heart disease, left ventricular hypertrophy, or marked pre-existing conduction disease (ie, complete left bundle branch block). Drugs such as sodium channel blockers are expected to widen the QRS duration thereby increasing vulnerability to heart block among patients with very significant pre-existing His-Purkinje system dysfunction.

Table 3: Oral Medications for Long-Term Maintenance of Sinus Rhythm for Patients With Atrial Fibrillation

Drug	Dose	Notes
Quinidine		
Sulfate immediate release	200 mg every 6 hours, increase with caution	• Less negative inotropic effect • Narrow toxic-to-therapeutic ratio; interacts with many drugs, including digoxin, warfarin, verapamil; high incidence of side effects (particularly GI intolerance, neurologic side effects, thrombocytopenia) • Rate controlling medication are required prior to initiating quinidine secondary to its vagolytic properties • Diarrhea is most common and significant side effect
Sulfate extended release	300 mg every 8 to 12 hours	
Gluconate	324 to 648 mg every 8 hours	
Flecainide	50 to 200 mg once every 12 hours	• Generally, well tolerated • Significant incidence of central nervous system, visual side effects • Avoid use in patients with coronary or structural heart disease • One of the most negative inotropic antiarrhythmics • Shown to increase mortality when used to treat and suppress ventricular arrhythmias in patients after MI • Typically need to combine with an AV nodal blocking agent
Propafenone		
Immediate release	150 to 300 mg every 8 hours	• Generally, well tolerated • Twice-daily extended release form results in more stable blood levels than immediate-release form • Three times daily dosing • Avoid use in patients with coronary or structural heart disease and patients with broncospastic lung disease as has significant beta blocker properties
Extended release	225, 325, or 425 mg every 12 hours	
Disopyramide		
Immediate release	100 to 200 mg every 6 hours	• Reduce dose by one-third for adults weighing less than 50 kg • May be useful in hypertrophic cardiomyopathy because of its

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		negative inotropic side effects • Anticholinergic effects (eg, cardiomyopathy, constipation, urinary retention)
Extended release	200 to 400 mg every 12 hours	• Adjust dose in patients with renal dysfunction • Most negative inotropic of the antiarrhythmic drugs • Avoid or use with extreme caution in patients on dialysis
Amiodarone	100 to 200 mg once daily	• Can be used in patients with coronary or structural heart disease • Half-life elimination (≤120 days) • Many side effects with long-term use • Baseline chest x-ray, LFTs, TFTs, should be performed • Approved only for life-threatening ventricular arrhythmias (but still often used for atrial or supraventricular arrhythmias)
Sotalol	40 to 160 mg once every 12 hours	• Can be used in patients with coronary structural heart disease • Beta- blocking properties allow single-agent therapy for almost all arrhythmias • Causes QTc prolongation • Use limited by side effects related to beta-blocking properties (eg, exacerbation of reactive airway disease, depression, negative inotropy) • Renally cleared; avoid use in patients with moderate to severe renal dysfunction • Inpatient telemetry recommended for initiation of therapy
Dofetilide	125 to 500 mcg every 12 hours	• Generally well tolerated; few extra cardiac effects; can be used in patients with coronary or structural heart disease • Requires monitored initiation in hospital; inpatient telemetry mandated for initiation of therapy • Causes QTc prolongation; electrocardiogram must be checked within 2 to 3 hours of administration for evidence of QTc prolongation > 15% above baseline or > 500 msec (550 msec for patients with intraventricular conduction delay) • Many drug interactions

Based on data from January et al.[1]

AF, atrial fibrillation; AV, atrioventricular; ECG, electrocardiogram; GI, gastrointestinal; LFT, liver function test; MI, myocardial infarction; SR, sinus rhythm; TFT, thyroid function test

Sotalol is a class III antiarrhythmic that has beta-blocking properties and is generally well tolerated. Patients may have difficulty tolerating the beta blocker side effects, such as fatigue, and there is a potential risk of excessive bradycardia. As with other class III antiarrhythmic agents, sotalol causes QT prolongation and may result in ventricular proarrhythmia, such as torsades de pointes. Careful monitoring of renal function, electrolytes, and QT interval is recommended. In addition, initiation in hospital while on telemetry monitoring should be considered although it is not required by the FDA. Lastly, drug interactions should be carefully avoided, particularly those resulting in QT prolongation.

Dofetilide, a class III antiarrhythmic, has good efficacy rates and is one of the best tolerated antiarrhythmic drugs in terms of its side effects profile. Importantly, dofetilide has also been shown to be safe for patients with cardiomyopathy, CHF, and ischemic heart disease. Therefore, dofetilide may be considered as an alternative treatment option to amiodarone. Like sotalol, dofetilide drug causes QT prolongation that may result in proarrhythmia and rarely death if excessive and is restricted to patients without advanced renal disease. Its use has been restricted by the FDA to certified prescribers and requires monitored initiation in a hospital setting

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followed by structured outpatient follow-up. Unlike sotalol, however, dofetilide does not cause excessive bradycardia and thus can be administered to patients without concern for exacerbating preexisting bradycardia. Dofetilide has many potentially lethal drug-to-drug interactions, including with many commonly prescribed antibiotics and antihypertensive drugs. Despite these limitations, many patients experience improved AF control with dofeilide with fewer daily side effects compared with other antiarrhythmic drugs.

Amiodarone is generally reserved for patients with AF for whom other antiarrhythmic drugs have been contraindicated, ineffective, or poorly tolerated. This is primarily because amiodarone has potential time- and dose-dependent organ toxicities that can affect the liver, thyroid, lungs, and eyes. It is recommended that baseline tests be performed at initiation of the drug, including an ophthalmologic examination, pulmonary spirometry and diffusion capacity tests, and blood tests to assess liver and thyroid function. The blood tests are often repeated at regular intervals, approximately every 6 to 12 months, and the ophthalmologic examination should be performed yearly. Cumulative toxicity with amiodarone occurs at a rate of approximately 1% to 2% per year.

Dronedarone is an antiarrhythmic drug designed to function similarly to amiodarone but without the molecular iodine interface associated with some of the previously described amiodarone toxicities. Early enthusiasm for this drug, based on results from the initial studies, was later tempered by safety concerns and limitations. The biggest safety concern with this drug involves use in patients with CHF. It is contraindicated for patients with advanced (New York Heart Association functional class IV failure) and was found to increase cardiovascular death rates when given to patients with permanent AF in the Permanent Atrial Fibrillation Outcome Study Using Dronedarone on Top of Standard Therapy (PALLAS) study.[47] This drug also has gastrointestinal side effects that can be partially mitigated by taking the drug with food. It also has some important drug-to-drug interactions, including with the anticoagulant drug dabigatran. That said, it is a reasonable treatment option for patients without structural heart disease or advanced liver disease and does not require hospital-based initiation like dofetilide. It has also been one of the most heavily studied antiarrhythmic drugs on the market.

Implantable Devices

Implantable cardiac devices are also used in the treatment of patients with AF. There is a substantial incidence of sinus node and AV node dysfunction in the AF population requiring cardiac pacing. Pacemakers have several purposes, including bradycardia pacing support, ventricular response regularization, and AF suppression or termination. Clinical practice guidelines detail the recommended uses of implantable pacemakers and anti-tachycardia devices.[48] Pacemakers may be implanted simply for pacing support in patients with post-AF conversion pauses or symptomatic bradycardia while in AF. Sinus node dysfunction in association with AF is often referred to as tachycardia-bradycardia syndrome. Sinus node dysfunction can be exacerbated by medications used to control AF and the presence of a pacemaker may allow use of or up titration of rate-controlling or antiarrhythmic medications.

Pacemakers are also implanted in conjunction with catheter ablation of the AV node. This type of ablation is the ultimate method of ventricular rate control and is often reserved for patients with permanent or paroxysmal AF refractory to medical or ablative therapy. The potential benefits of this type of approach extend beyond simply controlling ventricular response, because there is evidence that regularization of the ventricular rhythm also confers hemodynamic or symptomatic benefits, particularly in the heart failure population in conjunction with the use of a biventricular pacemaker. This approach has been shown to be effective and leads to improved quality of life for patients. However, this approach does not address the fibrillating atria, and such patients still require systemic anticoagulation for thromboembolism and stroke prevention.

Several features of pacemaker systems may be useful for patients with AF. A pacemaker that has the capability to change automatically into a nontracking pacing mode at the onset of an episode of AF (known as *mode switching*) is essential to avoid the rapid heart rate that might otherwise occur when the pacemaker responds to rapid atrial activity by pacing the heart inappropriately fast in the ventricles. Implantable atrial defibrillators have been developed, either as a stand-alone device or in combination with a ventricular defibrillator. However, the

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atrial defibrillator has not been widely accepted by patients or physicians. In general, patients have difficulty tolerating even the low-energy internal cardioversion shocks or frequent antitachycardia pacing sequences without the deep sedation provided during conventional external cardioversion.

Catheter Ablation

Catheter ablation has emerged as a safe and effective alternative to antiarrhythmic drug therapy for the maintenance of sinus rhythm. However, as is the case with antiarrhythmic drug therapy, it has not demonstrated a reduced risk of mortality, stroke, or heart failure and thus is not regarded as a substitute for stroke prevention strategies.[49] Conceptually, a standard catheter ablation approach involves achieving electrical pulmonary vein isolation (PVI) given the importance of atrial ectopy originating from the PVs in AF-related pathogenesis. Postablation, spontaneous electrical impulses originating from within any of the 4 PVs cannot propagate into the atrial body to initiate or trigger AF. Pulmonary vein isolation is thus a stand-alone treatment approach, but has also been incorporated into larger ablative efforts aimed at non-PV triggers and substrate modification. Non-PV triggers include other focal sources of spontaneous or induced atrial ectopy, and substrate modification, which targets atrial tissue that sustains atrial fibrillation, includes mapping/ablation of complex fractionated electrograms, denervation of cardiac ganglionic plexuses and, most recently, mapping and ablation of AF rotors. Substrate modification or ablation of non-PV triggers are often incorporated into procedures for patients with persistent or long-standing persistent AF. Outcomes data suggest that PVI alone without substrate modification works best in patients with paroxysmal AF. The role for more extensive ablation for patients with persistent AF remains unclear after the recent STAR AF II trial showing no reduction in the rate of recurrence after extensive ablation.[50] Focal impulse and rotor modulation-guided ablation is a substrate-based ablation strategy that targets AF rotors believed to be drivers of AF.[10] Studies have shown that although rotors can be safely identified and ablated, they are not effective in AF termination and prevention of AF recurrence in patients with non-paroxysmal AF.[10]

Published 1-year efficacy rates of AF ablation range from 66% to 86 % in randomized control trials comparing ablation to antiarrhythmic drugs or rate control agents.[51] Refinement in techniques have resulted in a lower incidence of complications, notably PV stenosis, which was common in the early era of catheter ablation. Experienced centers have reported high rates of successful AF ablation resulting in discontinuation of antiarrhythmic drug therapy.[52,53] The ideal candidate is a patient with paroxysmal AF in the absence of structural heart disease.

In virtually all studies involving catheter ablation, efficacy rates are lower among patients with persistent AF and long-standing persistent AF. The degree of atrial myopathy, scar burden and comorbidities may also influence outcomes. Weight loss strategies for patients with obesity and treatment of sleep apnea are recognized as increasingly important in clinical outcomes. There are currently 2 different energy sources in use for the purposes of catheter ablation. The more commonly used radiofrequency current leads to tissue death by heating and is applied using a point-by-point method. Cryoablation uses cryogenic energy delivered in a single step by means of a balloon resulting in tissue necrosis by freezing. The FIRE and ICE trial comparing the 2 energy sources concluded that cryoablation was not inferior to radiofrequency ablation with respect to efficacy in patients with drug refractory paroxysmal atrial fibrillation.[50] The FIRE and ICE trial also did not find any significant differences in overall safety between the 2 methods. However phrenic nerve injury was more common (2.7 %) in the cryoballoon group. While such phrenic nerve injuries typically resolve spontaneously, it may take up to 1 year and can be associated with significant morbidity. Other procedure-related complications include serious events such as stroke (0.5%), acute PV stenosis (0.32%), persistent PV stenosis (1.3%), cardiac tamponade (1.5%), thromboembolism (0% to 7%), serious esophageal injury(< 1%), and death (0.1%).[51,50] More common, typically not life threatening complications include femoral vascular related complications (2%) requiring intervention or delayed hospital discharge. Procedures typically take 4 to 6 hours, involve the use of radiation X-ray, and have an expected hospital course of overnight observation with planned discharge the next day. Recurrence of AF after a blanking period of 3 months postablation may indicate recovery of pulmonary vein conduction and can be an appropriate indication for repeat ablation or antiarrhythmic therapy. Oral

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anticoagulation is recommended for at least 3 months following ablation and thereafter based on the individual patient risk for stroke.[54]

Experienced centers, such as Cleveland Clinic, have reported freedom from AF rates of 75% to 80% at 1 year for patients not taking antiarrhythmic drugs with paroxysmal AF following a single catheter ablation procedure and 85% to 90% following a second ablation procedure.[55] Approximately 20% to 30% of patients require a second ablation for AF due to recovery in the PVs, the presence of non-PV triggers, or advanced atrial substrate/myopathy. Outcomes for patients with persistent and long-standing persistent AF are lower than for patients with paroxysmal disease with reported 1-year efficacy rates between 50% and 70% following a single procedure and 70% and 80% following a second procedure.

Surgical Approaches

The original Cox-Maze surgical procedure for the treatment of AF has substantially evolved from its initial form. In general, it involves a series of incisions or lesions in the atria. These are carefully placed to compartmentalize the atrial tissue to channel atrial activity and prevent the re-entry required for the maintenance of AF. To a certain extent, there has been a confluence with some of the lesions sets delivered during catheter ablation techniques. For example, achieving anatomic PVI is now considered standard with both approaches. Non-incisional lesions may be placed using bipolar radiofrequency, cryothermy, or microwave energy. Outcomes associated with surgical approaches are comparable with catheter ablation (reported higher in some series) and offer the advantage of concomitant exclusion of the left atrial appendage.[56,57] However, surgical approaches are more invasive than catheter ablation and requires either a sternotomy or a thoracotomy, plus general anesthesia and a longer postoperative recovery. The incidence of perioperative complications has been low but perhaps higher than catheter ablation. There is a potential need for a permanent postoperative pacemaker in as many as 7% to 10% of patients. [58] This may occur because of the procedure itself or underlying sinus node dysfunction. The invasiveness of this approach makes it a less desirable option for patients with AF alone, but it might be attractive for patients undergoing cardiac surgery for another indication (eg, valve replacement or coronary bypass surgery) or for patients with a particularly strong indication for exclusion of the left atrial appendage (ie, recurrent thrombus despite antithrombotic therapy). Surgical approaches have continued to become less invasive. Several centers have been using minimally invasive incisions and even thoracoscopic approaches with robotic equipment. Some surgical centers incorporate electrophysiologic testing and even catheter-based techniques with the procedure (known as hybrid procedures).

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Future Directions

The prevalence of AF, already at epidemic proportions, is expected to continue to increase as the population ages and more patients with heart disease live longer. This is especially true for patient with heart failure. The rapid growth of catheter-based and surgical ablation procedures is promising and has already relieved many patients of the burden of AF and the side effects and toxicities of antiarrhythmic medications. However, these approaches are invasive and inherently destructive, and associated with a small but important risk of serious complications. Technological innovation in mapping systems, catheter design (including the use of contract force sensors), and novel energy sources are further expected to improve the safety and perhaps effectiveness of these procedures.

Additional research informing the genetic aspects of AF is also expected to impact the management of AF. Genetic approaches to AF have identified common genetic variants (like chromosome 4q25 locus) that modulate susceptibility to AF and response to contemporary therapy.[59] If perfected, AF therapy for AF may be personalized to improve treatment outcomes. Further research into the underlying molecular and genetic causes of AF may lead to novel methods of disease prevention.

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Summary

- Atrial fibrillation is the most common sustained tachyarrhythmia in the United States and worldwide.
- Therapy for atrial fibrillation focuses on 3 goals: minimize thromboembolic stroke risk, control ventricular rate, and control the atrial rhythm in selected patients.
- Any unstable patient presenting with atrial fibrillation should undergo immediate electrical cardioversion as documented in the Advance Cardiovascular Life Support guidelines. Elective cardioversions are safe and effective with attention to appropriate anticoagulation strategies, including a transesophageal echocardiogram when needed.
- Treatment strategies involving rate control only and rhythm control are comparable in terms of mortality rates, but many studies support quality-of-life benefits associated with a rhythm-control approach. Thus, rhythm-control is recommended for patients that remain symptomatic despite adequate rate control.
- Procedure-based treatment for atrial fibrillation, namely catheter ablation, should be considered. Such procedures also include surgical approaches and implantable cardiac devices.

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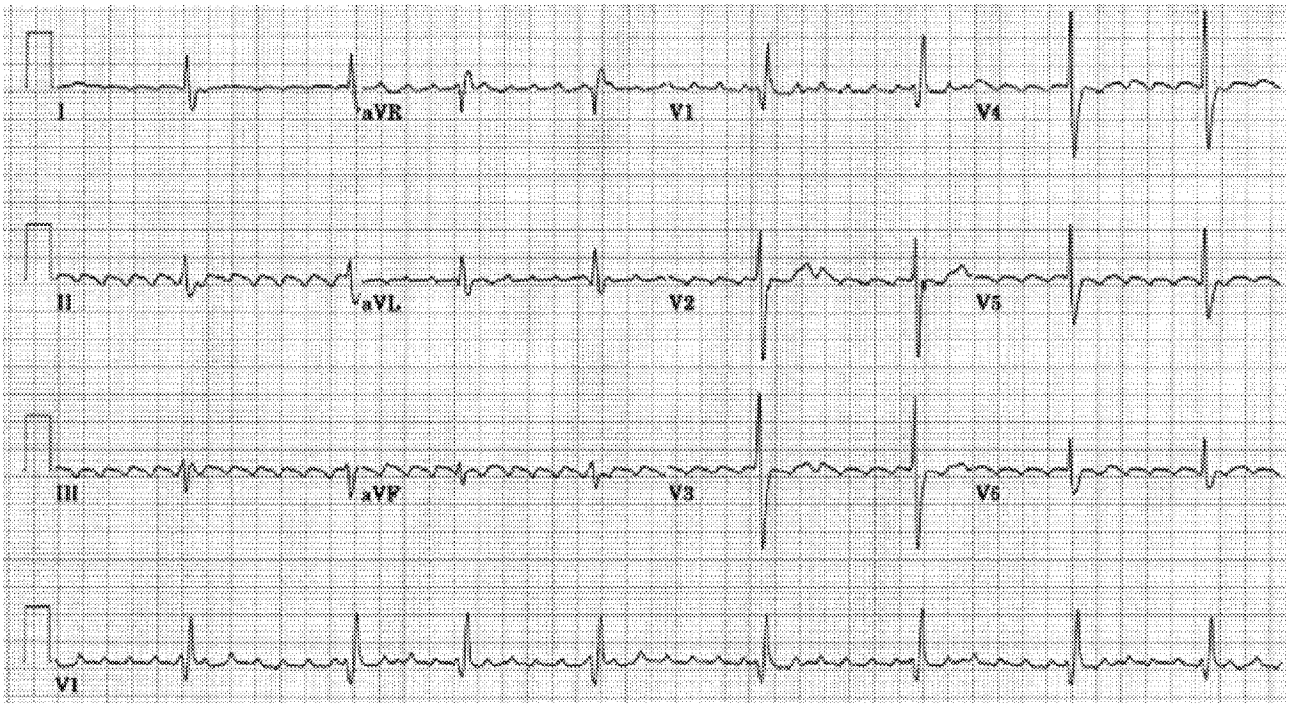

Figure 1: Typical atrial Flutter

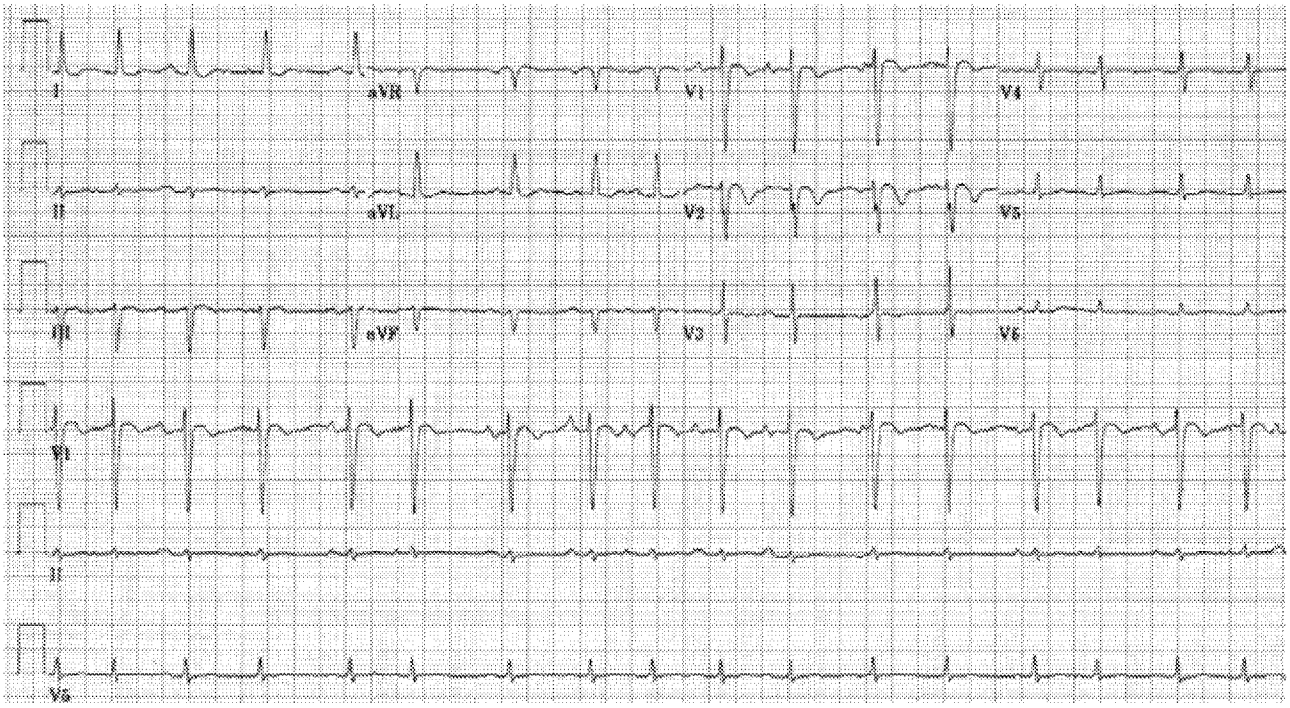

Figure 2: Multifocal atrial tachycardia

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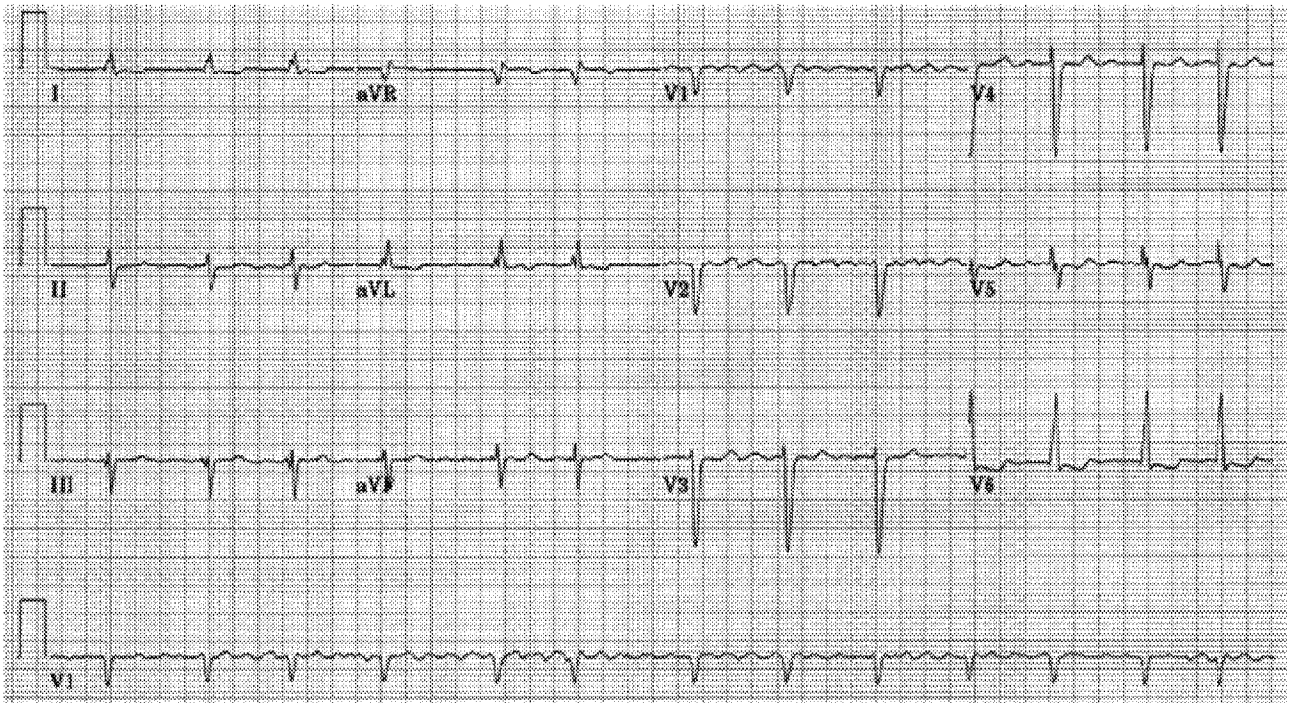

Figure 3: Coarse atrial fibrillation

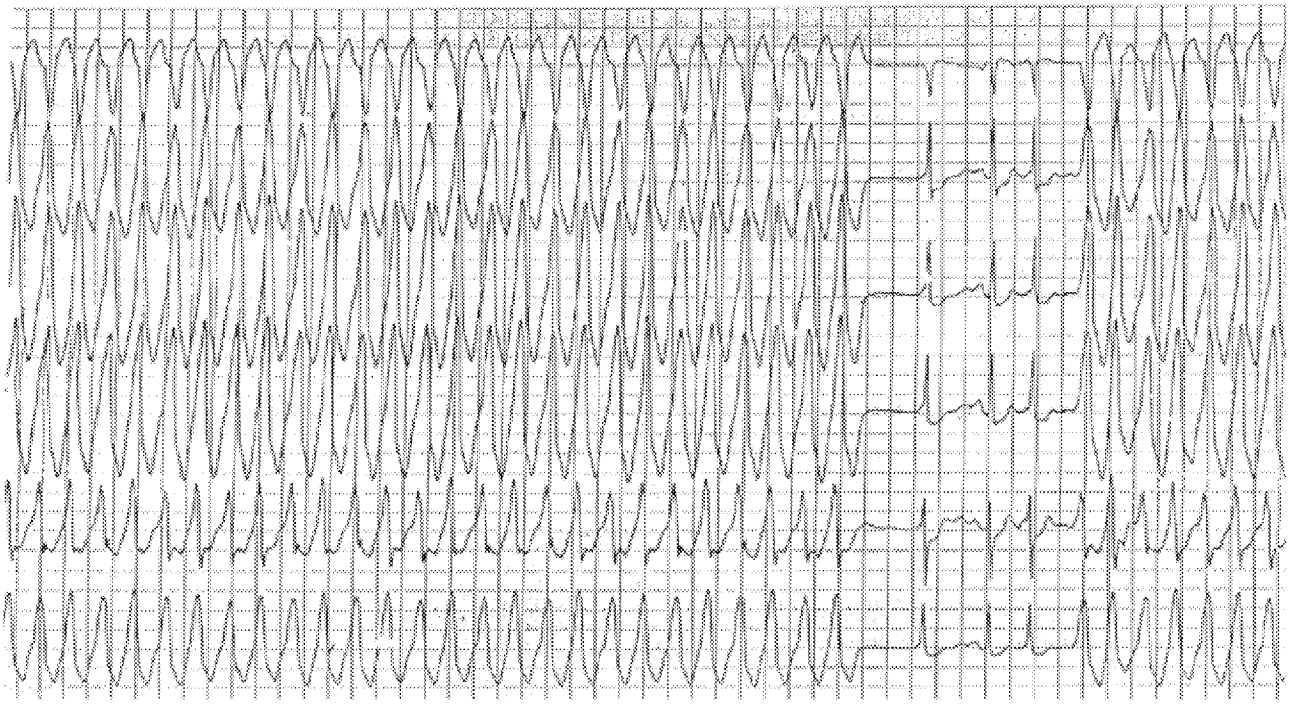

Figure 4: Wide complex tachycardia resulting from atrial fibrillation in a patient with Wolff-Parkinson-White syndrome.

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Corrected: Publisher Correction

Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network

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Computerized electrocardiogram (ECG) interpretation plays a critical role in the clinical ECG workflow[1]. Widely available digital ECG data and the algorithmic paradigm of deep learning[2] present an opportunity to substantially improve the accuracy and scalability of automated ECG analysis. However, a comprehensive evaluation of an end-to-end deep learning approach for ECG analysis across a wide variety of diagnostic classes has not been previously reported. Here, we develop a deep neural network (DNN) to classify 12 rhythm classes using 91,232 single-lead ECGs from 53,549 patients who used a single-lead ambulatory ECG monitoring device. When validated against an independent test dataset annotated by a consensus committee of board-certified practicing cardiologists, the DNN achieved an average area under the receiver operating characteristic curve (ROC) of 0.97. The average F_1 score, which is the harmonic mean of the positive predictive value and sensitivity, for the DNN (0.837) exceeded that of average cardiologists (0.780). With specificity fixed at the average specificity achieved by cardiologists, the sensitivity of the DNN exceeded the average cardiologist sensitivity for all rhythm classes. These findings demonstrate that an end-to-end deep learning approach can classify a broad range of distinct arrhythmias from single-lead ECGs with high diagnostic performance similar to that of cardiologists. If confirmed in clinical settings, this approach could reduce the rate of misdiagnosed computerized ECG interpretations and improve the efficiency of expert human ECG interpretation by accurately triaging or prioritizing the most urgent conditions.

The electrocardiogram is a fundamental tool in the everyday practice of clinical medicine, with more than 300 million ECGs obtained annually worldwide[3]. The ECG is pivotal for diagnosing a wide spectrum of abnormalities from arrhythmias to acute coronary syndrome[4]. Computer-aided interpretation has become increasingly important in the clinical ECG workflow since its introduction over 50 years ago, serving as a crucial adjunct to physician interpretation in many clinical settings[1]. However, existing commercial ECG interpretation algorithms still show substantial rates of misdiagnosis[1,5–7]. The combination of widespread digitization of ECG data and the development of algorithmic paradigms that can benefit from large-scale processing of raw data presents an opportunity to reexamine the standard approach to algorithmic ECG analysis and may provide substantial improvements to automated ECG interpretation.

Substantial algorithmic advances in the past five years have been driven largely by a specific class of models known as deep neural networks[2]. DNNs are computational models consisting of multiple processing layers, with each layer being able to learn increasingly abstract, higher-level representations of the input data relevant to perform specific tasks. They have dramatically improved the state of the art in speech recognition[8], image recognition[9], strategy games such as Go[10], and in medical applications[11,12]. The ability of DNNs to recognize patterns and learn useful features from raw input data without requiring extensive data preprocessing, feature engineering or handcrafted rules[2] makes them particularly well suited to interpret ECG data. Furthermore, since DNN performance tends to increase as the amount of training data increases[2], this approach is well positioned to take advantage of the widespread digitization of ECG data.

A comprehensive evaluation of whether an end-to-end deep learning approach can be used to analyze raw ECG data to classify a broad range of diagnoses remains lacking. Much of the previous work to employ DNNs toward ECG interpretation has focused on single aspects of the ECG processing pipeline, such as noise reduction[13,14] or feature extraction[15,16], or has approached limited diagnostic tasks, detecting only a handful of heartbeat types (normal, ventricular or supraventricular ectopic, fusion, and so on)[17–20] or rhythm diagnoses (most commonly atrial fibrillation or ventricular tachycardia)[21–25]. Lack of appropriate data has limited many efforts beyond these applications. Most prior efforts used data from the MIT-BIH Arrhythmia database (PhysioNet)[26], which is limited by the small number of patients and rhythm episodes present in the dataset.

In this study, we constructed a large, novel ECG dataset that underwent expert annotation for a broad range of ECG rhythm classes. We developed a DNN to detect 12 rhythm classes from raw single-lead ECG inputs using a training dataset consisting of 91,232 ECG records from 53,549 patients. The DNN was designed to classify 10 arrhythmias as well as sinus rhythm and noise for a total of 12 output rhythm classes (Extended Data Fig. 1). ECG data were recorded by the Zio monitor, which is a Food and Drug Administration (FDA)-cleared, single-lead, patch-based ambulatory ECG monitor[27] that continuously records data from a single vector (modified Lead II) at 200 Hz. The mean and median wear time of the Zio monitor in our dataset was 10.6 and 13.0 days, respectively. Mean age was 69 ± 16 years and 43% were women. We validated the DNN on a test dataset that consisted of 328 ECG records collected from 328 unique patients, which was annotated by a consensus committee of expert cardiologists (see Methods). Mean age on the test dataset was 70 ± 17 years and 38% were women. The mean inter-annotator agreement on the test dataset was 72.8%.

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Table 1 | Diagnostic performance of the DNN and averaged individual cardiologists compared to the cardiologist committee consensus ($n = 328$)

	Algorithm AUC (95% CI)[a]		Algorithm F_1[b]		Average cardiologist F_1	
	Sequence[a]	Set[b]	Sequence	Set	Sequence	Set
Atrial fibrillation and flutter	0.973 (0.966–0.980)	0.965 (0.932–0.998)	0.801	0.831	0.677	0.686
AVB	0.988 (0.983–0.993)	0.981 (0.953–1.000)	0.828	0.808	0.772	0.761
Bigeminy	0.997 (0.991–1.000)	0.996 (0.976–1.000)	0.847	0.870	0.842	0.853
EAR	0.913 (0.889–0.937)	0.940 (0.870–1.000)	0.541	0.596	0.482	0.536
IVR	0.995 (0.989–1.000)	0.987 (0.959–1.000)	0.761	0.818	0.632	0.720
Junctional rhythm	0.987 (0.980–0.993)	0.979 (0.946–1.000)	0.664	0.789	0.692	0.679
Noise	0.981 (0.973–0.989)	0.947 (0.898–0.996)	0.844	0.761	0.768	0.685
Sinus rhythm	0.975 (0.971–0.979)	0.987 (0.976–0.998)	0.887	0.933	0.852	0.910
SVT	0.973 (0.960–0.985)	0.953 (0.903–1.000)	0.488	0.693	0.451	0.564
Trigeminy	0.998 (0.995–1.000)	0.997 (0.979–1.000)	0.907	0.864	0.842	0.812
Ventricular tachycardia	0.995 (0.980–1.000)	0.980 (0.934–1.000)	0.541	0.681	0.566	0.769
Wenckebach	0.978 (0.967–0.989)	0.977 (0.938–1.000)	0.702	0.780	0.591	0.738
Frequency-weighted average	0.978	0.977	0.807	0.837	0.753	0.780

[a]DNN algorithm area under the ROC compared to the cardiologist committee consensus. [b]DNN algorithm and averaged individual cardiologist F_1 scores compared to the cardiologist committee consensus. Sequence-level describes the algorithm predictions that are made once every 256 input samples (approximately every 1.3 s) and are compared against the gold-standard committee consensus at the same intervals. Set-level describes the unique set of algorithm predictions that are present in the 30-s record. Sequence AUC prediction, $n = 7{,}544$; set AUC prediction, $n = 328$.

Supplementary Table 1 shows the number of unique patients exhibiting each rhythm class.

We first compared the performance of the DNN against the gold standard cardiologist consensus committee diagnoses by calculating the AUC (Table 1a). Since the DNN algorithm was designed to make a rhythm class prediction approximately once per second (see Methods), we report performance both as assessed once every second—which we call "sequence-level" and consists of one rhythm class per interval—and once per record, which we call "set-level" and consists of the group of unique diagnoses present in the record. Sequence-level metrics help capture the duration of an arrhythmia, such as its onset and offset within a record, whereas set-level metrics focus only on the existence of a rhythm class within a record. The DNN achieved an AUC of greater than 0.91 for all rhythm classes; at the sequence-level all but one AUC was above 0.97. The class-weighted average AUC was 0.978 at the sequence-level and 0.977 at the set-level. The model demonstrated high AUCs for arrhythmias of greater clinical significance such as AF, atrio-ventricular block, and ventricular tachycardia. The sequence and set-level results were similar, though sequence-level AUC was higher in the majority of cases. In sensitivity analyses, we calculated multi-class AUC using the method described by Hand and Till[28] and results were materially unchanged. Supplementary Table 2 shows the maximum sensitivity achieved by the DNN with specificity >90%, and vice versa. With one exception, all sensitivity and specificity pairs were >90%.

In addition to a cardiologist consensus committee annotation, each ECG record in the test dataset received annotations from six separate individual cardiologists who were not part of the committee (see Methods). Using the committee labels as the gold standard, we compared the DNN algorithm F_1 score to the average individual cardiologist F_1 score, which is the harmonic mean of the positive predictive value (PPV; precision) and sensitivity (recall) (Table 1). Cardiologist F_1 scores were averaged over six individual cardiologists. The trend of DNN F_1 scores tended to follow that of the averaged cardiologist F_1 scores: both had lower F_1 on similar classes, such as ventricular tachycardia and ectopic atrial rhythm (EAR). The set-level average F_1 scores weighted by the frequency of each class for the DNN (0.837) exceeded those for the averaged cardiologist (0.780). We performed multiple sensitivity analyses, all of which were consistent with our main results: both AUC and F_1 scores on the 10% development dataset ($n = 8{,}761$) were materially unchanged from the test dataset results, although they were slightly higher (Supplementary Tables 3 and 4). In addition, we retrained the DNN holding out an additional 10% of the training dataset as a second held-out test dataset ($n = 8{,}768$); the AUC and F_1 scores for all rhythms were materially unchanged (Supplementary Tables 5 and 6). We note that unlike the primary test dataset, which has gold-standard annotations from a committee of cardiologists, both sensitivity analysis datasets are annotated by certified ECG technicians.

We plotted receiver operating characteristic curves (ROCs) and precision-recall curves for the sequence-level analyses of three example classes: atrial fibrillation; trigeminy; and AVB (Fig. 1a,b). Individual cardiologist performance and averaged cardiologist performance are plotted on the same figure. Extended Data Fig. 2 presents ROCs for all classes, showing that the model met or exceeded the averaged cardiologist performance for all rhythm classes. Fixing the specificity at the average specificity level achieved by cardiologists, the sensitivity of the DNN exceeded the average cardiologist sensitivity for all rhythm classes (Table 2). We used confusion matrices to illustrate the discordance between the DNN's predictions (Fig. 2a) or averaged cardiologist predictions (Fig. 2b) and the committee consensus. The two confusion matrices exhibit a similar pattern, highlighting those rhythm classes that were generally more problematic to classify (that is, supraventricular tachycardia (SVT) versus atrial fibrillation, junctional versus sinus rhythm, and EAR versus sinus rhythm).

Finally, to demonstrate the generalizability of our DNN architecture to external data, we applied our DNN to the 2017 PhysioNet Challenge data (https://physionet.org/challenge/2017/), which contained four rhythm classes: sinus rhythm; atrial fibrillation; noise; and other. Keeping our DNN architecture fixed and without any other hyper-parameter tuning, we trained our DNN on the publicly available training dataset ($n = 8{,}528$), holding out a 10% development dataset for early stopping. DNN performance on the hidden test dataset ($n = 3{,}658$) demonstrated overall F_1 scores that were among those of the best performers from the competition (Supplementary Table 7)[24], with a class average F_1 of 0.83. This demonstrates the ability of our end-to-end DNN-based approach to generalize to a new set of rhythm labels on a different dataset.

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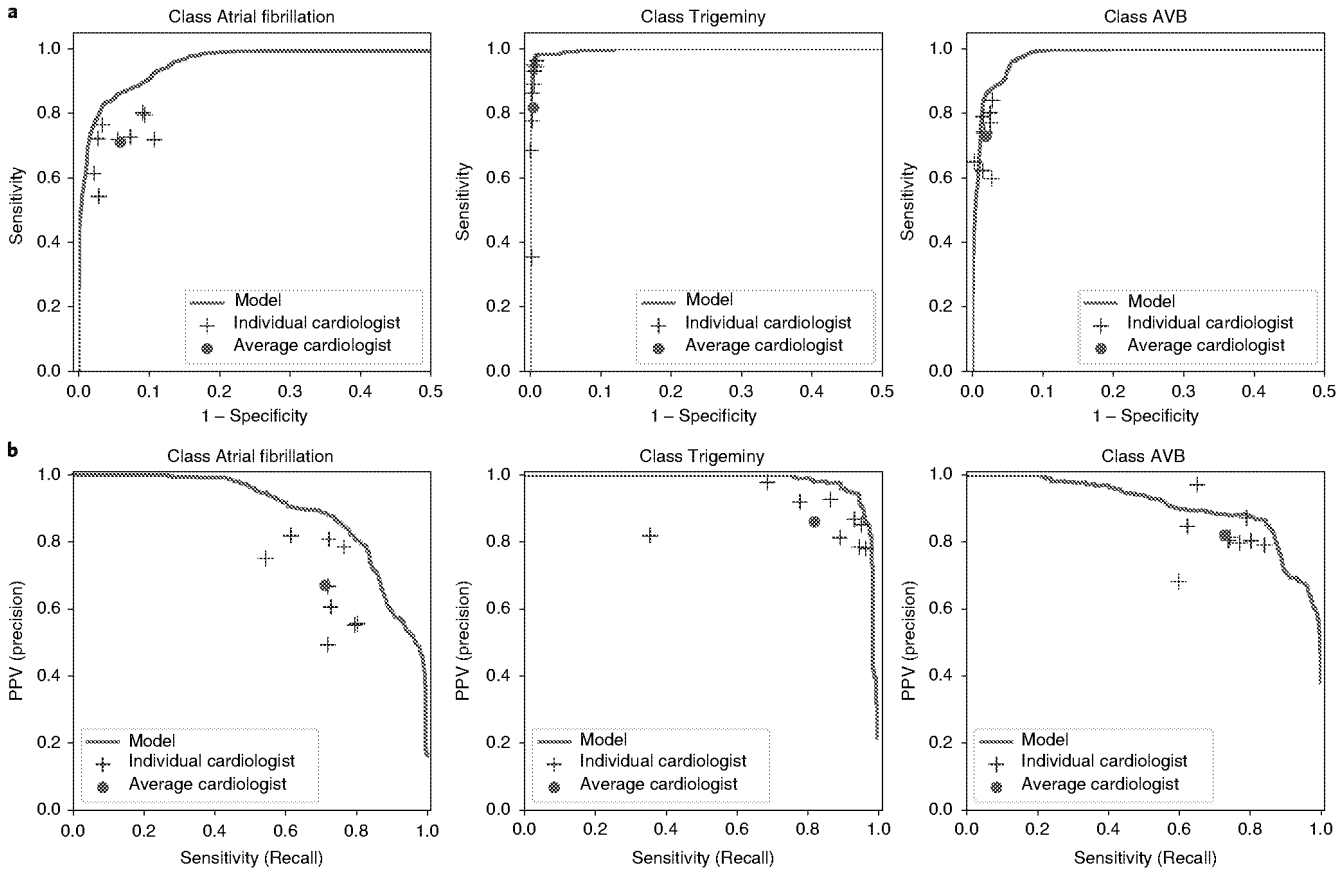

Fig. 1 | ROC and precision-recall curves. a, Examples of ROC curves calculated at the sequence level for atrial fibrillation (AF), trigeminy, and AVB. **b**, Examples of precision-recall curves calculated at the sequence level for atrial fibrillation, trigeminy, and AVB. Individual cardiologist performance is indicated by the red crosses and averaged cardiologist performance is indicated by the green dot. The line represents the ROC (**a**) or precision-recall curve (**b**) achieved by the DNN model. $n = 7{,}544$ where each of the 328 30-s ECGs received 23 sequence-level predictions.

Our study is the first comprehensive demonstration of a deep learning approach to perform classification across a broad range of the most common and important ECG rhythm diagnoses. Our DNN had an average class-weighted AUC of 0.97, with higher average F_1 scores and sensitivities than cardiologists. These findings demonstrate that an end-to-end DNN approach has the potential to be used to improve the accuracy of algorithmic ECG interpretation. Recent algorithmic and computational advances compel us to revisit the standard approaches to automated ECG interpretation. Furthermore, algorithmic approaches whose performance improves as more data become available, such as deep learning[2], can leverage the widespread digitization of ECG data and provide clear opportunities to bring us closer to the ideal of a learning health care system[29]. We emphasize our use in this study of a dataset large enough to evaluate an end-to-end deep learning approach to predict multiple diagnostic ECG classes, and our validation against the high standard of a cardiologist consensus committee. (Most cardiologists were subspecialized in rhythm abnormalities.) We believe this is the most clinically relevant gold standard, since cardiologists perform the final ECG diagnosis in nearly all clinical settings.

Our study demonstrates that the paradigm shift represented by end-to-end deep learning may enable a new approach to automated ECG analysis. The standard approach to automated ECG interpretation employs various techniques across a series of steps that include signal preprocessing, feature extraction, feature selection/reduction, and classification[30]. At each step, hand-engineered heuristics and derivations of the raw ECG data are developed with the ultimate aim to improve classification for a given rhythm, such as atrial fibrillation[31,32]. In contrast, DNNs enable an approach that is fundamentally different since a single algorithm can accomplish all of these steps 'end-to-end' without requiring class-specific feature extraction; in other words, the DNN can accept the raw ECG data as input and output diagnostic

Table 2 | DNN algorithm and cardiologist sensitivity compared to the cardiologist committee consensus, with specificity fixed at the average specificity level achieved by cardiologists

	Specificity	Average cardiologist sensitivity	DNN algorithm sensitivity
Atrial fibrillation and flutter	0.941	0.710	0.861
AVB	0.981	0.731	0.858
Bigeminy	0.996	0.829	0.921
EAR	0.993	0.380	0.445
IVR	0.991	0.611	0.867
Junctional rhythm	0.984	0.634	0.729
Noise	0.983	0.749	0.803
Sinus rhythm	0.859	0.901	0.950
SVT	0.983	0.408	0.487
Ventricular tachycardia	0.996	0.652	0.702
Wenckebach	0.986	0.541	0.651

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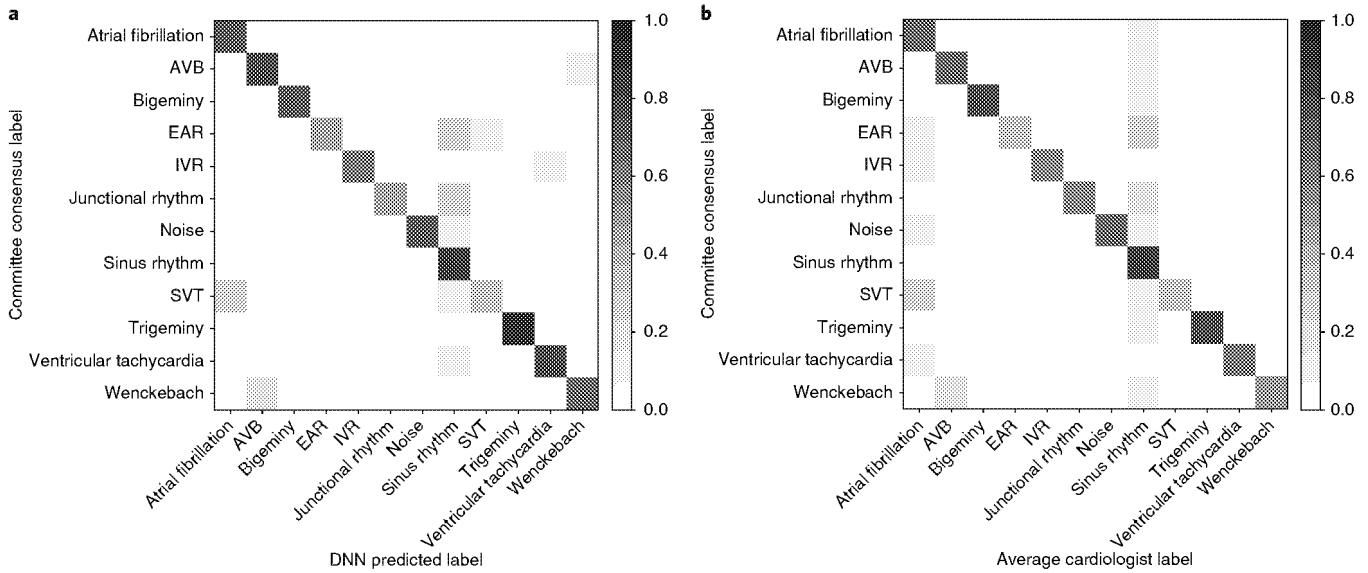

Fig. 2 | Confusion matrices. a, Confusion matrix for the predictions of the DNN versus the cardiology committee consensus. **b**, Confusion matrix for predictions of individual cardiologists versus the cardiology committee consensus. The percentage of all possible records in each category is displayed on a color gradient scale.

probabilities. With sufficient training data, using a DNN in this manner has the potential to learn all of the important previously manually derived features, along with as-yet-unrecognized features, in a data-driven way[2], and may learn shared features useful in predicting multiple classes. These properties of DNNs can serve to improve prediction performance, particularly since there is ample evidence to suggest that the currently recognized, manually derived ECG features represent only a fraction of the informative features for any diagnosis[33,34].

While artificial neural networks were first applied toward the interpretation of ECGs as early as two decades ago[3,35], until recently they only contained several layers and were constrained by algorithmic and computational limitations. More recent studies have employed deeper networks, although some only use DNNs to perform certain steps in the ECG processing pipeline, such as feature extraction[33] or classification[35]. End-to-end DNN approaches have been used more recently showing good performance for a limited set of ECG rhythms, such as atrial fibrillation[22,23,36], ventricular arrhythmias[21], or individual heartbeat classes[20,21,37,38]. While these prior efforts demonstrated promising performance for specific rhythms, they do not provide a comprehensive evaluation of whether an end-to-end approach can perform well across a wide range of rhythm classes, in a manner similar to that encountered clinically. Our approach is unique in using a 34-layer network in an end-to-end manner to simultaneously output probabilities for a wide range of distinct rhythm diagnoses, all of which is enabled by our dataset, which is orders of magnitude larger than most other datasets of its kind[26]. Distinct from some other recent DNN approaches[39], no substantial preprocessing of ECG data, such as Fourier or wavelet transforms[40], is needed to achieve strong classification performance.

Since arrhythmia detection is one of the most problematic tasks for existing ECG algorithms[1,5,6], if validated in clinical settings through clinical trials, our approach has the potential for substantial clinical impact. Paired with properly annotated digital ECG data, our approach has the potential to increase the overall accuracy of preliminary computerized ECG interpretations and can also be used to customize predictions to institution- or population-specific applications by additional training on institution-specific data. While expert provider confirmation will probably be appropriate in many clinical settings, the DNN could expand the capability of an expert over-reader in the clinical workflow, for example, by triaging urgent conditions or those for which the DNN has the least 'confidence'. Since ECG data collected from different clinical applications range in duration from 10 s (standard 12-lead ECGs) to multiple days (single-lead ambulatory ECGs), the application of any algorithm, including ours, must ultimately be tailored to the target clinical application. For example, even at the performance characteristics we report, applying our algorithm sequentially across an ECG record of long duration would result in nontrivial false-positive diagnoses. Faced with a similar problem, cardiologists probably incorporate additional mechanisms to improve their diagnostic performance, such as taking advantage of the increased context or knowledge about arrhythmia epidemiology. Similarly, additional algorithmic steps or post-processing heuristics may be important before clinical application.

An important finding from our study is that the DNN appears to recapitulate the misclassifications made by individual cardiologists, as demonstrated by the similarity in the confusion matrices for the model and cardiologists. Manual review of the discordances revealed that the DNN misclassifications overall appear very reasonable. In many cases, the lack of context, limited signal duration, or having a single lead limited the conclusions that could reasonably be drawn from the data, making it difficult to definitively ascertain whether the committee and/or the algorithm was correct. Similar factors, as well as human error, may explain the inter-annotator agreement of 72.8%.

Of the rhythm classes we examined, ventricular tachycardia is a clinically important rhythm for which the model had a lower F_1 score than cardiologists, but interestingly had higher sensitivity (94.1%) than the averaged cardiologist (78.4%). Manual review of the 16 records misclassified by the DNN as ventricular tachycardia showed that 'mistakes' made by the algorithm were very reasonable. For example, ventricular tachycardia and idioventricular rhythm (IVR) differ only in the heart rate being above or below 100 beats per minute (b.p.m.), respectively. In 7 of the committee-labeled IVR cases, the record contained periods of heart rate $\geq$ 100 b.p.m., making ventricular tachycardia a reasonable classification by the DNN; the remaining 3 committee-labeled IVR records had rates close to 100 b.p.m.. Of the 5 cases where the committee label was atrial fibrillation (4) or SVT (1), all but one displayed aberrant conduction, resulting in wide QRS complexes (the ECG waveform corresponding to ventricular activation) with a similar appearance to ventricular tachycardia. If we recategorize the 7 IVR records with a rate $\geq$ 100 b.p.m. as ventricular tachycardia, overall DNN performance on ventricular tachycardia exceeds that of cardiologists by F_1 score, with a set-level F_1 score of 0.82 (versus 0.77).

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This study has several important limitations. Our input dataset is limited to single-lead ECG records obtained from an ambulatory monitor, which provides limited signal compared to a standard 12-lead ECG; it remains to be determined if our algorithm performance would be similar in 12-lead ECGs. However, it may be in applications such as this, which have lower signal-to-noise ratio and where the current standard of care leaves more room for improvement, that approaches such as deep learning may provide the greatest impact. As discussed earlier, a limitation facing this, or any algorithm, before clinical application would be tailoring it to the target application, which may require additional training or post-processing steps. Additionally, systematic differences in the way technicians versus cardiologists labeled records in our dataset could have decreased DNN performance, although we took precautions to limit this by establishing standard operating protocols for annotation. In addition, as revealed in our manual review of discordant predictions, in some cases there remains uncertainty in the correct label. Given the resource-intensive nature of cardiologist committee ECG annotation, our test dataset was limited to records from 328 patients; confidence intervals (CIs) with our test dataset size were acceptably narrow, as we report in Table 1, although our ability to perform subgroup analysis (such as by age/sex) is limited. Finally, we also note that to obtain a sufficient quantity of rare rhythms in our training and test datasets, we targeted patients exhibiting these rhythms during data extraction. This implies that prevalence-dependent metrics such as the F_1 score would not be expected to generalize to the broader population.

In summary, we demonstrate that an end-to-end deep learning approach can classify a broad range of distinct arrhythmias from single-lead ECGs with high diagnostic performance similar to that of cardiologists. If confirmed in clinical settings, this approach has the potential to improve the accuracy, efficiency, and scalability of ECG interpretation.

Online content

Any methods, additional references, Nature Research reporting summaries, source data, statements of data availability and associated accession codes are available at https://doi.org/10.1038/s41591-018-0268-3.

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Author contributions

M.H., A.Y.N., A.Y.H., and G.H.T. contributed to the study design. M.H. and C.B. were responsible for data collection. P.R. and A.Y.H. ran the experiments and created the figures. G.H.T., P.R., and A.Y.H. contributed to the analysis. G.H.T., A.Y.H., and M.P.T. contributed to the data interpretation and to the writing. G.H.T., M.P.T., and A.Y.N. advised and A.Y.N. was the senior supervisor of the project. All authors read and approved the submitted manuscript.

Competing interests

M.H. and C.B. are employees of iRhythm Technologies, Inc. G.H.T. is an advisor to Cardiogram, Inc. M.P.T. is a consultant to iRhythm Technologies, Inc. None of the other authors have potential conflicts of interest.

Additional information

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Methods

Study participants and sampling procedures. Our dataset contained retrospective, de-identified data from adult patients >18 years old who used the Zio monitor (iRhythm Technologies, Inc) from January 2013 to March 2017. All extracted data were de-identified according to the Health Insurance Portability and Accountability Act Safe Harbor. According to the iRhythm Technologies privacy policy, fully de-identified patient data may be shared externally for research purposes; patients may opt out of this sharing. Accordingly, written informed consent was not necessary for this study given that the 30-s ECG samples of both the training and test datasets were appropriately de-identified before use. The study was reviewed and exempted from full review by the Stanford University Institutional Review Board.

We extracted a median of one 30-s record per patient to construct the training dataset. ECG records were extracted based on the report summaries produced by iRhythm Technologies clinical workflow, which includes a full review by a certified ECG technician of initial annotations from an algorithm which is FDA 510(k) approved for clinical use. We randomly sampled patients exhibiting each rhythm; from these patients, we selected 30-s records where the rhythm class was present. Although the targeted rhythm class was typically present within the record, most records contained a mix of multiple rhythms. To further improve the balance of classes in the training dataset, rare rhythms such as AVB, were intentionally oversampled, with a median of two 30-s records per patient. For the test dataset, 30-s records of each rhythm were sampled in a similar manner to achieve a greater representation of rare rhythms; however, the test dataset included only a single record per patient. The training, development, and test datasets had completely disjointed sets of patients.

Annotation procedures. All ECG records in the training and test datasets underwent additional annotation procedures. We used separate procedures to annotate the training and test datasets, reserving the resource-intensive cardiologist annotation for use as the gold standard in the test dataset. To annotate the training dataset, a group of senior certified ECG technicians reviewed all records and noted the onset and offset of all rhythms on the record. Every record was randomly assigned to be reviewed by a single technician specifically for this task, not for any other purpose. All annotators received specific instructions and training regarding how to annotate transitions between rhythms to improve labeling consistency. We held out records from a random 10% of the training dataset patients for use as a development dataset to perform DNN hyper-parameter tuning.

Eight board-certified practicing cardiac electrophysiologists and one board-certified practicing cardiologist (all referred to as cardiologists) annotated records in the test dataset. All iRhythm Technologies clinical annotations were removed from the test dataset. Cardiologists were divided into three committees of three members each; each committee annotated a separate one-third of the test dataset (112 records). Cardiologist committees discussed records as a group and annotated by consensus, providing the gold standard for model evaluation. Each of the remaining six cardiologists that were not part of the committee for that record also provided individual annotations for that record. These annotations were used to compare the model's performance to that of the individual cardiologists. In summary, every record in the test dataset received one committee consensus annotation from a group of three cardiologists and six individual cardiologist annotations.

Many ECG records contained multiple rhythm class diagnoses since the onset and offset of all unique classes were labeled within each 30-s record. The atrial fibrillation class combined atrial fibrillation and atrial flutter. The AVB class combined both type 2 second-degree AVB (Mobitz II/Hay) and third-degree AVB. We combined these classes because they have similar clinical consequences. The noise label was selected whenever artifact in the signal precluded accurate interpretation of the underlying rhythm.

Algorithm development. We developed a convolutional DNN to detect arrhythmias (Extended Data Fig. 1), which takes as input the raw ECG data (sampled at 200 Hz, or 200 samples per second) and outputs one prediction every 256 samples (or every 1.28 s), which we call the output interval. The network takes as input only the raw ECG samples and no other patient- or ECG-related features. The network architecture has 34 layers; to make the optimization of such a network tractable, we employed shortcut connections in a manner similar to the residual network architecture[42]. The network consists of 16 residual blocks with two convolutional layers per block. The convolutional layers have a filter width of 16 and $32*2^k$ filters, where k is a hyper-parameter which starts at 0 and is incremented by 1 every fourth residual block. Every alternate residual block subsamples its inputs by a factor of 2. Before each convolutional layer, we applied batch normalization[43] and a rectified linear activation, adopting the pre-activation block design[43]. The first and last layers of the network are special-cased due to this pre-activation block structure. We also applied Dropout[44] between the convolutional layers and after the nonlinearity with a probability of 0.2. The final fully connected softmax layer produces a distribution over the 12 output classes.

The network was trained de novo with random initialization of the weights as described by He et al.[7]. We used the Adam optimizer[45] with the default parameters $\beta_1 = 0.9$ and $\beta_2 = 0.999$, and a mini batch size of 128. We initialized the learning rate to 1×10^{-3} and reduced it by a factor of 10 when the developmentally set loss stopped improving for two consecutive epochs. We chose the model that achieved the lowest error on the development dataset.

In general, the hyper-parameters of the network architecture and optimization algorithm were chosen via a combination of grid search and manual tuning. For the architecture, we searched primarily over the number of convolutional layers, the size and number of the convolutional filters, as well as the use of residual connections. We found the residual connections useful once the depth of the model exceeded eight layers. We also experimented with recurrent layers including long short-term memory cells[46] and bidirectional recurrence, but found no improvement in accuracy and a substantial increase in runtime; thus, we abandoned this class of models. We manually tuned the learning rate to achieve fastest convergence.

Algorithm evaluation. Since the DNN outputs one class prediction every output interval, it makes a series of 23 rhythm predictions for every 30-s record. The cardiologists annotated the start and end point of each rhythm class in the record. We used this to construct a cardiologist label at every output interval by rounding the annotation to the nearest interval boundary. Therefore, model accuracy can be assessed at the level of every output interval, which we call 'sequence-level', or at the record level, which we call 'set-level'. To compare model predictions at the sequence level, the model predictions at each output interval were compared with the corresponding committee consensus labels for that same output interval. At the set level, the set of unique rhythm classes across a given ECG record that was predicted by the DNN was compared with the set of rhythm classes annotated across the record by the committee consensus. The set-level evaluation, unlike the sequence-level, does not penalize for time misalignment of a rhythm classification within a record.

Algorithm evaluation at the sequence level allows comparison against the gold standard at every output interval, providing the most comprehensive metric of algorithm performance, which we therefore employ for most metrics. The sequence-level evaluation is also similar to clinical applications for telemetry or Holter monitor analysis, whereby it is critical to identify the onset and the offset of rhythms. Evaluation at the set level is a useful abstraction, approximating how the DNN algorithm might be applied to a single ECG record to identify which diagnoses are present in a given record.

To train and evaluate our model on the Physionet Challenge data, which contains variable length recordings, we made minor modifications to the DNN. Without any change, the DNN can accept as input any record with a length that is a multiple of 256 samples. To handle examples that are not a multiple of 256, records were truncated to the nearest multiple. We used the given record label as the label for approximately every 1.3-s output prediction. To produce a single prediction for the variable length record we used a majority vote of the sequence-level predictions.

Statistical analysis. We calculated the ROC analysis and AUC to assess model discrimination for each rhythm class with a one versus other strategy[26,47]. AUCs for sequence-level and set-level analyses are presented separately. We give a two-sided CI for the AUC scores[35]. Sensitivity and specificity were calculated at binary decision thresholds for every rhythm class. We computed the precision-recall curve, which shows the relationship between PPV (precision) and sensitivity (recall)[48]. It provides complementary information to the ROC curve, especially with class-imbalanced datasets. To compare the relative performance of the DNN to the cardiologist committee labels, we calculated the F_1 score, which is the harmonic mean of the PPV and sensitivity. It ranges from 0 to 1 and rewards algorithms that maximize both PPV and sensitivity simultaneously, rather than favoring one over the other. The F_1 score is complementary to the AUC, which is particularly helpful in the setting of multi-class prediction and less sensitive than the AUC in settings of class imbalance[49]. For an aggregate measure of model performance, we computed the class frequency-weighted arithmetic mean for both the F_1 score and the AUC. To obtain estimates of how the DNN compares to an average cardiologist, the characteristics of cardiologist performance were averaged across the six cardiologists who individually annotated each record. We used confusion matrices to illustrate the specific examples of rhythm classes where the DNN prediction or the individual cardiologist's prediction were discordant with the committee consensus at the sequence level. Among the individual cardiologist annotations in the test dataset, we calculated inter-annotator agreement as the ratio of the number of times two annotators agreed that a rhythm was present at each output interval and the total number of pairwise comparisons.

Reporting Summary. Further information on research design is available in the Nature Research Reporting Summary linked to this article.

Code availability. Code for the algorithm development, evaluation, and statistical analysis is open source with no restrictions and is available from https://github.com/awni/ecg.

Data availability

The test dataset used to support the findings of this study is publicly available at https://irhythm.github.io/cardio_test_set without restriction. Restrictions apply to the availability of the training dataset, which was used under license from iRhythm

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Technologies, Inc. for the current study. iRhythm Technologies, Inc. will consider requests to access the training data on an individual basis. Any data use will be restricted to noncommercial research purposes, and the data will only be made available on execution of appropriate data use agreements.

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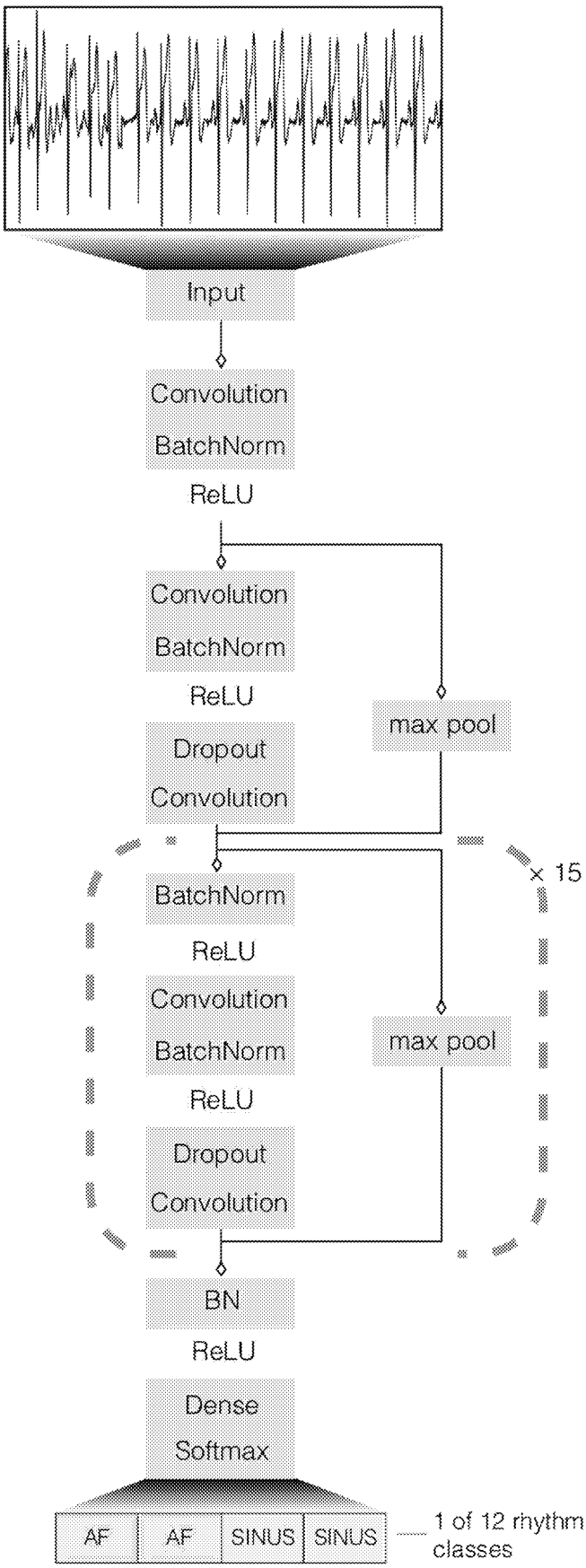

Extended Data Fig. 1 | Deep Neural Network architecture. Our deep neural network consisted of 33 convolutional layers followed by a linear output layer into a softmax. The network accepts raw ECG data as input (sampled at 200 Hz, or 200 samples per second), and outputs a prediction of one out of 12 possible rhythm classes every 256 input samples.

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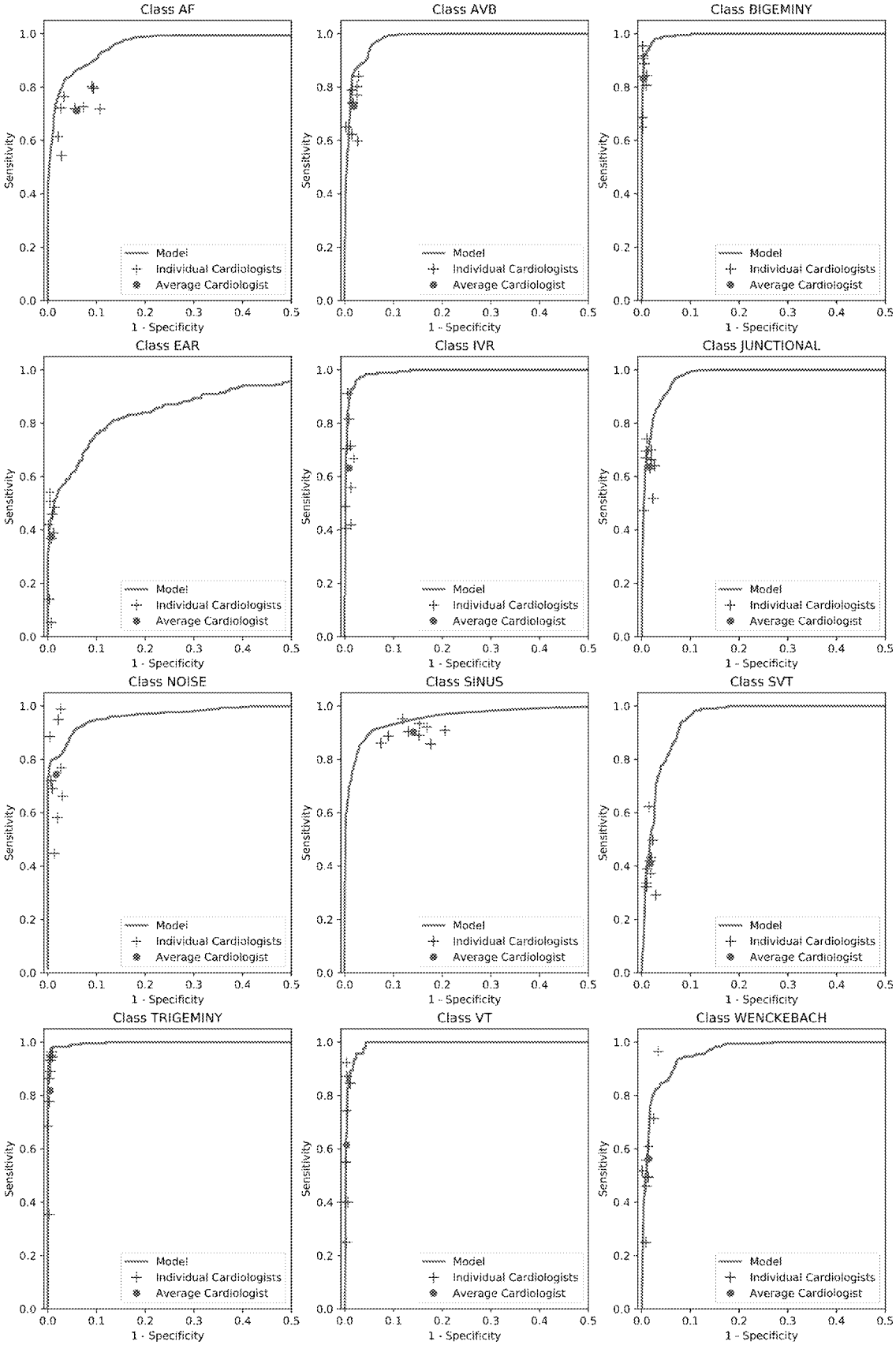

Extended Data Fig. 2 | Receiver operating characteristic curves for deep neural network predictions on 12 rhythm classes. Individual cardiologist performance is indicated by the red crosses and averaged cardiologist performance is indicated by the green dot. The line represents the ROC curve of model performance. AF-atrial fibrillation/atrial flutter; AVB- atrioventricular block; EAR-ectopic atrial rhythm; IVR-idioventricular rhythm; SVT-supraventricular tachycardia; VT-ventricular tachycardia. $n = 7{,}544$ where each of the 328 30-second ECGs received 23 sequence-level predictions.

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When statistical analyses are reported, confirm that the following items are present in the relevant location (e.g. figure legend, table legend, main text, or Methods section).

n/a	Confirmed	
☐	☒	The exact sample size (*n*) for each experimental group/condition, given as a discrete number and unit of measurement
☐	☒	An indication of whether measurements were taken from distinct samples or whether the same sample was measured repeatedly
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☒	☐	Clearly defined error bars *State explicitly what error bars represent (e.g. SD, SE, CI)*

Our web collection on statistics for biologists may be useful.

Software and code

Policy information about availability of computer code

Data collection	We used a small amount of custom software to build the data extraction and annotation tool. This software is not a major part of this work. The bulk of the custom and existing software we used is in the Data analysis section. The custom software we used for data collection was written in Python. It targeted records containing different rhythm classes, as described in the manuscript. Upon extraction, the data was saved in a PostgreSQL database. The extracted data was then pulled in a web-based tool to be reviewed. An html-based tool was designed for the purpose of accurately reviewing each record. Reviewers were able to see and scroll through 30-second ECG records and color code existing rhythms in the record from the onset to their offset. The full segmentation of the input record was then pushed to a different table in the same database. The reviewed records were finally de-identified and saved in json format to be used for model training purposes.
Data analysis	Code for the algorithm development, evaluation and statistical analysis is open source with no restrictions and available at https://github.com/awni/ecg.

For manuscripts utilizing custom algorithms or software that are central to the research but not yet described in published literature, software must be made available to editors/reviewers upon request. We strongly encourage code deposition in a community repository (e.g. GitHub). See the Nature Research guidelines for submitting code & software for further information.

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All manuscripts must include a data availability statement. This statement should provide the following information, where applicable:

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- A list of figures that have associated raw data
- A description of any restrictions on data availability

The test dataset used to support the findings of this study is publicly available at https://irhythm.github.io/cardiol_test_set without restriction. Restrictions apply to the availability of the training dataset, which was used under license from iRhythm Technologies Inc. for the current study. iRhythm will consider requests to access the training data on an individual basis. Any data use will be restricted to non-commercial research purposes, and the data will only be made available upon execution of appropriate data use agreements.

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Study design

All studies must disclose on these points even when the disclosure is negative.

Study description	We developed and validated the performance of a Deep Neural Network on ambulatory single-lead ECG. The data in the study is quantitative consisting of ECG records and their corresponding annotation.
Research sample	The dataset was a deidentified, retrospective dataset of adult patients >18 years of age who have used the iRhythm Zio monitor for clinical indications.
Sampling strategy	Records were chosen randomly from within the study period, though abnormal rhythms were intentionally over-sampled to provide more training examples for these rhythms. For the training set the sample size was chosen such that our model matched the performance of certified ECG technicians on a validation dataset. For the test set our sample size was chosen so that we would obtain roughly 20 (or more) examples for each rhythm class. We justified this sample size post-hoc with confidence intervals in our AUC computations.
Data collection	We extracted a median of 1 (and a maximum of 3) 30-second records per patient to construct the training dataset. To improve the balance of classes in the training dataset, records that exhibited less prevalent rhythms were intentionally oversampled, to a maximum of three 30-second records per patient. For the test dataset, 30-second records of each rhythm were randomly sampled from patients during the study period to achieve an equal number of records per class.
Timing	The data was collected retrospectively from a cohort who used the Zio monitor between January 2013 and March 2017
Data exclusions	We excluded patients under the age of 18 from the study. We preestablished this exclusion criteria in order to simplify any potential data use approval processes regarding the use of data from minors.
Non-participation	We did not require informed consent for this study given that the data belongs to iRhythm Technologies and that the data was fully de-identified.
Randomization	Our data was selected from the study period according to the selection strategy mentioned in the "Data Collection" section. Other than oversampling for certain arrhythmias all patients were randomly selected from pool of patients available in the study period.

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Steven Walfish, November 30, 2016, FOI Services Teleconference TC161130 Presentation, Slide ‘Sample Size for Proportions

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Determining a Statistically Valid Sample Size: What Does FDA Expect to See?

Presented by:

Steven Walfish

When:

November 30, 2016

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Determining a Statistically Valid Sample Size: What Does FDA Expect to See?

Steven Walfish, MBA MS
Principal Scientific Liaison, USP

An FOI Services Teleconference

November 2016

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Agenda

- Basic risk management principles
- The relationship of risk to sample size
- Tools for continuous data
  - One-sample
  - Individual values
  - One proportion
  - Capability index
  - Non-Inferiority
- Tools for attribute data
  - ANSI/ASQ Z1.4
  - C=0
  - Square root N plus 1
- A case study and examples

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What is *Unbiased & Representative?*

- The word bias is thrown around in the statistical literature. What does it mean?
  - "Bias is a quantitative term describing the difference between the average of measurements made on the same object and its true value."
  - The concept of unbiased means the sample is representative of the population.
- The problem is that an inadequate sample, or a poorly selected sample will induce bias.

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Sampling Plans are Poorly Written

- Most documents that detail a sampling plan state the sample size, but not the sampling method.
  - "Measure the pH of ten samples"
  - "Inspect thirty labels"

- Should be written:
  - "Measure the pH of ten samples throughout the process"
  - "Inspect thirty labels, ten each from the beginning, middle and end."

- Sampling plans should also reflect the acceptance levels and risks levels.
  - Inspect thirty labels, ten each from the beginning, middle and end with no defects. This reflects 95% confidence with 90% reliability.

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Principles of Risk Management

- Two primary principles of quality risk management are:
  - The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and
  - The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk.
- Sample size is a function of risk

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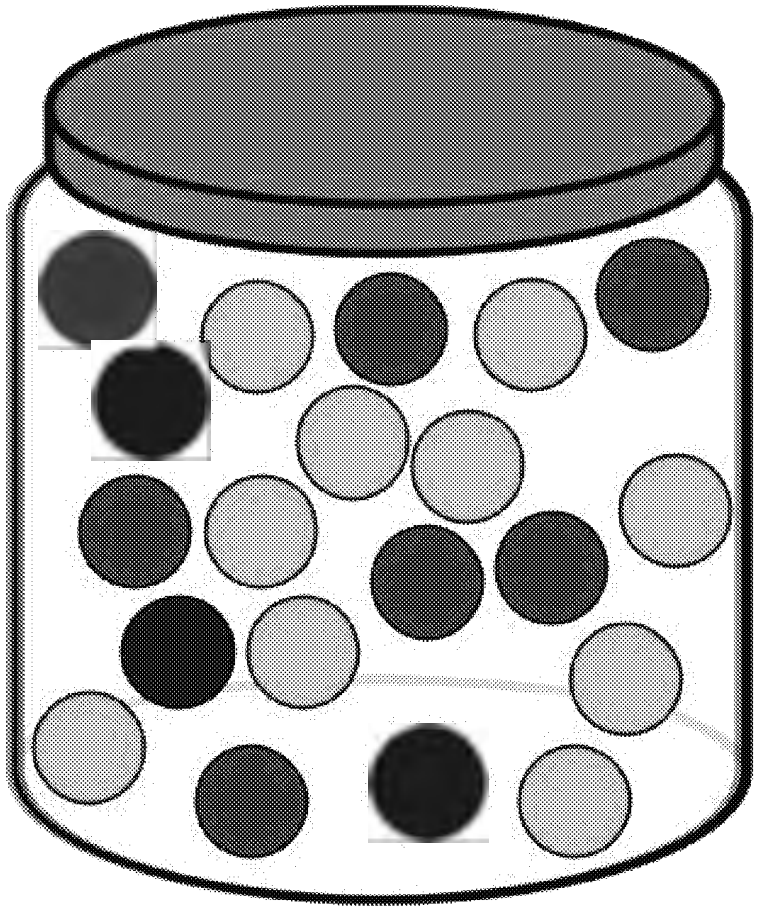
Representative Sampling

- Decisions are often based on our analysis of a sample.
- How we conduct a sample is very important.
  - Want:
    - Minimize bias
    - Sample reflects the characteristics of the lot or batch
    - Economical sample size



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Sampling Selection

- Simple random sampling (SRS) ensures that all units are selected independently with equal probability (i.e. raffle).
- Stratified random sampling ensures that each strata (subgroup) are represented in the sample.
- Composite sampling combines several samples into a single sample unit (10 tablets used to make a single sample prep).
- Systematic sampling is a convenient sampling method ensuring that items from the beginning, middle and end are sampled.

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Which is the Best?

- **As all good statisticians say…**
  - **It depends!**
- The selection of a sample is based on the answer needed to the question to be asked
- It is not a one size fits all problem

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Sampling Error

- Sampling has inherent risks and potential error.
- The number of samples should be sufficient to minimize the risks.
- Cost versus benefit

		Reality	
		Accept	**Reject**
Decision	**Accept**	Correct Decision (green)	Type II Error (β) Consumer Risk (red)
	Reject	Type I Error (α) Producer Risk (red)	Correct Decision (green)

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Definitions

- AQL – Acceptable Quality Level is the process average percent defective we will accept with high probability (usually set at 95%)
- LQ – Limiting Quality is the process average percent defective we will accept with low probability (usually set at 10%)
- Accept Number – Maximum number of defectives allowable in our sample and still accept the "lot or batch"
- Reject Number – Minimum number of defectives allowable in our sample that will cause "lot or batch" to be rejected
- Sample Size – The number of units to be tested from the lot or batch.
- Sampling Plan – A combination of sample size, accept/reject number with AQL and LQ levels.

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OC Curve

- The operating characteristic (OC) curve depicts the power of an acceptance sampling plan.
- Its a plot of the probabilities for accepting a lot given a fraction defective.
- Every sampling plan has an OC Curve associated with it.

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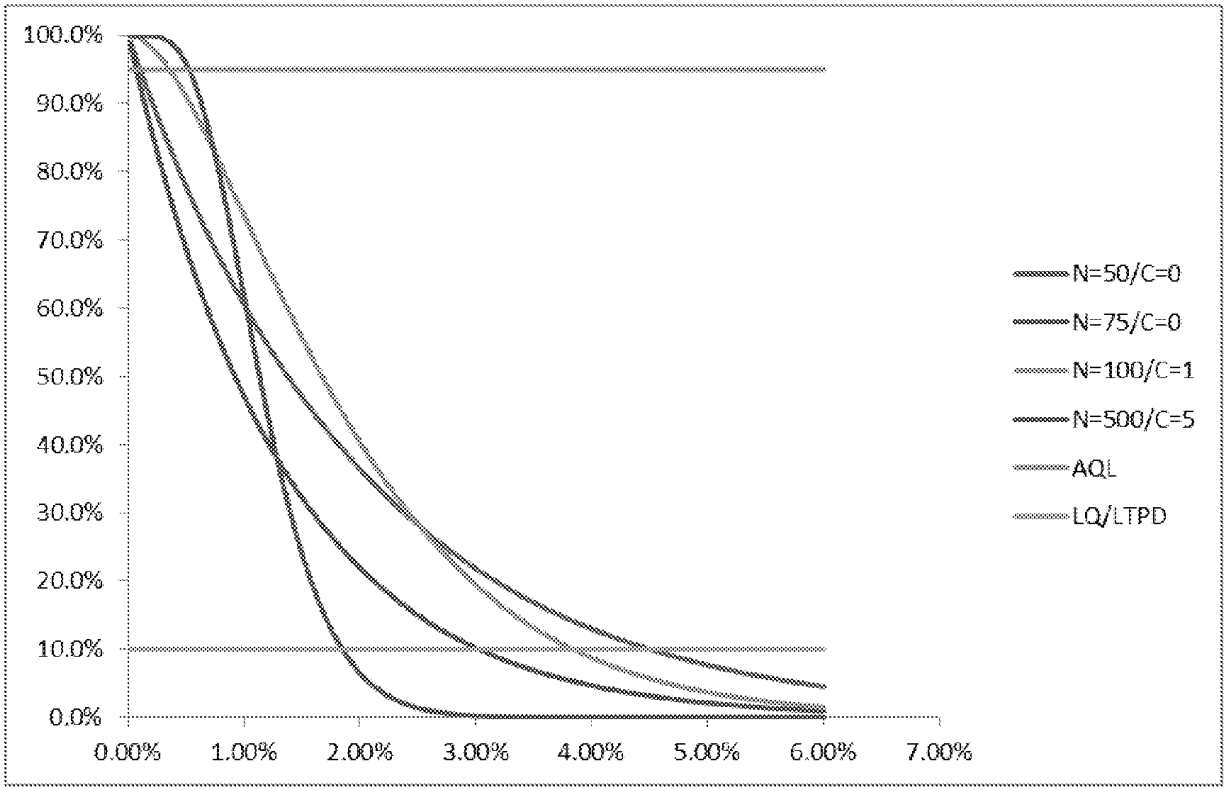
OC Curve



N	Accept Number (C)	AQL	LQ
50	0	0.101%	4.507%
75	0	0.069%	3.025%
100	1	0.355%	3.833%
500	5	0.526%	1.851%

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Reportable Value

- A reportable value is an average value of readings from one or more units of a test solution.
- Taking three values and averaging them into a single reportable value has a smaller error.
- This plays an important role in determining sample size.

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Reportable Value - Example

- Taking 6 individual samples with a standard deviation 0.58 has a 95% confidence interval of +/- 0.61
- Taking 6 sets of three value reduces the width of the interval.
- Determining which replication strategy to use is a function of the sources of variability seen in obtaining a reportable value.

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Sampling & Measurement Error

Two sources of "error"

1) The variability of the sample statistic around the population parameter – standard deviation.

2) The variability of the measurement itself due to the instrument we are using.
   - Measuring the same unit repeatedly.

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Sampling & Measurement Error

- Minimizing the variation:
  - To get a more precise estimate of the population parameter, take a larger sample.
    (i.e., more individual sampling units)
  - To obtain a more precise measurement, measure the same individual sampling unit multiple times (replicates) and take the average.

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Sample Size for Mean

$$n = \frac{\left(Z_\alpha + Z_\beta\right)^2 S^2}{\Delta^2}$$

- Z_α and Z_β are the Type I and Type II error rates.
- You can substitute the t-value for smaller sample sizes.
- Differs slightly from the method used by software such as JMP™.

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Example

- Type I error rate is 5% (95% Confidence)
  - $Z\alpha=1.96$
- Type II error rate is 1% (99% Power)
  - $Z\beta = 2.326$
- Standard deviation of 1 and a delta of 0.5.

$$n = \frac{(1.96 + 2.326)^2 (1)^2}{0.5^2}$$

$$n = 74$$

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Sample Size for Individual Values

- Can develop sample sizes for individual values instead of the mean.
- Requires a confidence level and percent of future values expected to be in the interval (coverage or reliability).
- This approach is for all future observations (beta-content approach)

$$\overline{X} + k * S < U$$

$$\overline{X} - k * S > L$$

- Two-sided tolerance limits for normal populations-Some improvements. Howe, W. G. 1969, Journal of the American Statistical Association, Vol. 64, pp. 610-620)

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Example

- How large a sample do I need to have 95% confidence with 95% reliability for a mean of 10.0 and standard deviation of 0.55?

- The specification are 8.5 to 12.0

- Since the mean is closest to the lower specification

$$10 - k * 0.55 > 8.5$$

$$k = 2.727$$

Sample size is approximately 21

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What is the Difference?

- We collected 20 results for purity of a supplement
  - Mean = 95.1%
  - Std Dev. = 6.97
  - LSL = 90
  - Min = 92
  - Max= 95

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Which is Right?

- Want to test if the MEAN is greater than 90.
  - The 95% Lower Bound on the mean of 95.1 is 92.4. This implies if we sample 20 units from a population whose mean is 95.1 with SD=6.97, the average will be greater than 92.4 approximately 95% of the time.

- Want to test if the INDIVIDUAL purity is greater than 95.
  - The lower bound with 95% confidence and 99% coverage (reliability) is on the distribution of the individuals is 72.1. This implies if we sample 20 units from a population whose mean is 95.1 with SD=6.97, 99% of the individual values would be greater than 72.1.

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Which is Right

- The mean of 20 results would meet the specification.
- A sample of 20 results would have a high probability of failure.
- Must be careful to specify what is the reportable value for the testing.

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Sample Size for Proportions

$$n = \left(\frac{z_{1-\frac{\alpha}{2}} \sqrt{p_0 q_0} + z_{1-\beta} \sqrt{p_1 q_1}}{p_1 - p_0} \right)^2$$

Where

- α = alpha level of the test (two-sided)
- $1 - \beta$ = power of the test
- p_0 = proportion under the null hypothesis
- p_1 = proportion under the alternative hypothesis

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Example

How large a sample is needed to test H_0: $p = .21$ against H_a: $p = .31$ at $\alpha = 0.05$ (two-sided) with 90% power?

$$n = \left(\frac{1.96\sqrt{(0.21)(0.79)} + 1.28\sqrt{(0.31)(0.69)}}{0.31 - 0.21} \right)^2$$

$$= 193.3 \Rightarrow 194$$

Note: The symbol $\Rightarrow$ means round up to ensure stated power

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Power Calculation

$$1-\beta=\Phi\left(\frac{|p_1-p_0|\sqrt{n}-z_{1-\frac{\alpha}{2}}\sqrt{p_0q_0}}{\sqrt{p_1q_1}}\right)$$

Where:

- α = alpha level of the test (two-sided)
- n = sample size
- p_0 = proportion under the null hypothesis
- p_1 = proportion under the alternative hypothesis

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Power - Example

What is the power of testing H_0: p = .21 against H_a: p = .31 at α = 0.05 (two-sided) when n = 57 ?

$$1-\beta = \Phi\left(\frac{|0.31-0.21|\sqrt{57}-1.96\sqrt{(0.21)(0.79)}}{\sqrt{(0.31)(0.69)}}\right)$$

$$= \Phi(-0.09)$$

$$= 0.4641 \text{ (or about 46\%)}$$

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Sample Size for Capability

- Some companies are calculating sample size based on capability indices.
- This can only be done using a confidence interval approach.
- Have to set a lower limit on the capability index and an observed capability index.

$$\hat{C}pk\left[1-Z_{\alpha/2}\sqrt{\frac{1}{9n(\hat{C}pk)^2}+\frac{1}{2(n-1)}}\right] \le Cpk \le \hat{C}pk\left[1+Z_{\alpha/2}\sqrt{\frac{1}{9n(\hat{C}pk)^2}+\frac{1}{2(n-1)}}\right]$$

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Capability Sample Size Example

$$\text{Lower Limit on Cpk} = \text{Observed } C_{pk} - Z_{\alpha}\sqrt{\frac{1}{9n} + \frac{\text{Observed } C_{pk}^2}{2n-2}}$$

95% Confidence that the "True" Cpk is no worse than 1.0

Sample Size	Observed Cpk
3	5.69
4	3.10
5	2.44
6	2.13
7	1.95
8	1.83
9	1.73
10	1.67

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Non-Inferiority

- The “at least good as” criterion.
- A one-sided significance test to reject the null hypothesis that standard therapy is better than experimental therapy by a clinically acceptable amount.
- To demonstrate that a new device is 'at least as good as' an existing device, a statistical test or confidence interval procedure must rule out clinical inferiority with a high probability.

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Sample Size - NonInferiority

The noninferiority hypothesis and sample size are attributable to Blackwelder (1982). The sample size computation is given below for equal sample size in each treatment group.

$$n \geq \left(\frac{(Z_{1-\alpha} + Z_{1-\beta})}{(P_T - P_C - \delta)} \right)^2 \left[P_T(1-P_T) + P_C(1-P_C) \right]$$

Blackwelder, W. "Proving the null hypothesis in clinical trials." *Controlled Clinical Trials* 3: 345-353, 1982.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Example

In a group of patients using an approved sleeping apparatus, 80% claim an improvement in their insomnia.

The new device is proved to be non-inferior to the predicate if the rate of insomnia is no worse than 75% (a=0.05, Power=80%).

$$790 \geq \left(\frac{(1.645 + 0.841}{(0.80 - 0.80 - 0.05)} \right)^2 \left[0.8(1 - 0.8) + 0.8(1 - 0.8) \right]$$

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Attribute Sampling Plans When All Units Pass

- At 95% Confidence and 90% Reliability
- $n = \frac{\ln(1-Confidence)}{\ln(Reliability)} = \frac{\ln(1-0.95)}{\ln(0.90)} = 28$

Confidence	Reliability	Sample Size
80%	80%	8
80%	90%	16
80%	95%	32
80%	99%	161
90%	80%	11
90%	90%	22
90%	95%	45
90%	99%	230
95%	80%	14
95%	90%	29
95%	95%	59
95%	99%	299
99%	80%	21
99%	90%	44
99%	95%	90
99%	99%	459

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ANSI Z1.4

- Z1.4 is a standard developed for incoming inspection where the attribute is pass/fail.
- ANSI Z1.4 system is a collection of sampling plans with switching rules.
- Plans are intended primarily to be used for a continuing series of lots or batches.

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Attribute Sampling Plans

AQL: Acceptable Quality Level "is the maximum percent nonconforming (or the maximum number of nonconformities per hundred units) that, for purposes of sampling inspection, can be considered satisfactory as a process average." §4.2

Note: AQL is not lot or batch specific but rather a process average.

AQL is stated in the standard as a percent:
an AQL = 0.15 is a rate of 0.15 nonconforming units per 100 units or 0.15%.

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ANSI Z1.4 – Normal Inspection

SINGLE NORMAL PLANS

AQL=0.15%

Table II-A—Single sampling plans for normal inspection (Master table)

(See 9.4 and 9.5)

Sample size code letter	Sample size	Acceptable Quality Levels (normal inspection)																																	
		0.010		0.015		0.025		0.040		0.065		0.10		0.15		0.25		0.40		0.65		1.0		1.5		2.5		4.0		6.5		10		15		25		40		65		100		150		250		400		650		1000	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2																															1	2																
B	3																															2	3																
C	5																															3	4																
D	8																															5	6																
E	13																															7	8																
F	20																															10	11																
G	32																															14	15																
H	50																															21	22																
J	80																																																
K	125																																															
L	200																																															
M	315																																															
N	500																																															
P	800																																															
Q	1250																																															
R	2000																																															

↓ = Use first sampling plan below arrow. If sample size equals, or exceeds, lot or batch size, do 100 percent inspection.
↑ = Use first sampling plan above arrow.
Ac = Acceptance number.
Re = Rejection number.

N=1250, acc=5

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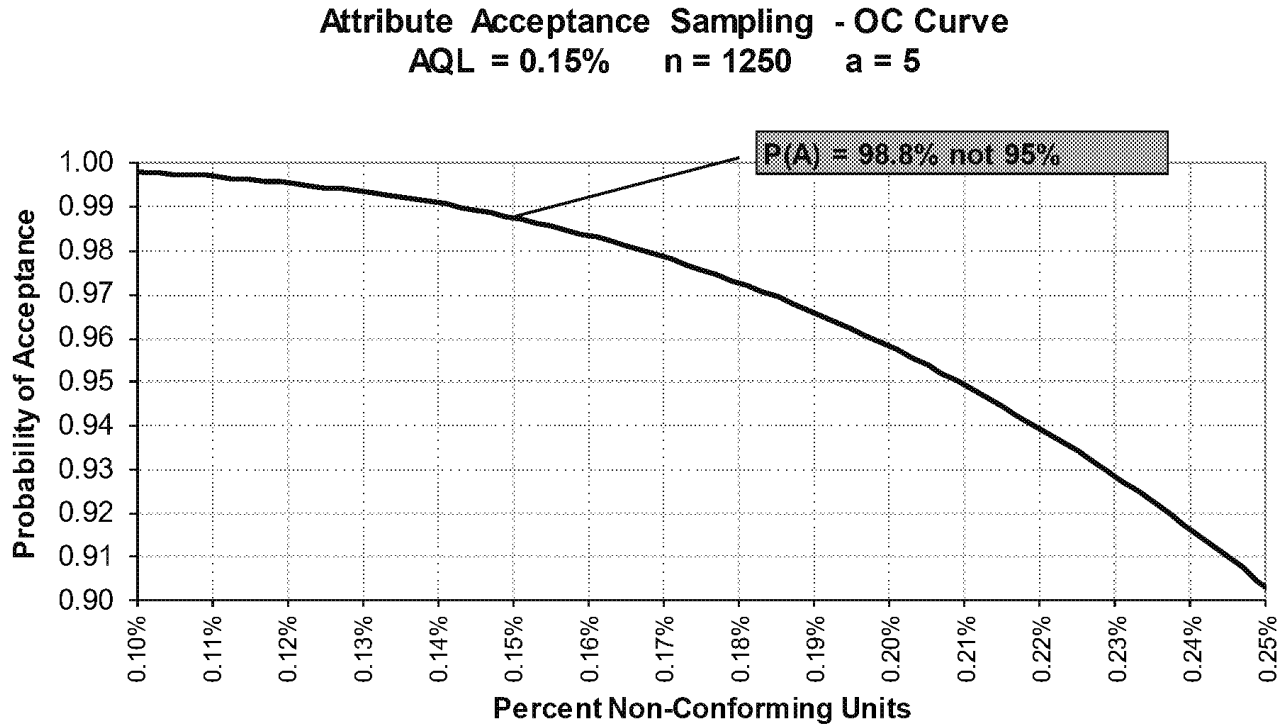
Power of Attribute Sampling Plans



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$\sqrt{N} + 1$

- $\sqrt{N} + 1$ was an unpublished report by the AOAC in 1927.
- It was intended to be a quick rule of thumb for inspection of foods.
- Since it was unpublished, there was not a description of the statistical basis of it.

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$\sqrt{N} + 1$

- There is no known statistical justification for the use of the square root of n plus one' sampling plan.

- "Despite the fact that there is no statistical basis for a 'square root of n plus one' sampling plan, most firms utilize this approach for incoming raw materials."

  Henson, E., A Pocket Guide to CGMP Sampling, IVT.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Compare the Plans

- ANSI/ASQ Z1.4
- Lot Size N=1000
- Sample size n=32
- Acceptance Ac=0
- Rejection Re=1
- AQL=0.160%
- LQ = 6.94%

- Square root N plus one
- Lot Size N=1000
- Sample size n=33
- Acceptance Ac=0
- Rejection Re=1
- AQL=0.153%
- LQ = 6.63%

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Case Study

- Have a new product that requires potency of 45± 5. During development, the average was found to be 45.2 with a SD of 3.2.

- What sample size do we need to have 95% confidence with 99% reliability that the average will meet the requirement?

- What sample size do we need to have 95% confidence with 99% reliability that the individual values will be the requirement?

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Calculations (Mean)

$$N = \frac{(z_\alpha + z_\beta)^2 s^2}{\Delta^2}$$

$$N = \frac{(1.96 + 2.326)^2 * 3.2^2}{(50 - 45.2)^2}$$

$$N = 8.2$$

Round up to 9

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Calculations (Individual)

$$\overline{X} + k * S < U$$

$$45.2 + k * 3.2 < 50$$

$$k = 1.5$$

$$N > \infty$$

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Why the Difference?

- A mean difference of 4.8 is different than having all the individual values between 40 and 50.
- The capability analysis would show a Ppk of 0.50

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Parting Thoughts

- There is no RIGHT answer, just different options. It depends on the risks you are willing to take
- Sampling plans can be developed for continuous or attribute characteristics
- It is important to know what you want your sample to tell you.
- Reportable units what sampling size calculations are based.

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Thank You! Questions?

All questions are welcome

To protect your privacy, anyone asking a question will be announced only by the first name of the person reported to the operator at initial dial-in. However, anyone in your group is welcome to ask a question. Please try to avoid using a speakerphone while asking your question.

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TC161130

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What Does FDA Expect to See
Steven Walfish - November 30, 2016

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What is your overall rating of the course?	1	2	3	4	5
How do you rate the content of the course?	1	2	3	4	5
Were course materials clear and understandable?	1	2	3	4	5
Was the length of the course adequate to cover the content?	1	2	3	4	5
Was the instructor knowledgeable about the subject matter?	1	2	3	4	5
How would you rate the instructor overall?	1	2	3	4	5

Other comments:

Please feel free to comment on any aspect of this course, including the instructor, content, and technical arrangements:

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Sent: Tuesday, August 1, 2023 12:42 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Subject: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request

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Hi Vincent,

Thank for your quick review. I am attaching the updated cover letter and response to the AINN as you requested. Sorry for the mis-understanding.

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Tuesday, August 1, 2023 9:53 AM
To: steurerbob@gmail.com
Subject: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request

Good morning Bob,

I hope you and your team are doing well.

(b)(4)

Please let me know if you have any questions.

Best Regards,

Vincent

Vincent Do
Lead Reviewer

Cardiac Ablation, Mapping and Imaging Devices Team
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices
Office of Product Evaluation and Quality

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From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Monday, August 28, 2023 6:19 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Cc: 'Srini Murali' <srinivasan.murali@smartcardia.com>; 'Francisco Rincon' <francisco.rincon@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; 'James Welch' <jwelch@arcbiomed.com>
Subject: RE: [EXTERNAL] Interactive Response 3

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Thank you for your response. This time is OK but I haven't heard from the team in Switzerland but those of us in the US are available. Go ahead and schedule and send us the invite. I will let you know if there are any issues.

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Monday, August 28, 2023 5:09 PM
To: steurerbob@gmail.com
Cc: Srini Murali <srinivasan.murali@smartcardia.com>; Francisco Rincon <francisco.rincon@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; James Welch <jwelch@arcbiomed.com>
Subject: RE: [EXTERNAL] Interactive Response 3

Hi Bob,

Thank you so much for your email. (b)(4) (b)(4) I found a potential slot to hold a teleconference with you and your team tomorrow (I have sent out invites to the review team and have not received confirmation yet, but it should be okay). I will keep you and your team updated. Please check if the following date/time is okay with your team:

- Tuesday 08/29/2023 at 1PM E.T.

Please let me know if there is anything.

Thank you,

Vincent

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Monday, August 28, 2023 2:57 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Cc: Srini Murali <srinivasan.murali@smartcardia.com>; Francisco Rincon <francisco.rincon@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; James Welch <jwelch@arcbiomed.com>
Subject: [EXTERNAL] Interactive Response 3

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Attached is the SmartCardia response to Interactive Request 3 you sent on Friday, August 25, 2023, (b)(4)

(b)(4)

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

If you need anything else, please don't hesitate to contact me.

Best Regards,

Bob Steurer

Steurer Consulting Group

http://www.scgconsulting.net

m: +1 425-358-1072

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

K231276
SmartCardia SA
Trade/Device Name: SmartCardia 7L Platform
Contact Name: Robert Steurer

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Steurer Consulting Group

August 1, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: 510(k) submission number K213276-S001. FDA Request for Additional Information (AINN)

Dear Sir or Madam:

This letter provides a response to FDA Request for Additional Information received on 29 June 2023.

Included in this response are several SmartCardia SA documents and references which are considered confidential information by SmartCardia SA.

The eSTAR document submitted includes two parts; part 1 is the eSTAR form itself, part 2 is the 510(k) summary document and the Indications for Use form as requested in the AINN. Part 2 was submitted as an eCopy.

SmartCardia SA trusts this completes the requirements for the 510(k), and looks forward to a favorable response from FDA. If any additional information is required, please contact me directly at (425) 358-1072, or via email at steurerbob@gmail.com.

Kindest regards,

(b)(6)

Mr. Robert Steurer
Application Correspondent for SmartCardia SA
SCG Consulting

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

SmartCardia

EPFL Innovation Park
Building
1015, Lausanne, Switzerland contact@smartcardia.com

K231276

May 1, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation Document
Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC
MAY 02 2023
RECEIVED

Re: Traditional 510(k) Notification

Dear Sir or Madam:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act and 21 CFR §807, SmartCardia SA, hereby submits this 510(k) Premarket Notification for the ***SmartCardia 7L Platform***. This 510(k) is submitted to obtain clearance from FDA to commercially distribute this device.

(b)(4)

Attachment 1 to this cover letter is the Administrative Information content recommended by Appendix A of the FDA guidance document "*Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, 13 September 2019*".

This submission is provided as an electronic eSTAR copy.

SmartCardia trusts the contents of this submission completes the requirements for the 510(k) and looks forward to a favorable response from FDA. If any additional information is required, please contact the Application Correspondent, Mr. Robert Steurer, directly at (425) 358-1072, or via email at steurerbob@gmail.com.

Kindest regards,

(b)(6)

Srinivasan Murali, CEO
SmartCardia SA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231276

Device Name
SmartCardia 7L Platform

Indications for Use *(Describe)*
The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

K231276
SmartCardia SA
Trade/Device Name: SmartCardia 7L Platform
Contact Name: Robert Steurer

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K231276 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K231276 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

MINOR DEFICIENCY LIST

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

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business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

June 29, 2023</br></br> We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Vincent Do.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10993 New Hampshire Avenue
Silver Spring, MD 20993

DATE: June 27, 2023

FROM: Kevin Dang, Biomedical Engineer
CDRH/OPEQ/OHT2/DHT2A/EHRRT

SUBJECT: ECG Consult
K231276 – SmartCardia "7L Platform"

TO: Vincent Do, Biomedical Engineer
CDRH/OPEQ/OHT2/DHT2A

RECOMMENDATION: (b)(5)

Digital Signature Concurrence Table	
For each of the specific issues identified in the recommended requests to the applicant above, I provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard or confirmed to the best of my ability (for requests 1-4 and minor request 1) that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s)	
Consultant	Kevin Dang -S Digitally signed by Kevin Dang -S Date: 2023.06.27 15:54:02 -04'00'

(b)(5)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10993 New Hampshire Avenue
Silver Spring, MD 20993

Lead Reviewer

Device Description / Indications for Use

Device: SmartCardia 7L Platform

Intended Population: Adults and Pediatrics (ages 18+)

Environment of Use: Hospital and home use

Procode: DSI

Predicate Device: VitalPatch (Primary Predicate, K192757), MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System (Reference Device, K160064)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Martin, Crystal * [Crystal.Martin@fda.hhs.gov]
Sent: 5/2/2023 9:47:00 PM
To: steurerbob@gmail.com
Subject: K231276 User Fee Hold Letter Notification
Attachments: User Fee Hold Letter-K231276.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

User Fee Hold Letter

5/2/2023

Robert Steurer, Consultant
Steurer Consulting Group LLC
800 Blue Quail Rd
Keller, TX 76248
UNITED STATES

Dear Robert Steurer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) acknowledges receipt of your submission. This submission has been assigned the following unique document control number. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K231276
Received: 05/02/2023
Applicant: SmartCardia SA
Device: SmartCardia 7L Platform

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), the Medical Device User Fee Amendments of 2012 (MDUFA III), and the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain types of submissions. This submission cannot be accepted for review until the user fee is paid in full.

You have received this letter because we have not received your payment in full. Additional information on user fees, including how and where to submit your user fee payment and how to generate a User Fee Cover Sheet, may be found on our webpage entitled, "User Fees" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm540444.htm.

In addition, please fax a completed copy of the User Fee Cover Sheet that includes the specific submission number above and the Payment Identification Number for this submission to our CDRH Document Control Center at (301) 847-8113.

You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to pay by check, make the check out to the Food and Drug Administration and reference the payment identification number, include a copy of the User Fee Cover

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sheet with the check, and mail them to one of the addresses listed below:

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Food and Drug Administration
P.O. Box 979033
St. Louis, MO 63197-9000

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(314) 418-4821

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If payment has not been received within 30 days, your submission will be deleted from our system.

If you have any questions concerning this letter, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or by email at OPEQSubmissionSupport@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

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(b)(4)

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013_Instructions for Use K231276 (b)(4)

- PL-08 SmartCardia 7L Patient Guide
- PL-09 SmartCardia 7L Clinician User Guide
- PL-10 SmartCardia 7L Clinician QRG
- PL-17 SmartCardia 7L Platform Technical Manual

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· PL-08 SmartCardia 7L Patient Guide

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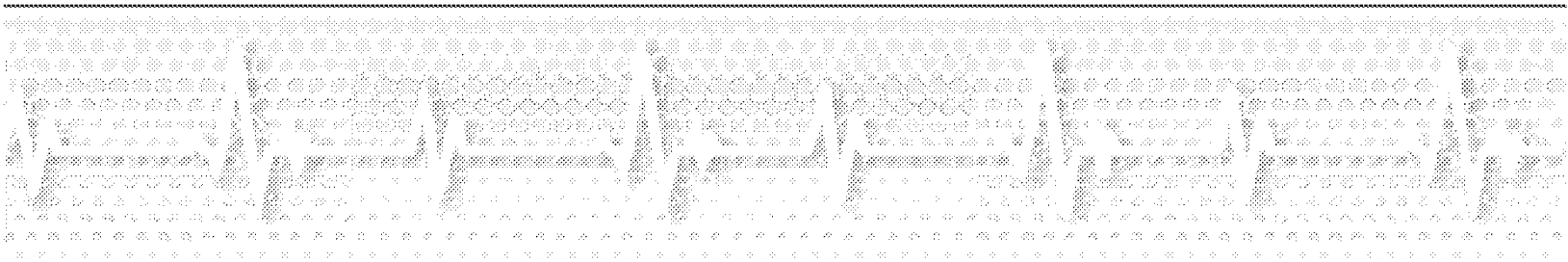

SmartCardia 7L™ – Patient Guide

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Welcome!

Your doctor has prescribed this device so they can remotely view your vital signs.

We are here to help you.

So feel free to give us a call anytime at 800-363-8151.

SmartCardia 7L
monitoring the fabric of life®

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About This Manual

This Patient Guide describes how to use the SmartCardia 7L™ Platform.
For more information about SmartCardia 7L, visit www.SmartCardia.com.

Safety Precautions

This manual contains safety precautions as shown below.

	WARNING
	Indicates a hazard or unsafe use that could cause death or serious injury.

	CAUTION
	Indicates a hazard or unsafe use that could cause minor injury or product damage.

Note	A note shows more information about using the product.

Note: *The information contained in this document is subject to change without notice.*

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Warnings and Cautions

WARNING

- **The SmartCardia 7L system is not an emergency response service. If you experience symptoms that are cause for concern, immediately seek medical help.**
- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**
- **If you have severe skin irritation or burning feeling, remove 7L Patch right away and contact your doctor.**
- **Do not use this device in an MRI**

CAUTION

- Do not try to service the SmartCardia 7L system. The SmartCardia 7L system is not field reparable and there are no replaceable components.
- Do not use in a hospital operating room.
- To avoid the risk of fire, do not use the SmartCardia 7L system around anything flammable. Do not try to take apart the *7L Patch* or *7L Sensor*.
- Do not try to change the battery in the *7L Patch*.
- Stay away from heavy electrical equipment or other sources of interference.
- The SmartCardia 7L system is used for adults over the age of 18 years.
- Take care if showering. Caution should always be taken when wearing in a wet location.
- Install and use the SmartCardia 7L system as instructed. Do not attempt to connect it to another piece of equipment.
- Only use the charger provided with the Phone.
- Place the *7L Sensor* and *7L Patch* on the body as instructed.
- Keep the SmartCardia *Phone* closer than 10 feet at all times.

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	• The SmartCardia 7L Platform should not be used in an aircraft.

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Intended Use/Indications for Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

Measurements include: electrocardiogram (ECG signal), R-R interval, and Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

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Getting Started

Product Description

The SmartCardia 7L Platform is used to monitor your heart using the SmartCardia *7L Sensor* and *7L Patch*. This is worn on the body and monitors and saves your vital signals and sends this data to your doctor using the SmartCardia *Phone*.

SmartCardia 7L Components

SmartCardia 7L Sensor (the *7L Sensor*)

A reusable Sensor **(do not throw away)**

- Inserts into the *7L Patch*
- Monitors ECG
- Sends your data to the SmartCardia *Phone*
- Is waterproof when used with the 7L Patch

SmartCardia 7L Patch (the *7L Patch*)

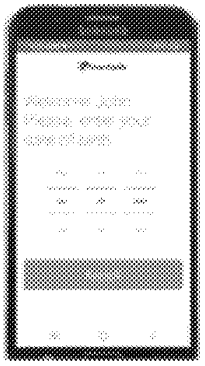
A single-use patch **(you can throw away)**

- Includes batteries
- Holds the reusable *7L Sensor*
- Sticks to your skin
- Expected shelf life up to 14 days

	WARNING
	The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.

SmartCardia Phone (the *Phone*)

Sends your data to the doctor



- Always keep it close to the SmartCardia *7L Sensor* (within 10 ft.)
- Charge daily (or more often)

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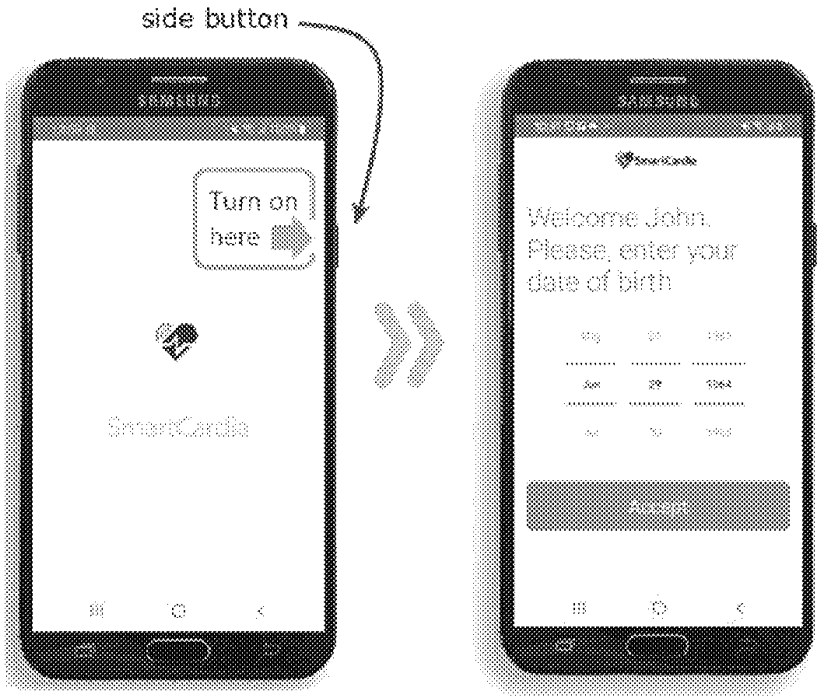
Start the Phone

Step 1
Push the side button on the *Phone* to turn on. (This may take several minutes) Swipe up to unlock *Phone*

Step 2
Enter your date of birth on the screen display.



Note: *You cannot make personal phone calls on this phone. This phone will not make calls or send emails. It is for SmartCardia use only.*

Note: *After you attach the 7L Patch, your heart rhythm will appear on the screen. See page 12 for more details.*

⚠	**CAUTION**
	Keep the SmartCardia *Phone* closer than 10 feet at all times.

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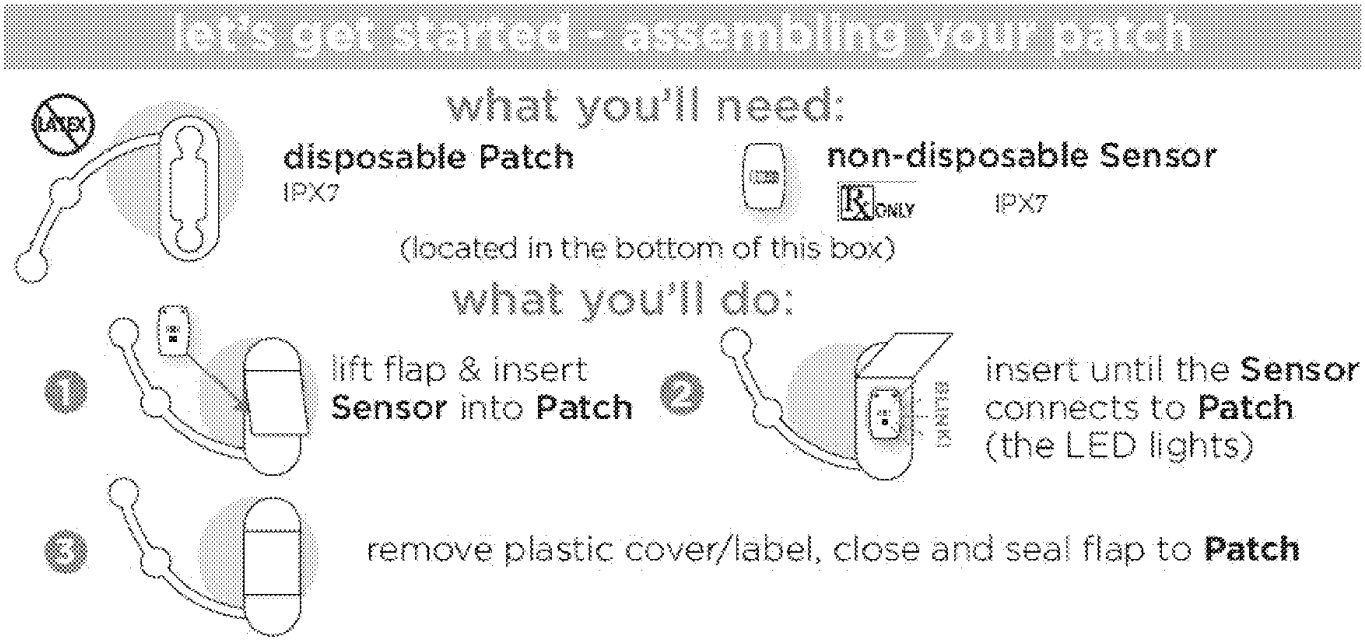
Attach Patch with Sensor

The *7L Patch* is placed on your skin to monitor your heart (shown in the diagrams below).

Step 1

The *7L Sensor* (**not disposable**) is inserted into the disposable *7L Patch*.

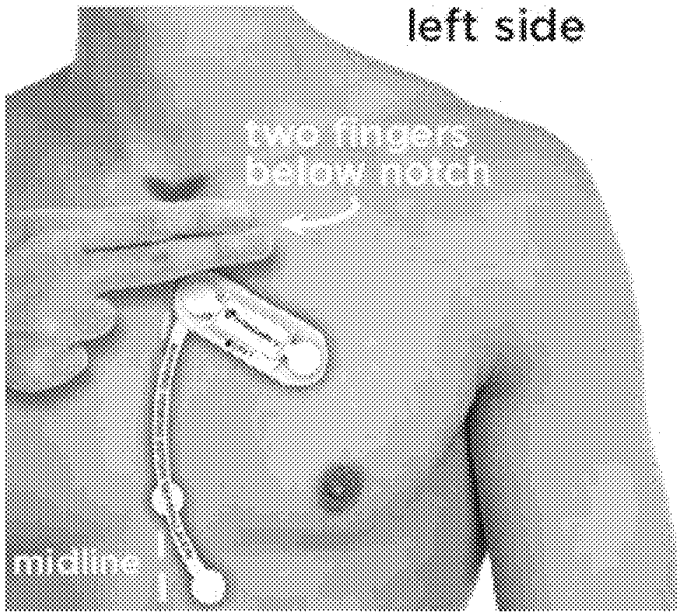
Note: *The 7L Sensor will fit into the 7L Patch in only one direction. Make sure to align the 'marks' on the 7L Sensor to those on the 7L Patch.*



Step 2

Clean and dry your skin before the *7L Patch* is placed on your body.

For men, chest hair should be shaved or clipped where the *7L Patch* will be placed.



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	WARNING **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**

	CAUTION The 7L Patch should be applied immediately after the pouch is opened. Dispose of the patch and do not use if the pouch has been opened before.

Note: *The 7L Patch should never be placed on injured areas of skin or on open wounds.*

Note: *Failure to prepare the skin area can make removal of the 7L Patch difficult.*

	WARNING **If you have severe skin irritation or burning feeling, remove *7L Patch* right away and contact your doctor.**

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Monitoring

Once finished you are free to go about your normal daily activities, unless told otherwise.

Note: *Once you start, do not remove the 7L Patch and 7L Sensor. It must be worn all the time, even when you sleep.*

- Your doctor will tell you how long you should wear the *7L Patch* and *7L Sensor*. You must change the patch if you have to wear the patch for longer than 14 days. Refer to page 15.
- When you are finished, you will return the *7L Sensor*, the *Phone*, and phone charger in the enclosed prepaid package.
- Your doctor will review your data.

IMPORTANT

- Always keep the SmartCardia *Phone* closer than 10 feet from you.
- You may shower.

Note: *The body worn system is waterproof, but the Phone is not.*

CAUTION

Do not get the SmartCardia *Phone* wet or in water.

CAUTION

If water seeps into the *7L Patch* or the *7L Patch* falls off, replace the *7L Patch*.

Note: *If the Patch peels or lifts at the edges, try to press, and hold along the edges to re-apply.*

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	CAUTION
	Continue to wear the *7L Patch* for the length of time prescribed by your doctor.

SmartCardia Phone

The *Phone* is used to:

- Send your data from the *7L Sensor*
- Mark events when you press the EVENT button
- Show your heart rate

Note: *The Phone is for use only with the SmartCardia 7L Platform. It will not work as a cell phone.*

Note: *Do not drop the Phone and always keep it in a dry and safe place.*

Note: *Do not worry if you are in an area where the Phone has no cell service. The 7L Sensor and 7L Patch saves the data. When cell service comes back, the saved data is sent to your doctor.*

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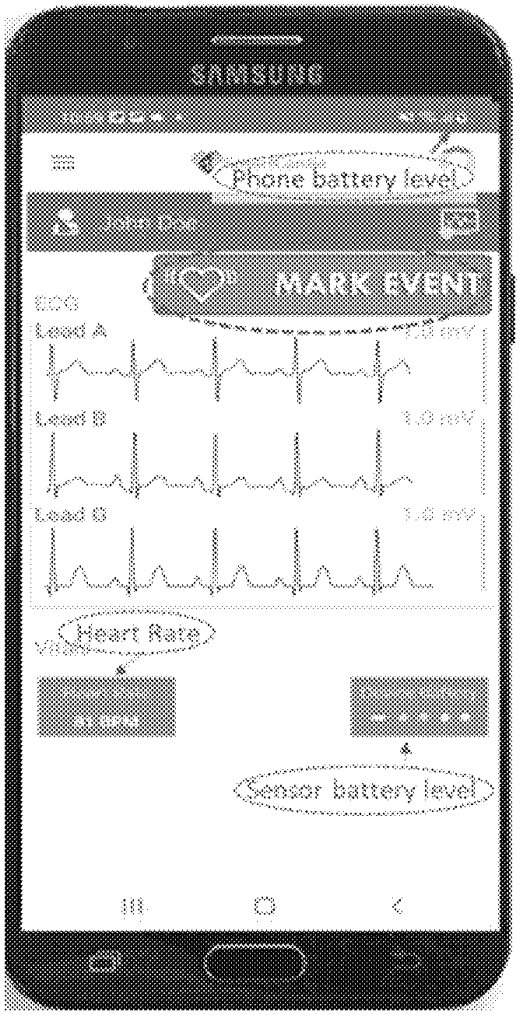
Phone Screen Display

The *Phone* allows you to see your data. When the *Phone* is turned on it shows:

- Your name
- Phone battery level (always keep charged)
- MARK EVENT button to press when you do not feel well
- Your ECG waveform
- Your heart rate
- The *7L Sensor* battery level (device battery)
  - The battery level of the *7L Sensor* is shown when it is connected to the *Phone*
  - The battery level is shown by four dots. When the dots are green that is the battery life remaining
  - A low battery level alert will be shown in red



Using the MARK EVENT Button on SmartCardia Phone

If you feel dizzy, short of breath, or have chest pain, press the MARK EVENT button, and select event duration then select what you are feeling.

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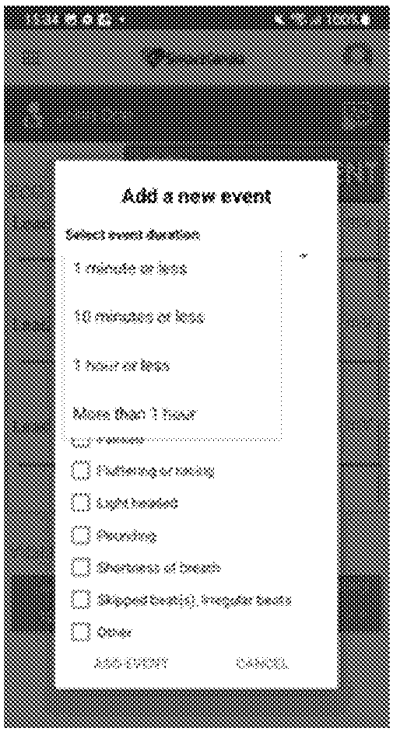

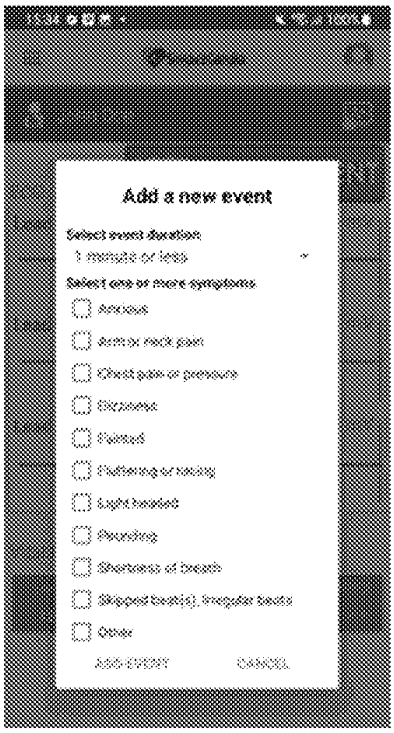

	WARNING
⚠	**The SmartCardia 7L Platform is not an emergency response system. If you experience a symptom that you feel is a medical emergency, call 911 immediately for emergency medical attention.**

Charging the *Phone*

The *Phone* must be charged all the time. It is best to do this every day when you are resting or sleeping.

When to Change the *7L Patch*

Do not remove the *7L Sensor* and *7L Patch* unless:

- The *7L Sensor* and *7L Patch* become damaged.
- Your skin under the *7L Sensor* and *7L Patch* has a rash.
- The *7L Sensor* and *7L Patch* begins to come off.
- You are told to do so by your doctor or caregiver.

How to Change the *7L Patch*

Step 1

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Carefully remove the *7L Sensor* and *7L Patch*. Use of baby oil to loosen the adhesive may make it easier to remove.

Step 2

Gently take out the *7L Sensor* from the *7L Patch.*

Get the new *7L Patch* and repeat the Set-Up Process (refer to pages 9/10).

Cleaning and Disinfecting the *7L Sensor*

Step 1

Clean the *7L Sensor* with warm water and dish soap using a cloth or sponge to remove surface dirt.

Step 2

Disinfect the *7L Sensor* with PDI Super Sani-Cloth® Germicidal Disposable Wipe for five minutes following the instructions on the package.

When You Are Finished

- Remove the *7L Sensor* and the *7L Patch* from your body.
- Take out the *7L Sensor* from inside the *7L Patch* and place it into the SmartCardia large pre-addressed shipping envelope for return.
- Place the *Phone* in the small envelope and put into larger pre-addressed shipping envelope along with the 7L Sensor, phone charger and cable for return.
- Discard the used *7L Patch*.

Note: *If you have difficulty removing the 7L Sensor from the 7L Patch, return both.*

Return to SmartCardia

- Seal pre-addressed shipping envelope tightly.
- Drop the shipping package off at the specified carrier shipping location.
- Document the tracking number from the carrier for your records.

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Troubleshooting

What to do if you get skin irritation

The *7L Patch* uses a medical adhesive that can be worn for a long time.

- Mild itching, irritation or rash on the skin may occur. This is normal and usually temporary.
- If you have severe itching or redness, contact your doctor.

WARNING

If you have severe skin irritation or burning feeling, remove *7L Patch* right away and contact your doctor.

Problem	What is the Cause	What to Do
7L Sensor will not go into *7L Patch*	*7L Sensor* is put in backward	• Check the instructions on the *7L Patch* for correct alignment • Make sure the connector (green side) on the *7L Sensor* is facing the *7L Patch* • Align the marks on the *7L Sensor* with the marks on the *7L Patch*
Phone will not turn ON	The *Phone* is out of battery	Plug in phone charger and check to see if phone is charging
ECG is not shown on *Phone*	• *7L Sensor* and *7L Patch* are not sending ECG to *Phone* • *Phone* is out of battery • *7L Sensor* and *7L Patch* are out of battery	• Make sure the *Phone* is closer than 10 feet from you at all times • Plug in the phone charger and check to see if it is charging • Check the battery level on the *Phone* and if it does not indicate“Device Battery” remaining, replace the *7L Patch* as instructed

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Warranty and Services

For help at any time, call 1-800-363-8151.

The *7L Sensor* requires no calibration.

In the event the *7L Sensor* is not working properly, use the troubleshooting steps outlined above. If the *7L Sensor* is still not working properly, contact SmartCardia SA for technical and service support by calling 1-800-363-8151 or email info@smartcardia.com.

SmartCardia SA warrants the *7L Sensor* hardware against defects in materials and workmanship when used normally per the *7L Sensor* instructions for a period of Two (2) Years from the date of original retail purchase by the end- user purchaser (“Warranty Period”).

SmartCardia does not warrant that the operation of the *7L Sensor* will be uninterrupted or error-free.

SmartCardia SA is not responsible for the damage arising from the failure to follow instructions relating to the *7L Sensor* device.

The *7L Patch* has a shelf life of Two (2) Years when handled properly and stored within its stated environmental conditions (see *Specifications*).

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Symbols Used

Symbol	Title of Symbol	Symbol Description
	Manufacturer	Shows who manufactured the product
	European Conformity	The product meets the standards for Medical Device in the European Union
	Batch code	Indicates the manufacturer's Lot code
	Catalog number	Indicates the manufacturer's catalogue number
	Serial number	Indicates the serial number of the medical device
	Non-sterile	The product is not sterile
	Do not use if package is damaged	Do not use if package has been damaged or opened
	Fragile, handle with care	Indicates you should handle the product with care
	Not made with natural rubber latex	There is no natural rubber latex in the product or its package
	Do not use in MRI	Do not use the product in a magnetic resonance imaging instrument
	Keep dry	The product needs to be kept dry
	Temperature limits	Indicates the high and low temperatures for storage and use
	Humidity limits	Indicates the high and low humidity for storage and operation
	Do not re-use	Product is for single use only and not to use on another patient
	Consult instructions for use	For more information, read the operation manual or instructions for use
	Caution or Warning	Consult the instructions for use of important warnings and cautions that are printed on the product
	Use-by-date	The date after which the product or accessories should not be used
	Crossed-off wheeled bin	The product contains electrical parts and must be disposed of properly, not into any bin, but must be placed in an electrical equipment bin
	Non-ionizing radiation	The product does radiate RF, but it is non-ionizing
	BF applied part	To identify a type BF applied part complying with IEC 60601-1

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Specifications

Physical and Environmental	
Size (approximate)	*7L Sensor*: 1.97 x 1.18 x .39 inch; (50 x 30 x 10 mm) *7L Patch* (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14 mm)
Weight (approximate)	*7L Sensor and 7L Patch*: Less than 3.52 oz. (100 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C) Operating: +41 to +104°F (+5 to + 45°C)
Humidity	0 to 90% at +41 to 95°F (+5 to +35°C) (non-condensing) / 70 – 106 kPa
Safety	Type BF
Water Ingress	IPX7 (Waterproof)
Battery Life	Up to 14 days depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993-5, ISO 10993-10, ISO 10993-12 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30-200	Beats per minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-8118

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Unique Device Identifier(s)

7L Sensor 7640375610058
7L Patch 7640375610041

SmartCardia SA
EPFL Innovation Park, Building C 1015Lausanne, Switzerland
Customer Support: 800-363-8151

PL-08 SmartCardia 7L™ Platform – Patient Guide

Prescription Only

Consult Instructions for Use or User Manual

Type BF

See Warnings and Cautions

SmartCardia SA
EPFL Innovation Park,
Building C
1015 Lausanne, Switzerland

FCC

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:

1. These devices may not cause harmful interference, and
2. These devices must accept any interference received, including interference that may cause undesired operation.

FCC ID: XPYNINAAB30

Non-ionizing electromagnetic radiation

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SmartCardia 7L™
monitoring the fabric of life™

SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

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· PL-09 SmartCardia 7L Clinician User Guide

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SmartCardia 7L Platform™
Clinician User Guide

Questions? Contact FDA/CDRH/OCE/PAB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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About SmartCardia

SmartCardia, SA is a Swiss medical device company that focuses on clinical quality data and validation. The company works with key opinion leaders across a variety of clinical fields; from cardiology, vascular medicine, sleep, and COPD to validate the unique insights our systems provide.

SmartCardia is an ISO 13485 certified medical device manufacturer that meets the strict quality control standards for our solutions. The company is also ISO 27001 certified for data security and privacy.

Through rigorous clinical testing and validation, the 7L Patch, cloud and software are CE-marked as a Class IIa medical device.

CE 2803 ISO 13485:2016 HTCert Health Technology Certification

This *Clinician User Guide* describes the features of this product, main structure, function, specifications, correct method for transportation, installation, usage, operation, repair, maintenance, and storage, as well as safety procedures to protect both the user and the equipment.

EPFL Innovation Park, Building C

1015 Lausanne, Switzerland

Email: contact@smartcardia.com

Customer Support (800) 363-8151

Questions? Contact FDA/CDRH/OCE/DAB at CDRH-PQISTAFF@fda.hhs.gov or 301-796-8118

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About this User Guide

User Guide Use and Audience

This user guide is a key part of the SmartCardia 7L Platform™ and describes the use of the system.

This user guide is for use by clinical professionals. They should have the appropriate training to observe and interpret patients' heart condition and check for abnormalities of heart rate and arrhythmias. It is important for the clinician to recognize and respond appropriately to changes in patient's heart rate and any abnormal conditions in patients' heart rhythm. In addition, analysis and creation of reports is necessary to provide a complete and accurate record of time that patients are monitored. Using the SmartCardia 7L Platform should not replace using sound clinical judgment when monitoring patients.

User Guide Style

The following styles and naming are used in the user guide to emphasize text or indicate an action.

Bold	Important information
Italic	References the components of the SmartCardia 7L Platform
Bold italic	Used for emphasis
Bold red text	Most important information, used to bring attention to a warning or caution
Select	The word select means to choose and confirm
“ ”	Quotation marks indicates this is an option to select on the 7L Web Browser screen
NOTE	Provides additional helpful information

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SmartCardia 7L Platform Naming Convention

Component Name	Name	Part Number	Brief Description
SmartCardia 7L Sensor	*7L Sensor*	DS-36	Electronic unit collects ECG data
SmartCardia 7L Patch	*7L Patch*	DS-33	Connects to skin and holds and powers the *7L Sensor*
SmartCardia Phone	*Phone*	DS-39	Android phone configured in kiosk mode, uses cellular service to transmit ECG using the *7L Mobile Application* to Cloud, viewed on *7L Web Browser*
SmartCardia 7L Web Browser	*7L Web Browser*	DS-41	Chrome web browser for clinicians to manage ECG data

Illustrations and Names

This user guide uses illustrations to show examples. They may not include all possible configurations available in the SmartCardia 7L Platform.

Reference Materials

- PL-10 Clinician Quick Reference Guide (QRG)
- PL-13 Clinician training video
- PL-08 Patient User Guide
- SmartCardia Customer Support (800) 363-8151

Safety

Warnings and Cautions

To ensure safe use of the equipment, please read the following statements. This user guide contains safety precautions that are explained below.

	WARNING
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

	CAUTION
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

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SmartCardia 7L Platform

WARNING: The 7L Platform™ is not an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

CAUTIONS:

- The 7L Platform is used for adults over the age of 18 years.
- Install the 7L Platform and use as instructed. Do **not** attempt to connect it to another piece of equipment.
- Do **not** try to service the 7L Platform. It is **not** field repairable and there are no replaceable components.
- The 7L Platform is to be used by adequately trained personnel.
- Do not use with other devices, which have high-level electromagnetic radiation.
- The 7L Platform is not designated for use in the operating room or operating theater.
- Make sure to have a good internet connection and sufficient bandwidth.
- The SmartCardia 7L Platform should not be used in an aircraft.

7L Sensor, 7L Patch, and SmartCardia Phone

WARNINGS:

- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**
- **If a patient has severe skin irritation or burning feeling, they should remove the 7L Patch right away and contact their doctor.**
- **Do not use this device in an MRI.**

CAUTIONS:

- The 7L Platform is not intended to record the activity of an implanted pacemaker onto the ECG waveform. The 7L Platform is designed to operate in the presence of pacemaker pulses. Caution should be used to not locate the *7L Patch* with the *7L Sensor* on top of a pacemaker.
- The SmartCardia *Phone* should not be placed over a pacemaker.
- Do not try to take apart the *7L Patch* or *7L Sensor*.
- Do not try to change the battery in the *7L Patch*.
- Do not use the device if the *7L Sensor* or *7L Patch* is damaged.
- The *7L Patch* is single use for a single patient. Do not reuse.
- Follow the instructions to use correctly.
- Make sure the *7L Sensor* is installed correctly and is firmly sealed in the *7L Patch*.
- The *7L Sensor* and *7L Patch* should be placed on the patient's body as instructed.
- Care should be taken by the patient if showering. Caution should always be taken when wearing in a wet location.
- The SmartCardia *Phone* cannot get wet.
- Avoid extreme high or low temperature and humidity.
- Follow the instructions for the correct cleaning solution and process.

Questions? Contact FDA/CDRH/OHT5/DHT5P at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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- Do not use the device if the battery is depleted**.** Refer to the SmartCardia documentation for the battery life expectancy.
- Do not place the *7L Patch* on open wounds.
- The patient must keep the SmartCardia *Phone* within 10 ft of the *7L Sensor* at all times.
- Make sure the SmartCardia *Phone* is fully charged. It is best to charge the phone each night.
- If the Bluetooth on the SmartCardia *Phone* Is OFF, contact SmartCardia Customer Support.
- Only use the charger provided with the SmartCardia *Phone*.
- It is very important to have a good internet connection.
- For best results, the patient's skin where the *7L Patch* is applied should be cleaned and hair clipped or shaved to reduce artifact and prevent a noisy signal.
- Do not use the *7L Patch* if date of manufacture is more than two years. Refer to the *7L Patch* labeling.
- The patient must stay away from heavy electrical equipment or other sources of interference. For additional information regarding Electromagnetic Compatibility (EMC), see Attachment B.

SmartCardia 7L Web Browser

CAUTIONS:

- Keep username and login in a safe place and do not share them with anyone.
- Do not leave your session open if you leave the device unattended. Always log out.
- Do not access the cloud platform from a shared computer.
- Make sure to set the correct mode of monitoring operation for the patient (Holter, Extended Holter, Event, or Mobile Cardiac Telemetry).
- Measured vital sign values should be reviewed and verified by alternate means if measurements are suspected to be inaccurate.

Alarms

WARNINGS:

- **Alarm conditions must be set to ON for a notification to be presented at the remote viewing station.**
- **Make sure that parameter limit settings are appropriate for the clinical condition of the patient being monitored - do not set parameter limit settings outside the physiological range for the patient.**
- **When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.**
- **Alarm limits are patient or facility specific. The clinician must set and verify alarm limits appropriate for each patient. Failure to set alarm limits properly can lead to false alarms or failure to alarm.**

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- **No computerized interpretation of patient data can correctly detect and classify a medical condition 100% of the time. Use sound clinical judgment when monitoring your patients.**
- **Audio on the PC used to view the *7L Web Browser* must be ON and sufficiently loud enough.**
- **When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**
- **Do not turn OFF the audible notifications without providing continuous observation of the patient.**
- **Check notification volume periodically! If the volume is too low, it could result in the inability to hear a notification.**
- **In certain circumstances the pacemaker pulse may be detected as a heartbeat. Verify heartbeat with an alternative method such as auscultation, radial artery palpation, or viewing ECG.**
- **Make sure that proper patient preparation and settings are in place to avoid sensitivity to excessive artifact which can result in inaccurate notifications.**
- **Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a clinician views these events, they should follow their practice guidelines and manually document the event in the patient record.**
- **The alarms provided on the SmartCardia 7L Platform should be properly assessed by medically trained or relevant qualified and accredited personnel.**
- **It is the responsibility of the clinician or care provider to respond to alarms consistent with their practice license.**

CAUTIONS:

- When remote monitoring a patient, remember they may not have a caregiver or helper nearby and they may not be able to respond to communications. Always know how to provide aid for each patient.
- Receipt of alarm signals is not confirmed.
- Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.
- If the wireless connection from the *7L Sensor* and *7L Patch* to the SmartCardia *Phone* or the *Phone* to the internet/cloud application is disconnected, a notification will show on the display. Periodically check to make sure the connection is intact.

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Indications for Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

Measurements include: electrocardiogram (ECG signal), R-R interval, and Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

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SmartCardia 7L Platform™ Introduction

System Description

The SmartCardia, Inc. 7L Platform™ is a system comprising a wireless sensor component (the *7L Sensor*), an adhesive patch (the *7L Patch*) which the *7L Sensor* connects to, a mobile component (the SmartCardia *Phone*), and a backend server component (*SmartCardia 7L Web Browser*) to access the patient database. The SmartCardia *Phone* is an Android OS mobile phone that is configured by SmartCardia in a kiosk mode so it can only be used by the SmartCardia *7L Mobile Application* (it does not function as a usable phone, only as a mobile gateway for the SmartCardia data). The data are viewed on the SmartCardia *Phone* and via a SmartCardia *7L Web Browser* application.

The *7L Sensor* and *7L Patch* make up a body worn applied device consisting of the ***reusable*** electronic *7L Sensor* and a ***disposable*** adhesive *7L Patch* into which the *7L Sensor* is inserted and connection is made. The accessory *7L Patch* has four electrodes. The sensor and patch assembly adheres to the chest and contains the batteries to power the connected reusable *7L Sensor* to wirelessly monitor electrocardiogram (ECG) and heart rate of the patient.

The SmartCardia 7L Platform provides ~~near real time~~ monitoring for Holter applications and supports three monitoring service modes:

- Holter Monitoring (up to 48 hours) and Extended Holter Monitoring (greater than 48 hours)
- Event Monitoring
- Mobile Cardiac Outpatient Telemetry, or Mobile Cardiac Telemetry (MCT)

The SmartCardia 7L Platform has the following characteristics:

- It provides ~~a near-real time, continuous~~ monitoring for any operation mode,
- It is non-invasive and has no significant safety issues, and
- It uses electrode and ECG technology that is in use today.

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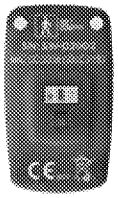
SmartCardia 7L Platform Components

SmartCardia 7L Sensor (the *7L Sensor*)
A reusable Sensor (do **not** throw away)

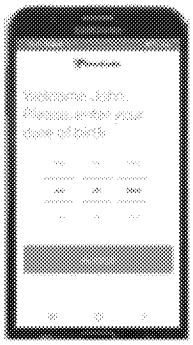


- Inserts into the *7L Patch*
- Monitors ECG
- Sends patient data to the SmartCardia *Phone*
- Is waterproof when used with the *7L Patch*

SmartCardia 7L Patch (the *7L Patch*)
A single-use patch (disposable)

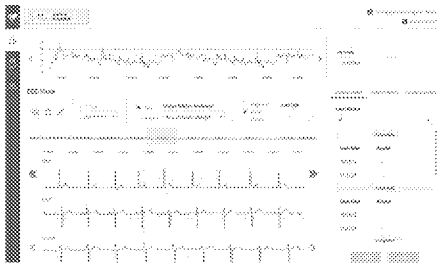
- Includes batteries
- Holds the reusable *7L Sensor*
- Includes ECG Electrodes
- Medical adhesive used to apply to the skin

SmartCardia Phone (the *Phone*)



- Is a gateway to send patient data to the provider viewed on the *7L Web Browser*
- Always kept close within 10 feet of the SmartCardia *7L Sensor*
- Charged daily (or more often as needed)
- Uses the *7L Mobile Application*
- Provided and configured by SmartCardia

SmartCardia 7L Web Browser (the *7L Web Browser*)



- Application is validated on Google Chrome browser only
- Service mode choices (Holter, Extended Holter, Event Recording, and Mobile Cardiac Telemetry
- View patient data, manage alarms, analyze ECG, and create reports

Responsibilities

Clinician responsibility

- Patient registration in the system
- Provide remote support for the patient

Responsibility of SmartCardia

- Remote clinical support
- Remote technical support

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Abbreviations

ECG: Electrocardiogram
HR: Heart Rate
BPM: Beats per minute

Icon & Symbol Table

Symbols on the Product and Packaging

Symbol	Title of Symbol	Symbol Description
	SmartCardia	Represents the SmartCardia logo
	European Conformity	The product meets the standards for Medical Device in the European Union and Subscript text next to the symbol indicates the code of the notified body
	Manufacturer	Indicates the medical device manufacturer
	Authorized Representative in the European Community	Indicates the Authorized representative in the European Community
	Date of manufacture	Indicates the date when the medical device was manufactured
	Use-by-date	The date after which the product or the accessories should not be used
	FCC Compliance Mark	Meets FCC requirements per 21 CFR Part 15
	Serial number	Indicates the serial number of the medical device
	Catalog number	Indicates the manufacturer's catalogue number so the medical device can be identified
	Batch code	Indicates the manufacturer's Lot code
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	Temperature limits	Indicates the high and low temperatures for storage and use
	Humidity limits	Indicates the high and low humidity for storage and operation

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Symbol	Title of Symbol	Symbol Description
	Do not re-use	Product is for single use only and not to use on another patient
	Keep dry	The product needs to be kept dry
	Non-ionizing electromagnetic radiation	This product does radiate RF, but it is non-ionizing
	Restriction of hazardous substances	Product is in accordance with the requirements restricting the use of specific hazardous materials
	BF applied part	To identify a type BF applied part complying with IEC 60601-1
	Do not use in MRI	Do not use the product in a magnetic resonance imaging instrument
	Not made with natural rubber latex	There is no natural rubber latex in the product or its package
	Non-sterile	The product is not sterile
	Crossed-off wheeled bin	The product contains electrical parts and must be disposed of properly, not into any bin, but must be placed in an electrical equipment bin
	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Consult instructions for use	For more information, read the operation manual or instructions for use
	Do not use if package is damaged	Do not use if the package has been damaged or opened
IPX7	Ingress protection (IP) rating	Indicates the assembled 7L Sensor and 7L Patch can withstand ingress of water in harmful quantity when immersed in water under defined conditions of pressure and time (up to 1 meter (3 ft 3 in) of submersion)
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Warning	Consult the instructions for use for important warning information that cannot be presented on the medical device itself
	Caution	Consult the instructions for use for important cautionary information that cannot be presented on the medical device itself

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Symbols on the User Interface

Symbol	Title of Symbol	Symbol Description
	Mail	Refers to email
	Phone	Refers to phone number
	Password	Refers to password
	Clinician	Refers to clinician
	Patient	Refers to patient
	Multi-Patient	Refers to the display of 12 or more patient tiles
	Device	Refers to the SmartCardia *7L Sensor*
	Chest device location	Represents the *7L Patch* with *7L Sensor* on the patient's chest
	Bell cancel	To identify the control where an audio alarm sound may be switched off or to indicate the operating status of the alarm audio.
	Edit	Represents that data can be edited
	Delete	Represents that data can be deleted
	Calendar	Refers to a calendar where date can be selected
	Clock	Refers to the time
	Time zone	Refers to the time zone
	Add	Refers to adding or seeing more information
	Heart	Represents the patient's heartbeat

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Symbol	Title of Symbol	Symbol Description
	Import Records / Upload File	Refers to the action of importing a record (upload a SmartCardia file)
	Clipboard	Represents information
	Return	Represents the action of coming back to the initial state
	Zoom	Represents the zoom action
	Undo	Represents that the action can be undone
	Search	Represents the action of searching
	Sort	Represents the action of sorting
	Logout	Refers to logout action
	Stop	Refers to stopping an action
	Measure	Represents ECG chart measurement
	Close	The tab can be closed
	Arrow	Clinicians use the arrows to scroll through the graph
	File	The report created by the clinician can be downloaded
	Link	Refers to the association between one patient and a device
	Unlink	There is no patient-device association
	Battery	Refers to the battery of the *7L Patch*
	Battery critically low	Battery of the *7L Patch,* less than 10% remains

Questions? Contact FDAAccessCDRH@fda.hhs.gov or 301-796-8118

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7L Web Browser Navigation

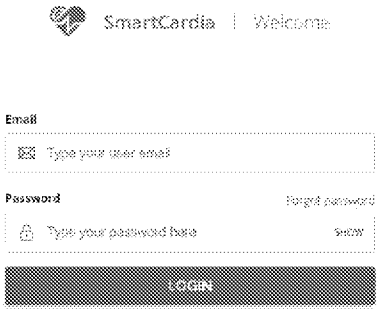
Clinician Login

General Recommendations

- The cloud platform known as the *7L Web Browser* should always be accessed using Google Chrome from an authorized and secured device with at least 4 GB of RAM.
- The *7L Web Browser* must only be used by clinical personnel who have been properly trained on the safe and efficacious use of the product.

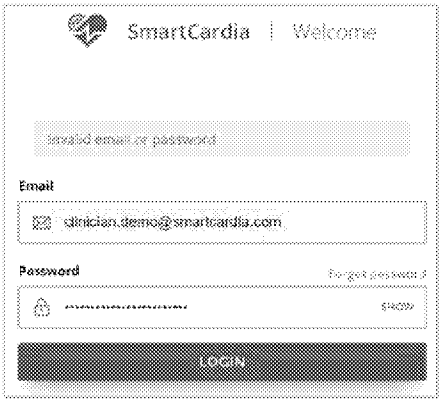
The first view accessed by the clinician when opening the application is the Login window. The user must enter his/her email address (email@example.com), which has been previously registered in the SmartCardia 7L Platform and their corresponding password.

- Enter your user Email and Password
- Click "LOGIN" to show a list of patients



NOTE: If there is a problem when entering your password without displaying it, you can press the "SHOW" button to the right side in the Password box to display it.

- If the email or password is entered incorrectly, an error message box is displayed.
- Re-enter the Email, Password, and LOGIN.



Questions? Contact FDAACDRHDOCSTAR at CDRH-FOISTAT@fda.hhs.gov or 301-796-8118

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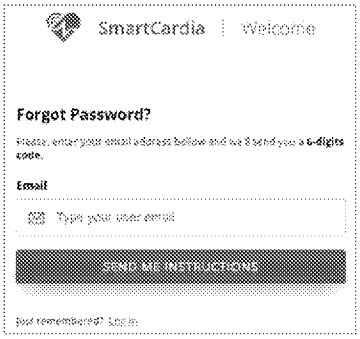
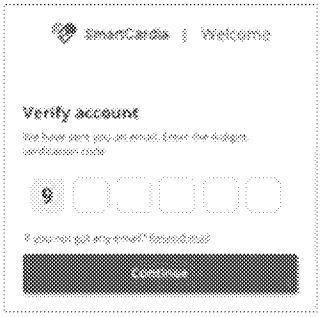
Forgot your password?



- Select the “Forgot password?” button located to the right of the Password box just above it. This new window opens to retrieve your password
- In the new window, in case the password is remembered, at the lower left corner of the box, the “Log in” hyperlink can be selected to return to the log in page
- In the event you do not remember your password, enter your email, and press the “Send me instructions” button



- You will then receive a message with a six-digit code to enter in the new window to verify your account
- In case you do not receive any message, you can request a new code again by pressing the “Resend mail” button.
- After entering the six-digit verification code, press the “Continue” button and if the verification code is correct, a new window will appear.

- In the reset password new window, you enter a new password according to the following rules:
  - Minimum length of 10 characters
  - At least 1 uppercase
  - At least 1 lowercase
  - At least 1 digit
- After pressing the “Update password” button, you will be redirected to the Login page

NOTE: In case of error, the user has three more attempts before being locked out. Contact SmartCardia Customer Support.

Questions? Contact FDAACCDRH/OCE/DB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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Main Menu: Navigation Bar

The *7L Web Browser* has a main navigation menu that allows the user to move through the application. The main navigation bar can be used showing symbols and item names or showing only the symbols. The main navigation, which always appears on the left side of the web application and consists of the following symbols that appear from top to bottom:

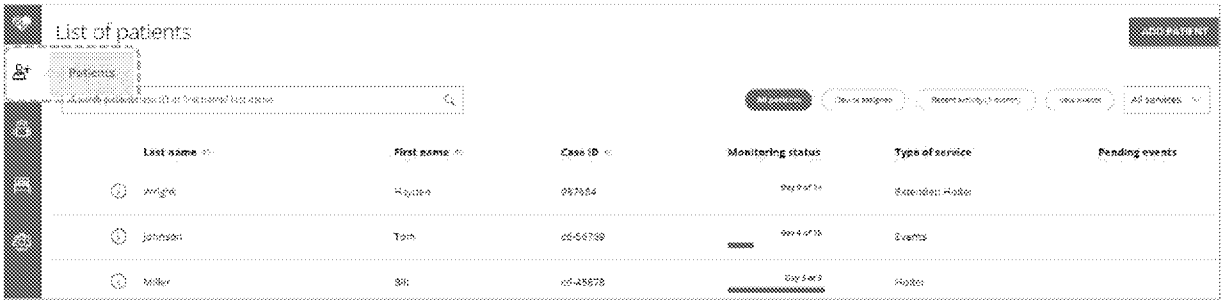
	SmartCardia logo
	Patients- press the button to access the list of patients
	Devices- press to access the list of devices
	Multi-Patient- press to access the view of multiple patient tiles
	Settings- access for clinician administrative information and settings
	Clinician- allows you to log out of the application

Patient Management

Main Page: List of Patients

Navigation Menu

The main page of the application is the “List of patients”, as shown below.

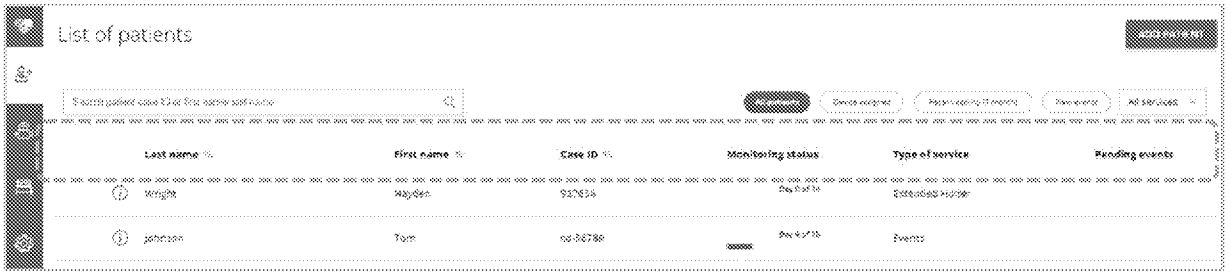


Questions? Contact FDAACDRHDOCSTAR at CDRH-FOISTAR@fda.hhs.gov or 301-796-8118

Functions to select across the top include:

- The search bar box can be used to search for a patient using the patient case ID, first name, or last name
- "All patients" provides the list of all patients ever added to the system
- "Device assigned" shows the list of patients that currently have a device assigned (the *7L Sensor*) presented in alphabetical and numerical order
- "Recent activity (1 month)" lists activity for the past one month
- "New events" displays the list of patients with pending events (all new events triggered based on the alarm and notification settings)
- "All services" provides a drop-down menu list of service types to sort list of patients (All services, Holter, Extended Holter, Events, or Mobile Cardiac Telemetry)

The column headers below provide navigation and information about the list of patients.



- Patients can be sorted by last name, first name, or case ID by clicking on the "Sort" icon on the right side of the column headers
- Monitoring status shows the current number of days that have been monitored and the number of days remaining
- Type of service displays the type of service currently in use for each patient
- Pending events lists pending events, the number of events is listed inside the red circle

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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List of Patients

One of the important functionalities for the clinician on the main page is to view additional information about a patient.

Clinicians can see detailed information for each patient by selecting the information sign to the left of the patient's name.

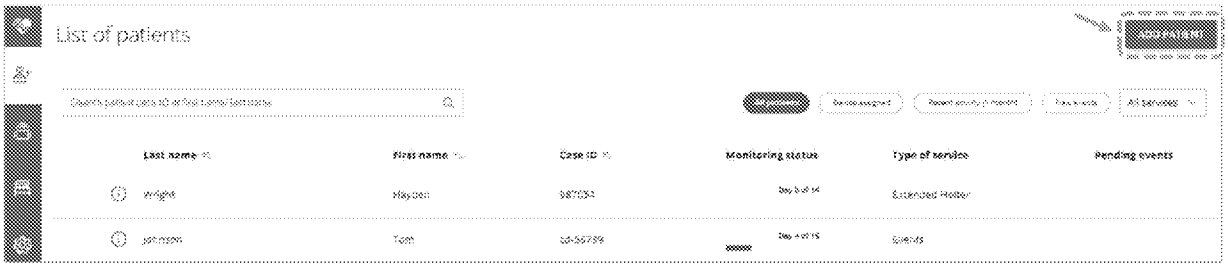
The detailed information includes:

- Last name, first name
- Age: patient's age
- Sex: patient's sex
- Multi-Patient Tile #: viewing location of patient tile assigned to the patient

  Note: The patient is automatically assigned to a Multi-Patient Tile when admitted
- Chest device: the device is attached to the chest and a green solid circle with the device name is listed

Add a Patient

The other important functionality for the clinician that appears on the main page is the addition of a new patient, this happens when the user selects the "ADD PATIENT" button located in the upper right corner.



The patient onboarding screen opens, and you are on the add new patient screen.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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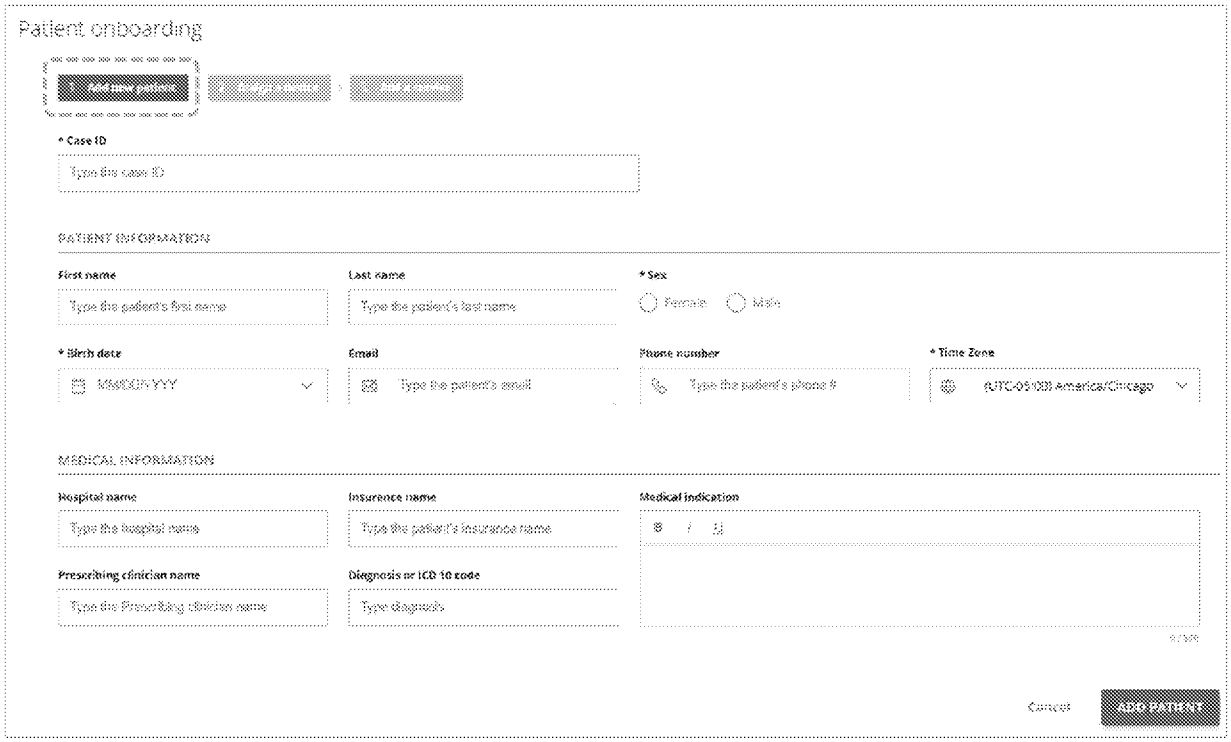
Patient Onboarding- Step 1: Add a new patient

Enter the patient and medical information on the form.



To exit the form without filling it out, press the “Cancel” button.

In the form, complete the following fields (* indicates required field):

- Case ID*- identifier associated with each patient (must be a unique number)
- Name- patient's first and last name
- Sex*- select the sex of the patient (female or male)
- Birth date*- use the calendar to enter the birth date of the patient (to enter the year, select the year displayed then scroll to the one desired and select it. To enter the month, select the month displayed, then scroll to the appropriate one and select it.)
- Time zone*- if not filled with the correct time zone, using the drop-down list select the time zone of the patient’s location

When finished filling out the form without errors, at the lower area of the patient onboarding screen, select the “ADD PATIENT” button. The screen then wraps to the next step in the process.

NOTE: If an error occurs when inserting the new patient information, the fields where errors are detected will be highlighted in red, indicating that there has been a problem and the new patient cannot be added until those errors are corrected.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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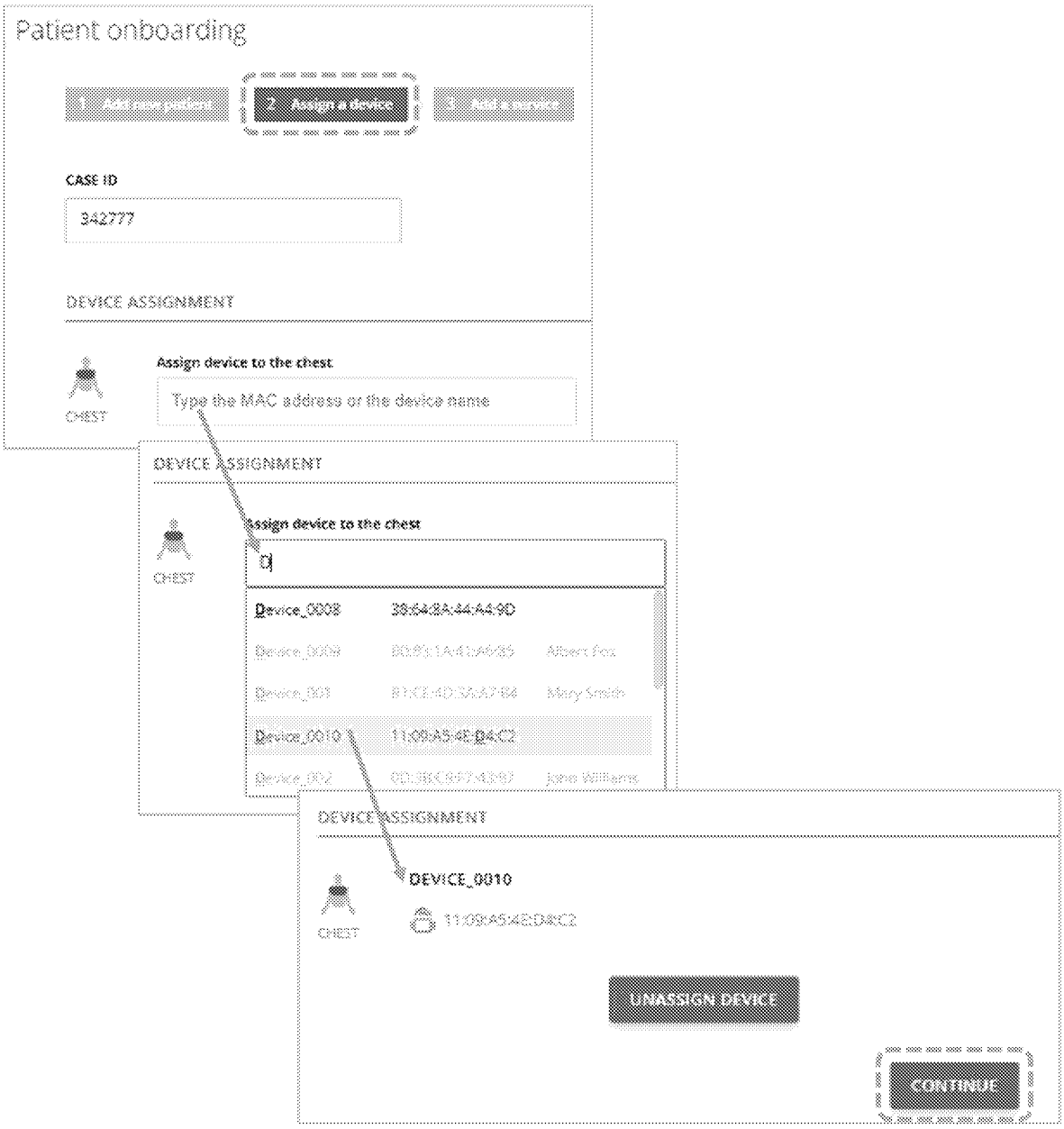
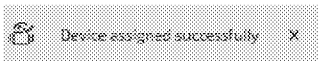
Patient Onboarding Step 2: Assign a device for the patient

- On the screen "ASSIGN A DEVICE"
- Type the MAC address or device name. As the information is typed, a box below begins to populate with the device, then select it from the list of options, next select "CONTINUE" to associate the *7L Sensor* to the patient.

NOTE: The MAC address is found on the surface of the *7L Sensor* that is inserted into the *7L Patch.*



After selection of "CONTINUE" a confirmation message 

is displayed and you advance to the next step in the onboarding process.

Questions? Contact FDAACDRHDOCSPDS at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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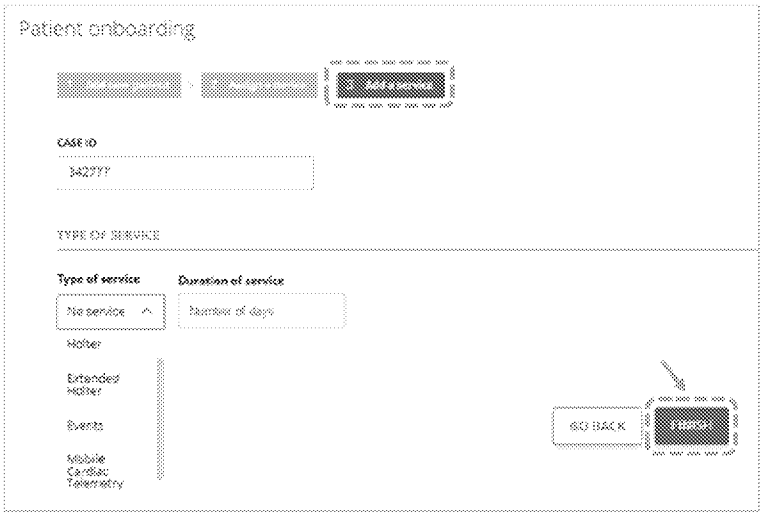
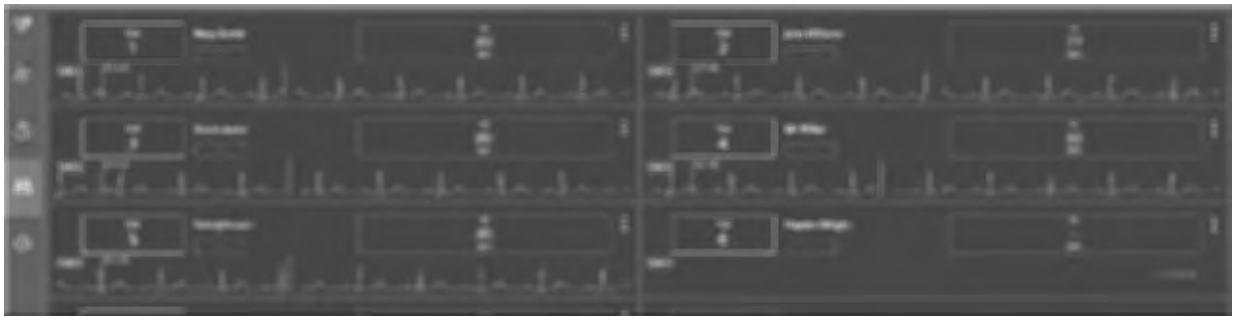
Patient Onboarding Step 3: Choose the monitoring service type for the patient

- From the drop-down menu, select the service type (No service, Holter, Extended Holter, Events, or Mobile Cardiac Telemetry)
- Enter the number of days for the duration of service
- Select "FINISH" this new patient is now added to the patient list
- Once "FINISH" is selected you are taken to the Alarm Settings screen to review and customize alarms for the patient just added (see *Alarms and Alarm Management* section on *page 35* for detailed information)



NOTE: Once admission is finished the new patient is added to the Multi-Patient view screen as shown below. No signal is displayed until service begins once the *7L Sensor* is on the patient's body and connected to the *7L Mobile Application*.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display. Consult the *PL-17 SmartCardia 7L PlatformTechnical Manual.*



Service type options and features:

		Features				
		Measurements	**Event Capture**	**Real Time View**	**Duration**	**Report Editing and Creation**
Service Type	**Holter**	7 leads ECG, Atrial Fibrillation	Yes	Optional	<48 hrs.	Yes
	Extended Holter	7 leads ECG, Atrial Fibrillation	Yes	Optional	>48 hrs.	Yes
	Event	7 leads ECG, Atrial Fibrillation	Yes	Optional	Ordered	Yes
	Mobile Cardiac Telemetry	7 leads ECG, Atrial Fibrillation	Yes	Yes, 24/7 monitor watchers	Ordered	Yes

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PolStat19@fda.hhs.gov or 301-796-8118

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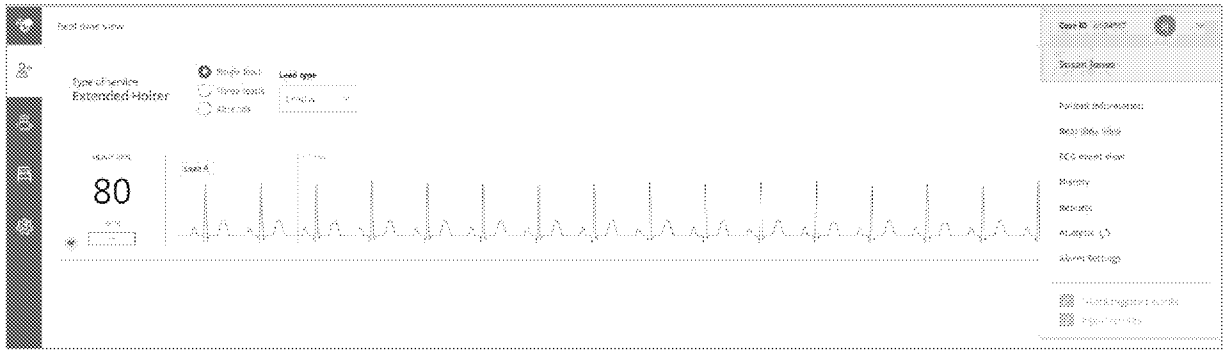
Individual Patient Page

Select “PATIENTS” on the left navigation menu, which displays the list of patients. Once the desired patient name is selected, the “real time” view for the patient is displayed. In the upper right corner, select the arrow on the right of the patient’s Case ID and blue circle with patient initials.

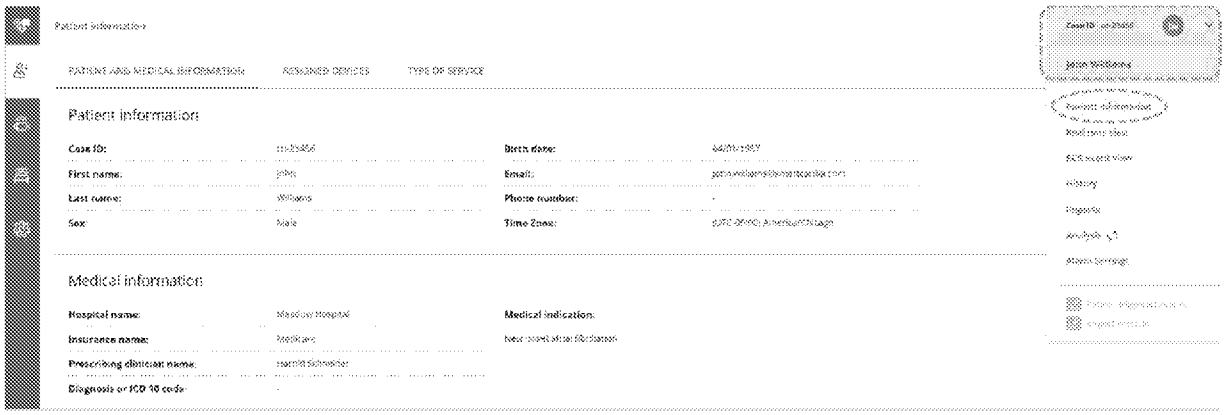
This dropdown menu displays the patient’s name and the options to view and manage this patient.

The term "Real Time" and "Real Time View" are used to indicate you can view the streaming ECG waveform and data as opposed to viewing the stored, retrospective data.



Patient Information/Medical Information

The following patient information is displayed for the selected patient. This data was entered manually when the patient was added to the system.



The information displayed is the patient's personal information (Case ID, first name, last name, sex, birth date, email, phone number, and time zone).

In addition, the medical information is displayed (hospital name, insurance name, prescribing clinician name, diagnosis or ICD 10 code, and medical indication).

This information can be edited by selecting the “Edit” button on the right side of the screen.

Questions? Contact FDA/CDRH/OCE/DHT8 at CDRH-PMISTATUS@fda.hhs.gov or 301-796-8118

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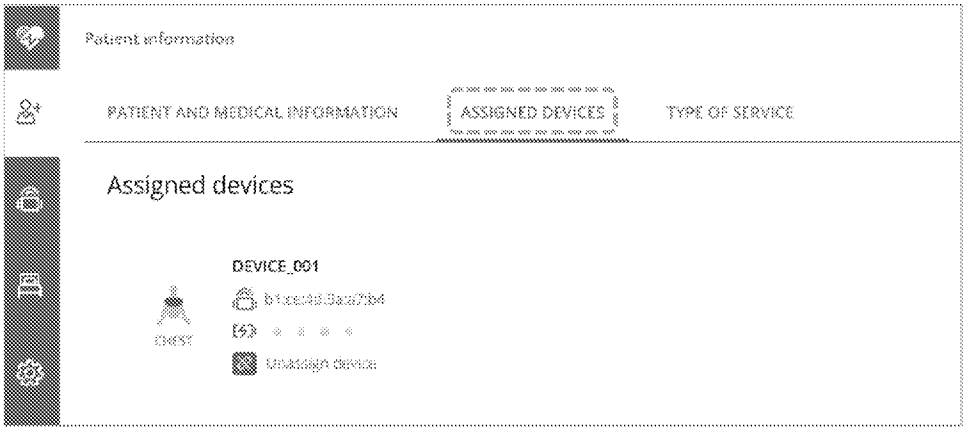
Assigned Devices

The "ASSIGNED DEVICES" tab displays the information related to the device (*7L Sensor*) for the selected patient. If the patient has an assigned device, it is shown next to the picture of the chest which is the location of the *7L Patch with 7L Sensor*. The designated device name, its MAC address, and the battery level are displayed.

In addition, the "Unassign device" button used to dissociate the patient to the device is shown.



The *7L Sensor* battery level displays as a percentage of fully charged.

Device battery is fully charged (100%)	
Device battery has 75% remaining	
Device battery has 50% remaining	
Device battery has 25% remaining	
Device battery level is critically low with less than 10% strength remaining	

Questions? Contact FDAACDRHOCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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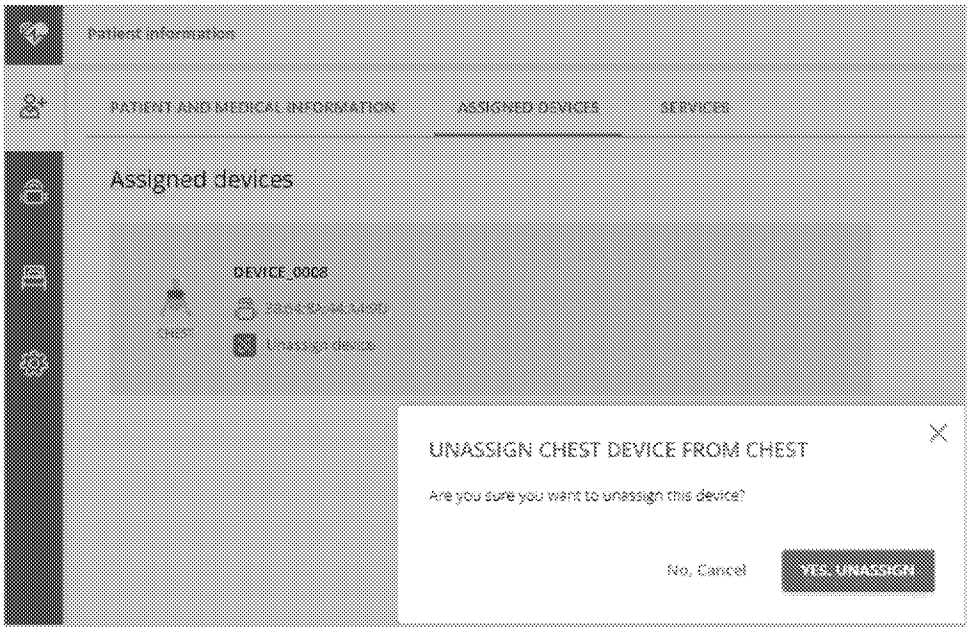
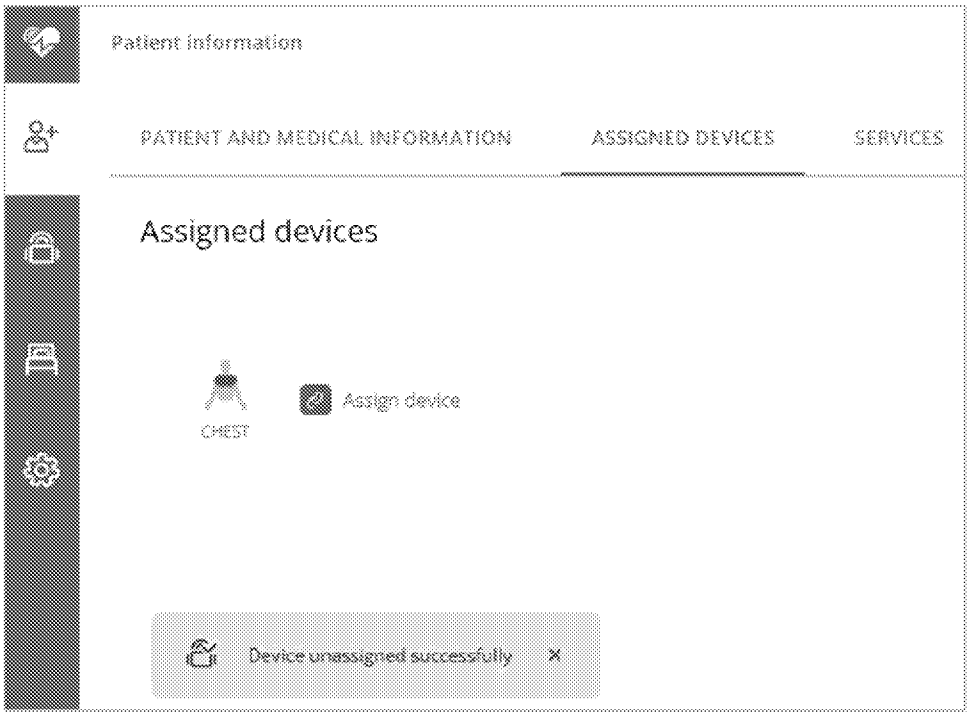
When you select the “Unassign device” button (in red text), a box is displayed with the options: “No, Cancel” or “YES, UNASSIGN”.



When “YES, UNASSIGN” is accepted, the confirmation message “Device unassigned successfully” in a green text box appears.



NOTE: You can only assign a device to a patient if the desired device has already been added to the device list.

Questions? Contact FDA/CDRH/OHT5/DHT5 at CDRH-PMISTAFF@fda.hhs.gov or 301-796-8118

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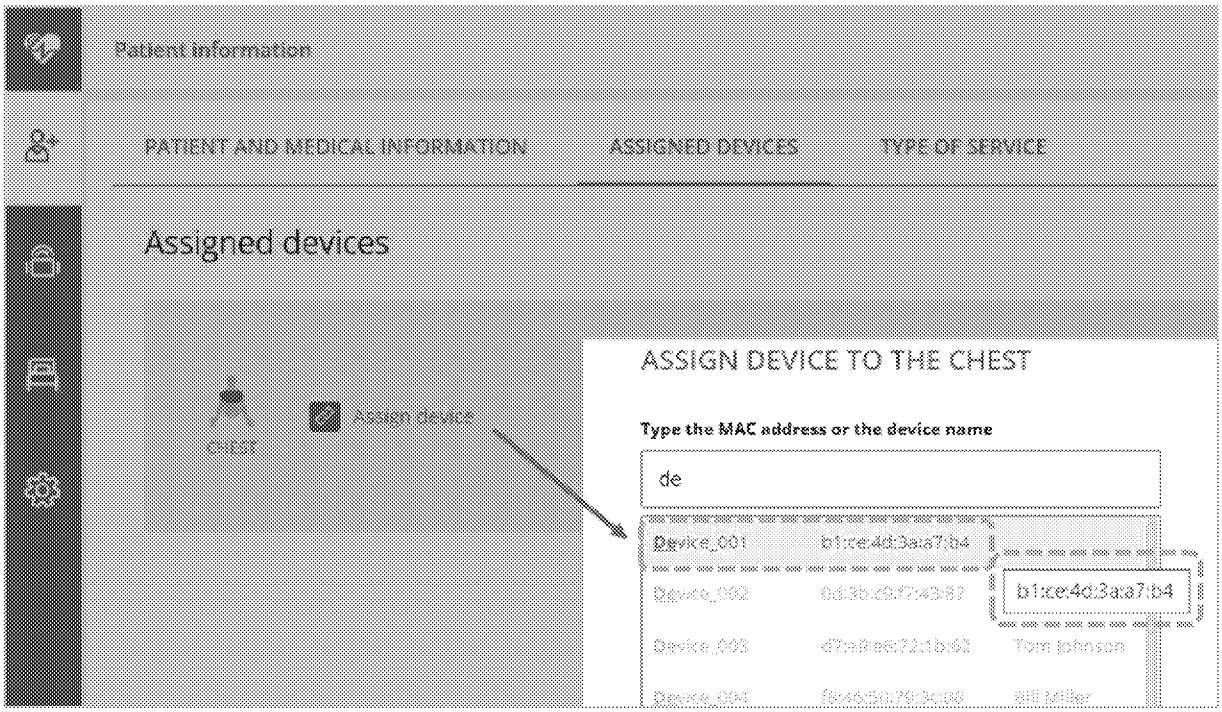
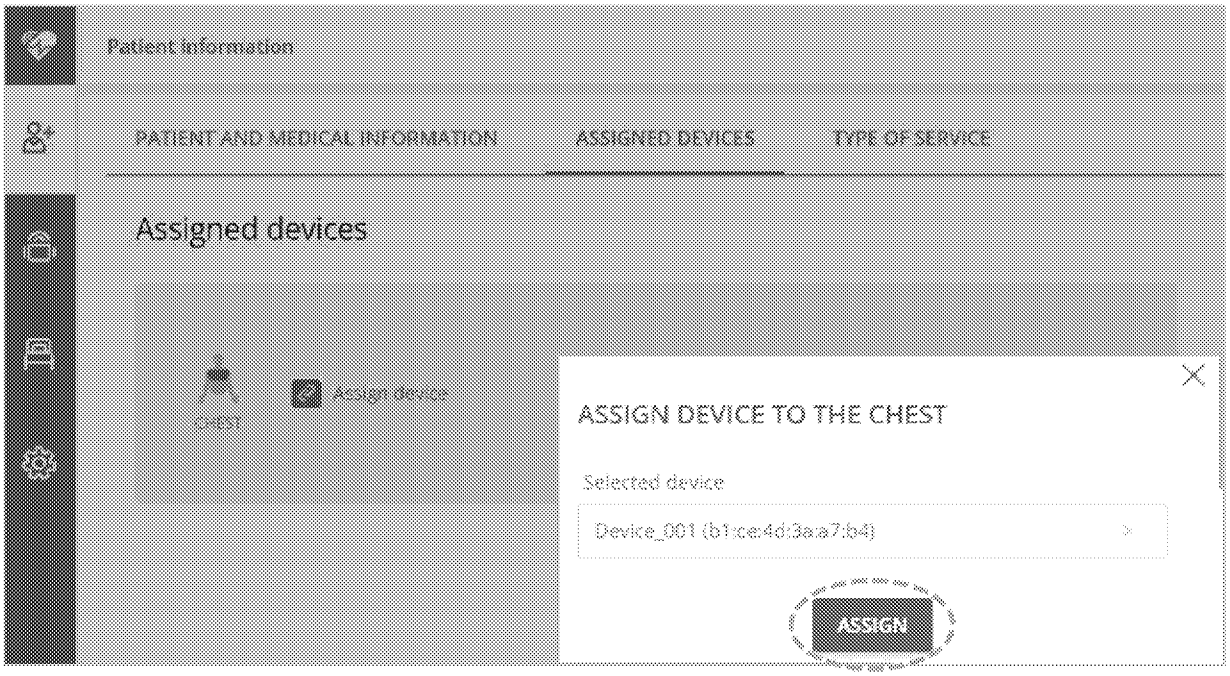
To help you interact with the application, when you start typing the name of the device or its MAC address, suggestions will appear in a text box. Listed devices in gray text indicate they are not available because they are assigned to a different patient. Available devices are those listed in black text that changes to blue text when hovering over it and it is selectable.



Once the desired device has been entered, select the “ASSIGN” button.



Questions? Contact FDAACCESS@fda.hhs.gov or 301-796-8118
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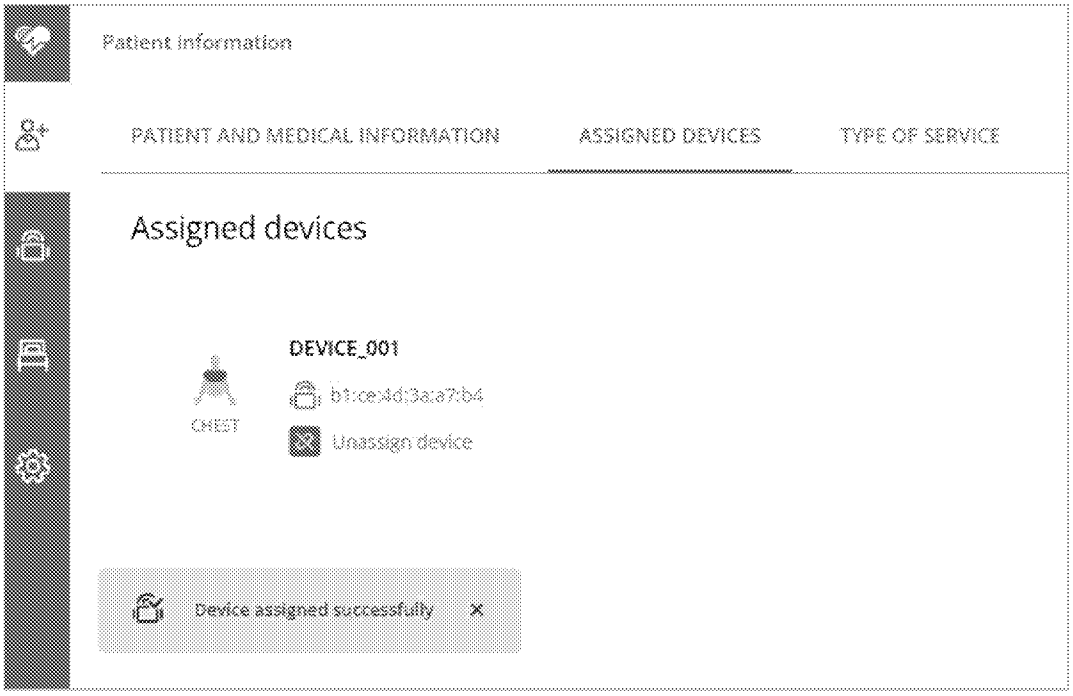
The confirmation message “Device assigned successfully” in the green text box is displayed. In case of an error, a red error message is displayed, explaining the error produced.

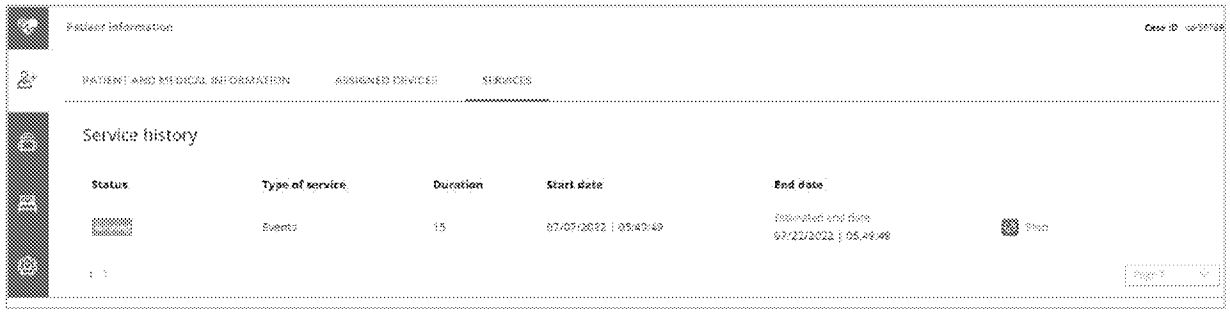


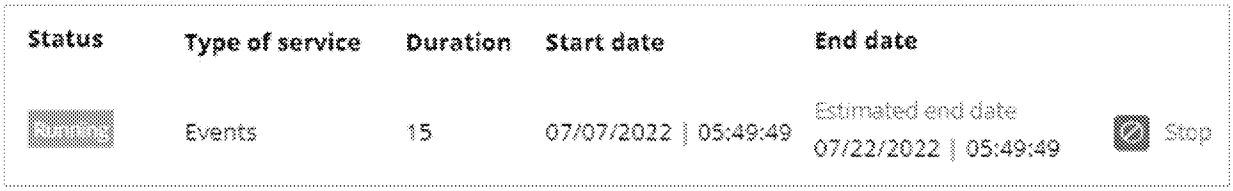
Type of Service

The type of service for monitoring is listed as ordered by the physician. Status is “Running” or “Not Started”. Service can be changed at any time as ordered by the physician.

NOTE: Service begins once the *7L Sensor* is on the patient’s body and connected to the *7L Mobile Application*.

Select “Stop” to change the type of monitoring service and/or the number of days.





Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATE@fda.hhs.gov or 301-796-8118
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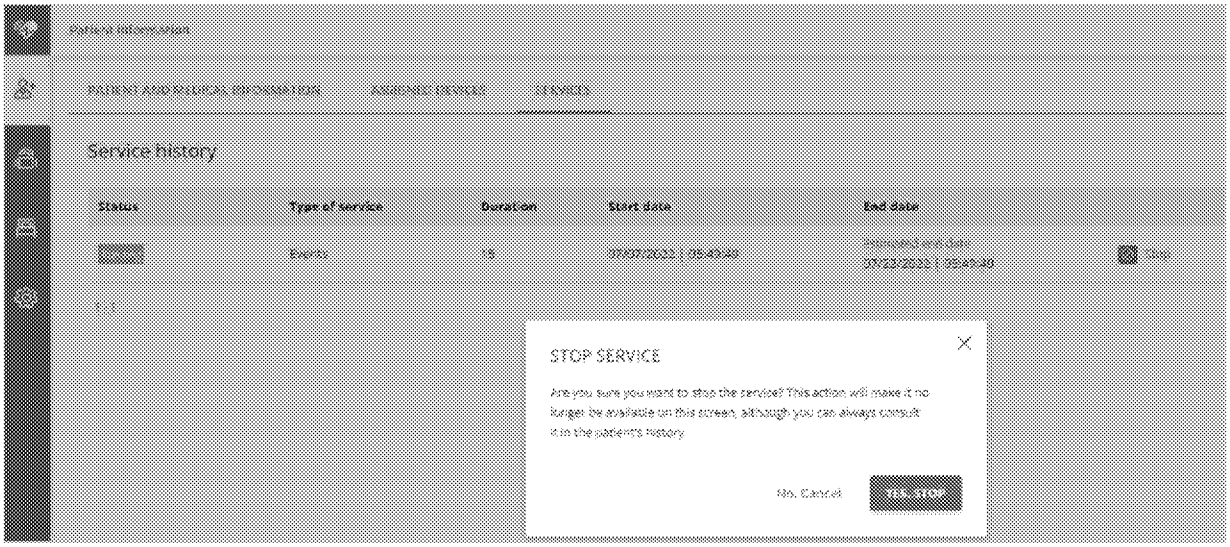
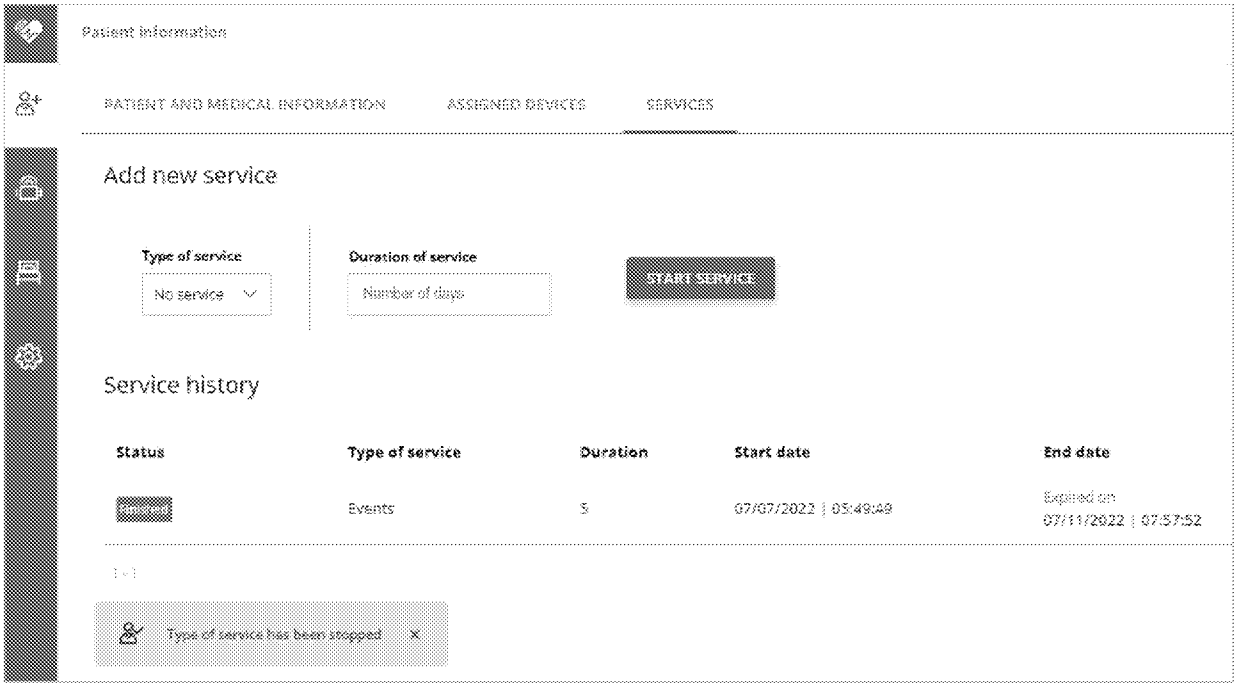
If monitoring is in progress, to discontinue current monitoring service type select “Stop”. The following text box is displayed with the option “No, Cancel” or “YES, STOP”.



Once service is stopped, the confirmation message “Type of service has been stopped” is shown in the green text box.



Questions? Contact FDAACDRHDOCSUB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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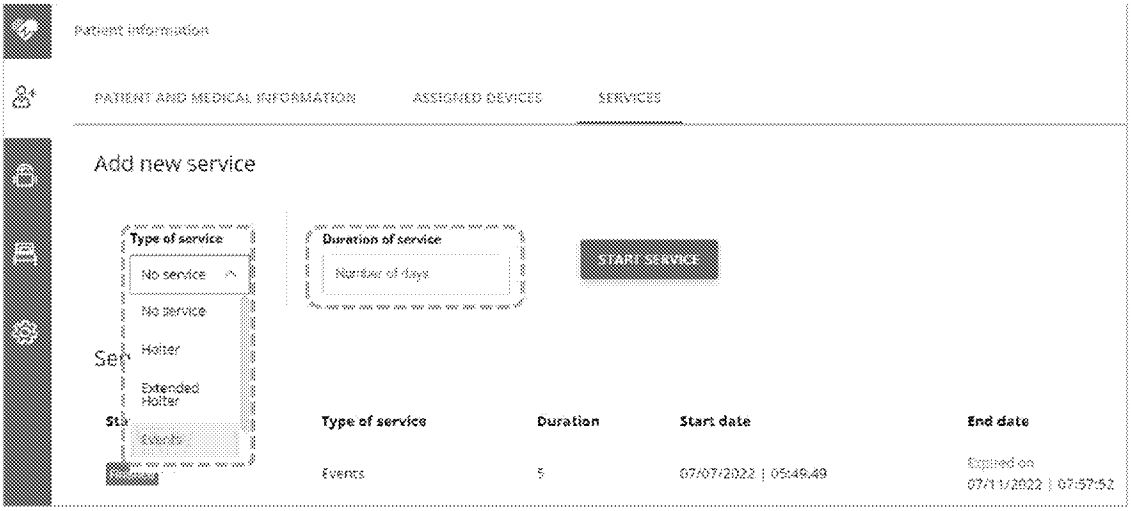
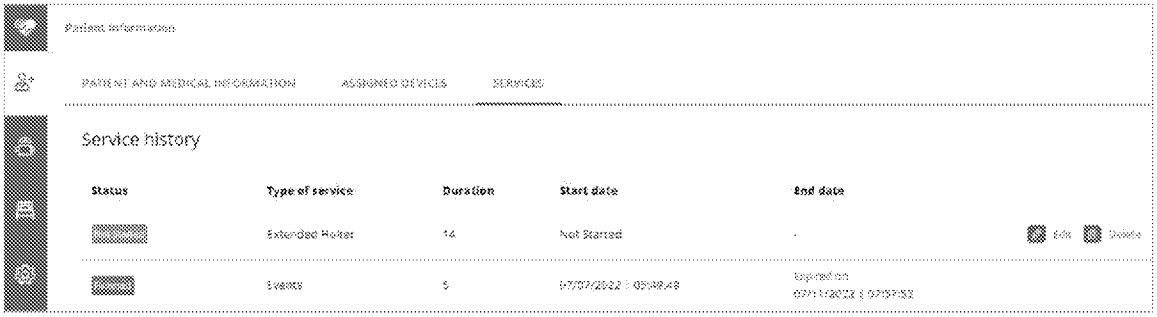
You can now make the new selection of type and duration of service

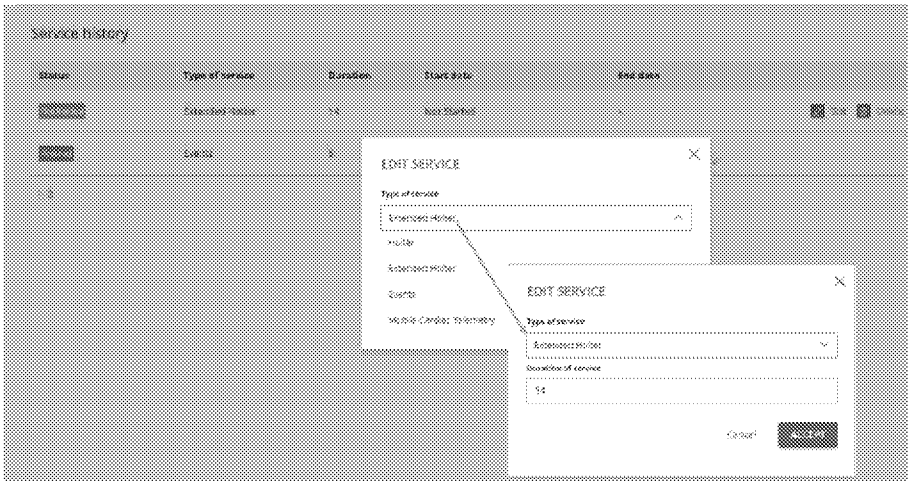


Once “START SERVICE” is selected, a message is displayed.

Service history is listed as shown below. Most recent service information is shown at the top with the option to edit or delete.



When “Edit” is selected, the box below allows you to make any changes then select “Cancel” or “ACCEPT”.



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118

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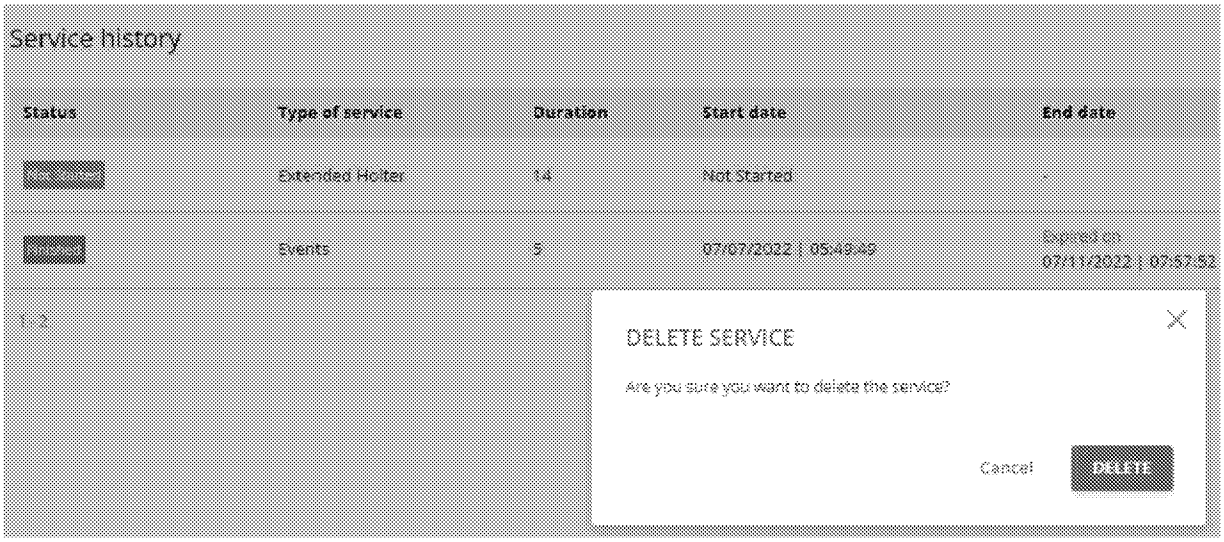
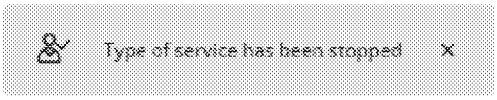
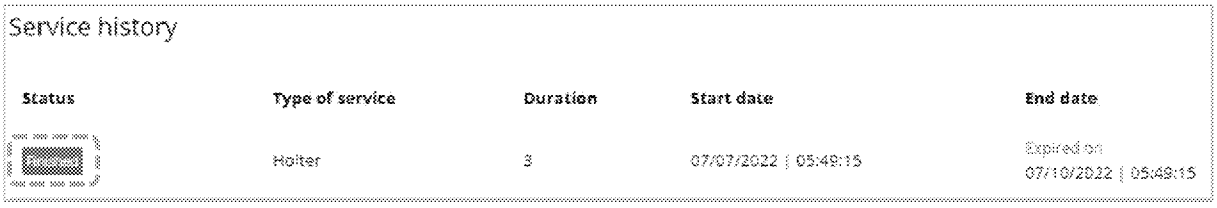
Selecting “Delete” provides option to “Cancel” or “DELETE”



Once service is deleted, it is no longer listed in Service history and a message is posted.



At the completion of the prescribed service period, select “Stop” to discontinue monitoring. The service history will display status as finished. The next step to discontinue monitoring is to Unassign device”. See page 105



Questions? Contact FDAACCDRH@OCS.HHS.gov or CDRH-POLSTATHELP@fda.hhs.gov or 301-796-8118
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Alarms and Alarm Management

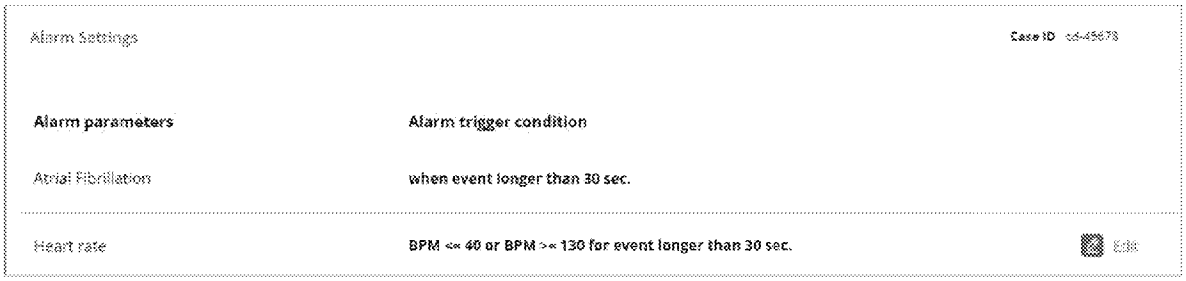
Alarm signals are created when a measured parameter value exceeds the threshold alarm limit settings or when algorithmic analysis (such as atrial fibrillation) detects an alarm condition. For additional information about the SmartCardia 7L Platform alarm system, see Attachment A.

Alarm Signals

Alarm signals are created and presented on the SmartCardia Web Browser when the heart rate exceeds pre-set limit thresholds or when specific arrhythmia events occur. Visual messages are shown when the heart rate and the ECG waveforms are displayed along with an auditory sound. It is the responsibility of the clinician to review and respond to alarm signals.

Alarm conditions that display an alarm signal include:

- Atrial fibrillation
- High or low heart rate



Alarm Signals and Indications

Parameter	Display Parameter	Alarm Trigger Condition	Visual and audio when alarm conditions are met	Alarm Priority
Electrocardiogram (ECG)	High heart rate (HR)	HR ≥ High HR threshold	HR parameter value display turns RED and background flashes Audio alarm provided every 10 seconds	High
	Low heart rate (HR)	HR ≤ Low HR threshold		
	Atrial fibrillation (AF)	Atrial Fibrillation Present	AF in yellow text posted on live ECG screen and flashes Audio alarm provided every 10 seconds	Medium

The following are the manufacturers preset limits for heart rate.

Vital Sign	Upper Threshold	Lower Threshold
HR	130 beats/min	40 beats/min

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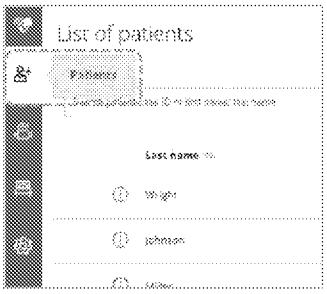
Customizing Alarm Settings for Individual Patients

Alarms are pre-set by the manufacturer, can be modified to meet the practice requirements, and can be customized for the clinical condition of the patient and any provider orders.

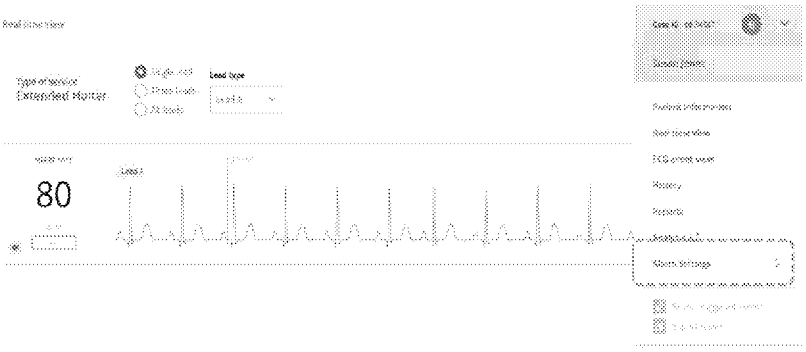
There are three ways to access the “Patient alarm settings” where you can adjust the patient alarm limit settings.

- Option 1: After adding a new patient, you are taken directly to the “Patient alarm settings” to review the current settings and customize to meet the clinical needs of the patient.
- Option 2: Select the patient from the list of patients, go to “Alarm Settings”.

  - On the left navigation menu, select “Patients” to bring up the list of patients



  - Next select the desired patient from the patient list and select “Alarm Settings” from the drop-down menu in the upper right corner



- Option 3: In the Multi-Patient view, on the desired patient tile, select the three dots in the upper right side, go to “Patient alarm settings”.

  - Select the three dots in the upper right corner
  - In the pop-up menu, select “Patient alarm settings”

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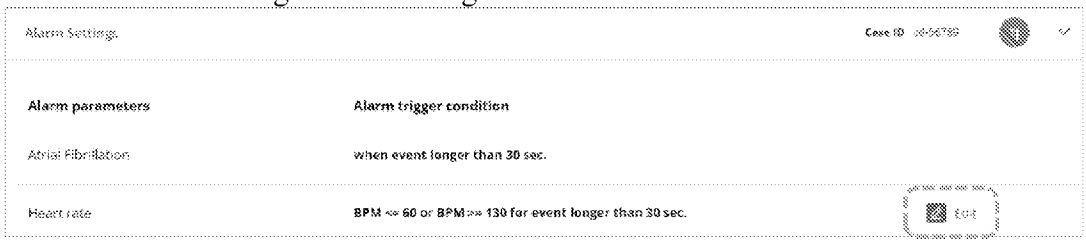
Heart Rate Alarm Parameter Settings

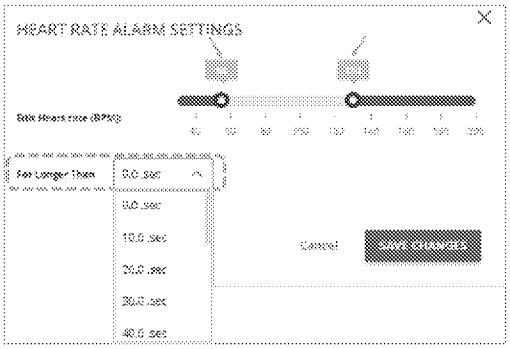
On the patient alarm settings screen, you can review the atrial fibrillation, heart rate alarms, and edit the heart rate alarm limits. (Lowest heart rate setting is 30 and highest heart rate setting is 200)

Customize the alarm trigger conditions

- Select “Edit” to change alarm setting values.



- In this Heart Rate Alarm Setting example, slide each circle above the scale to the left or right to adjust the alarm settings (options in increments of 5 BPM)
- Select length of time for the event, “For Longer Than”
  NOTE: Adding an alarm delay can help reduce clinical non-actionable alarms that result from momentary heart rates that exceed the limit settings
- Select “SAVE CHANGES” or “Cancel” if you choose to not make any changes



Responding to alarms

- Verify the alarm notification is clinically actionable (i.e., requires a patient intervention).
- Take appropriate action or notify the appropriate provider
- If the alarm is not clinically actionable, secure approvals from the provider to modify alarm settings
- Continue to monitor the patient. Call 911 (Emergency Services) if the patient's condition is an emergency

	WARNING: The SmartCardia 7L Platform is NOT an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

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Arrhythmia Event Notifications

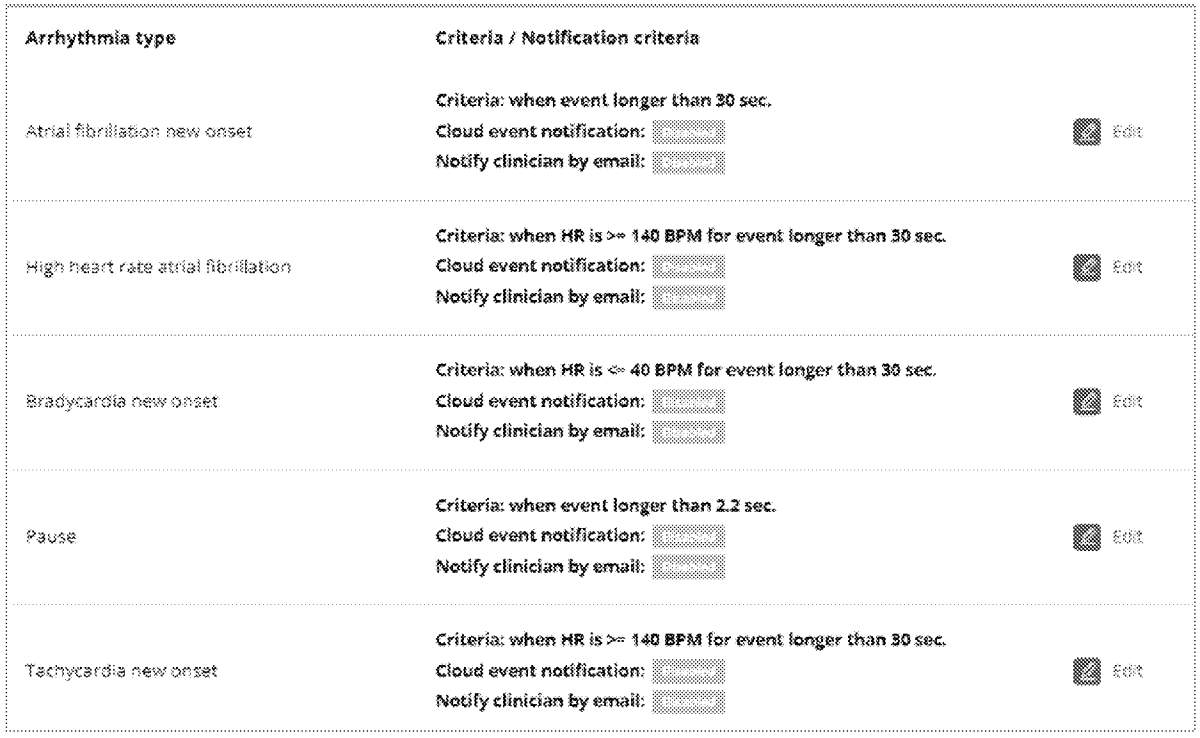
Arrhythmia Events

Arrhythmia events are triggered when specific arrhythmia criteria are met. Arrhythmia events are not alarms and do not provide automated alarm signal notifications. The user can view, accept, or discard an arrhythmia event. User settings can be enabled to notify a clinician of the event at their registered email address.

These events do not generate a real time visual or audible alarm signal.

Arrhythmia events include:

- Atrial fibrillation new onset
- Bradycardia new onset
- Pause
- Tachycardia new onset



When “Cloud event notification” is enabled, events will be identified and marked as pending in the patient list.

When “Notify clinician by email” is enabled, an email that describes the event will be sent to the clinician email that is registered in the system.

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Arrhythmia Event Notifications

The arrhythmia events or notifications are triggered as follows. The events are visible to the user and can be accepted or discarded. The accepted events go into subsequent reports generated by the clinician for the patient. The events that have not been accepted or discarded are visible to the user as "Pending Events".

Arrhythmia Condition	Cloud event Notification	Notification by email	Preset Thresholds for event notifications*
Atrial fibrillation new onset	User selectable for maximum number of event notifications per day	User selectable for maximum number of event notifications per day	Atrial fibrillation detection every 10 seconds using the last 30 seconds of ECG, maximum number of events per day set to 5
Bradycardia new onset	HR ≤ low HR threshold for N seconds	HR ≤ low HR threshold for N seconds	Low HR threshold = 40 beats/min for notification on cloud platform and notification by email. N is set to 40 seconds for cloud platform and notification by email
Pause	Pause ≥ Length, User selectable for maximum number of event notifications per day	Pause ≥ Length, User selectable for maximum number of event notifications per day	Length set to 2.2 seconds for cloud platform, 3 seconds notification by email
Tachycardia new onset	HR ≥ high HR threshold for N seconds	HR ≥ high HR threshold for N seconds	Notification when heart rate is 140 beats/min for greater than 30 seconds for cloud platform and notification by email

WARNING: Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a skilled clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118

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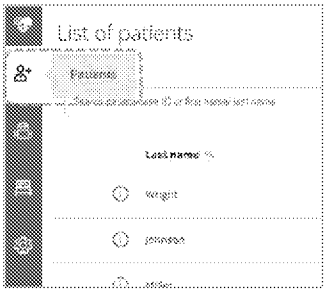
Customizing Notification Settings for Individual Patients

Alarms and notifications are pre-set by the manufacturer, can be modified to meet the practice requirements, and can be customized for the clinical condition of the patient and any provider orders.

There are three ways to access the "Patient alarm settings" where you can adjust the patient alarm limit settings, arrhythmia criteria and notifications.

- Option 1: After adding a new patient, you are taken directly to the "Patient alarm settings" to review the current settings and customize to meet the clinical needs of the patient.
- Option 2: Select the patient from the list of patients, go to "Alarm Settings".

  - On the left navigation menu, select "Patients" to bring up the list of patients



  - Next select the desired patient from the patient list and select "Alarm Settings" from the drop-down menu in the upper right corner

3. Option 3: In the Multi-Patient view, on the desired patient tile, select the three dots in the upper right side, go to "Patient alarm settings".

  - Select the three dots in the upper right corner
  - In the pop-up menu, select "Patient alarm settings"

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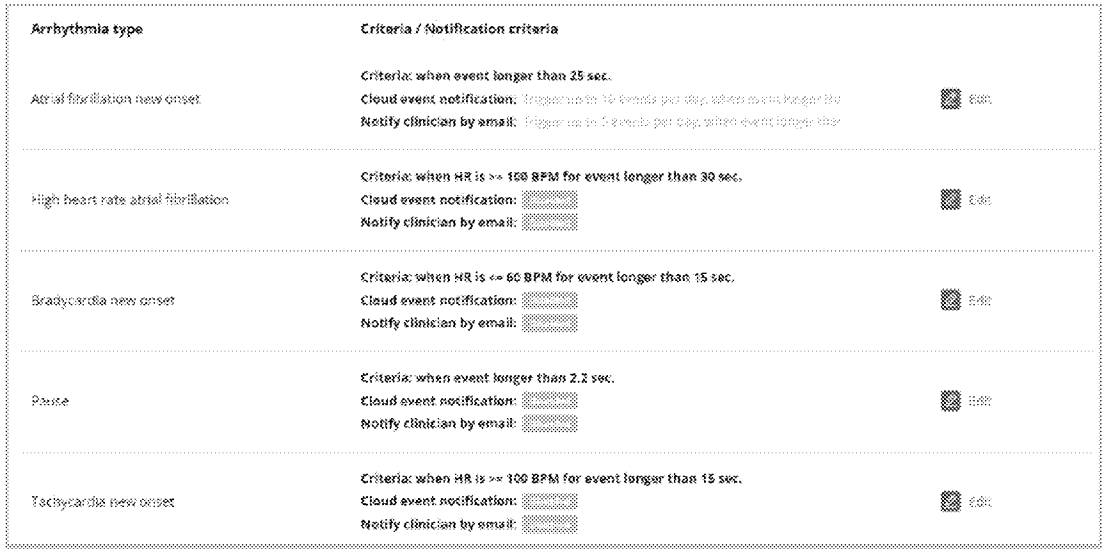
On the patient alarm settings screen, you can review the arrhythmia event notification, turn them on or off, and edit the settings value.



Arrhythmia Type Criteria and Notification Settings

Select “Edit” to change criteria and notification settings. You can also change and identify the events to be included in the patient’s report.

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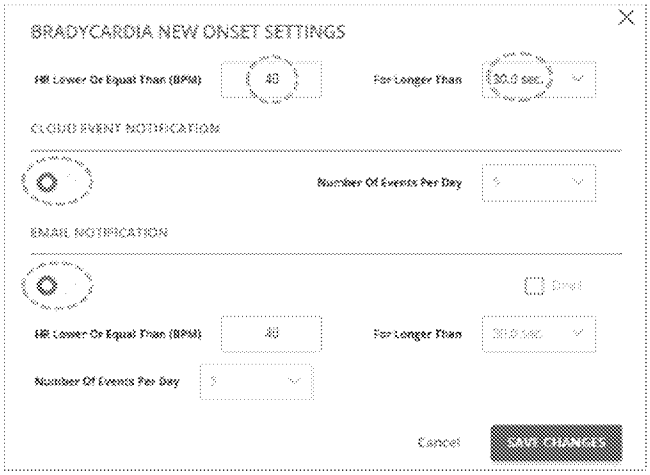
Customize the criteria and notification settings for each arrhythmia type

- Enter numerical value and select the number of seconds duration
- Cloud event notification- use radio button to turn Off/On and set number of events per day for notifications when enabled
- Email notification to clinician email listed in patient and medical information- use radio button to turn Off/On and enter the numerical value, select number of seconds duration, and number of events per day
- Select “SAVE CHANGES” or “Cancel” if you choose to not make any changes



⚠	**CAUTION: Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.**

Patient Preparation for Monitoring

There are two ways for the patient to begin monitoring with the SmartCardia 7L Platform.

- Patient goes to the physician office and the clinical staff applies the device
- The SmartCardia Kit is sent to the patient’s home for them to apply themselves

Refer to the Patient User Guide PN PL-08 that is included in the SmartCardia Patient Kit.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHS@fda.hhs.gov or 301-796-8118

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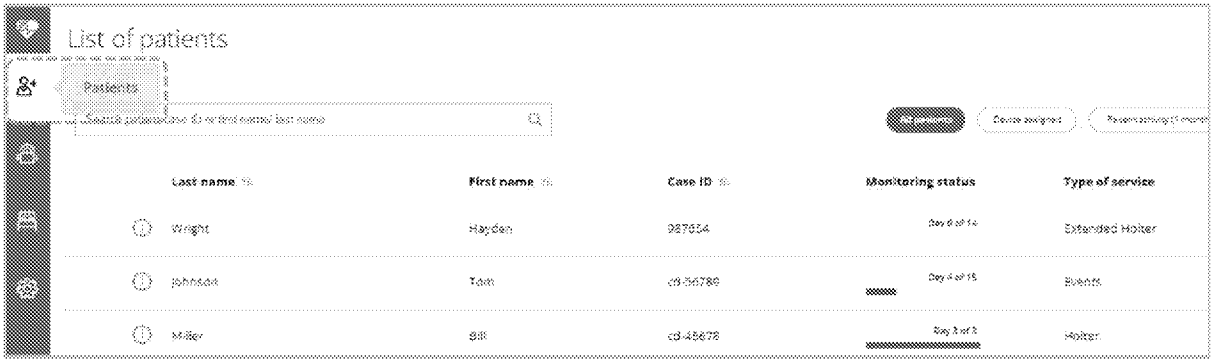
Viewing Patient Data

There are two ways to view a patient's ECG. You can view a patient one at a time or many patients on the Multi-Patient view.

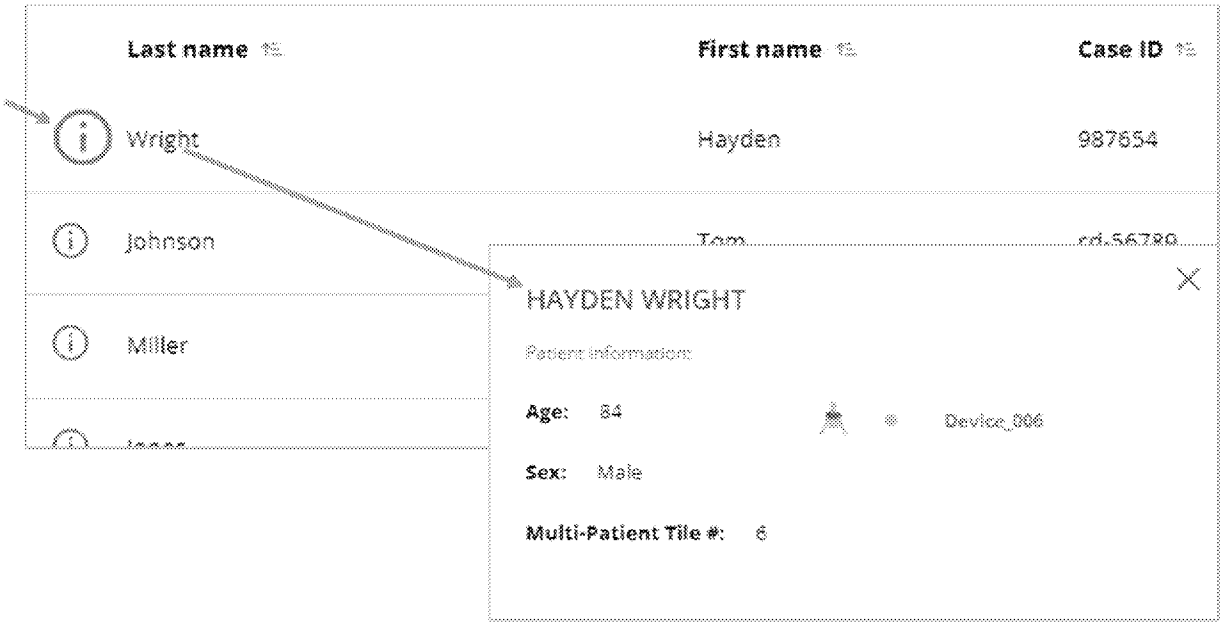
Individual Patient Page: Real Time View

Viewing one patient at a time

On the left navigation menu, click on "PATIENTS" to see the list of patients.



From the list of patients, select the patient's name you want to view. If you want to know additional details about the patient click on the "ⓘ" symbol to the left of the patient's last name to see additional information about the patient (Age, Sex, Multi-Patient Tile #, and Device name).



NOTE: If it is a new patient you wish to view and is not listed, you will need to first "ADD PATIENT", go to page 23.

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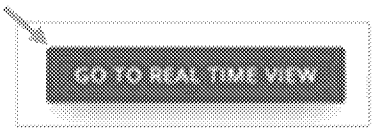
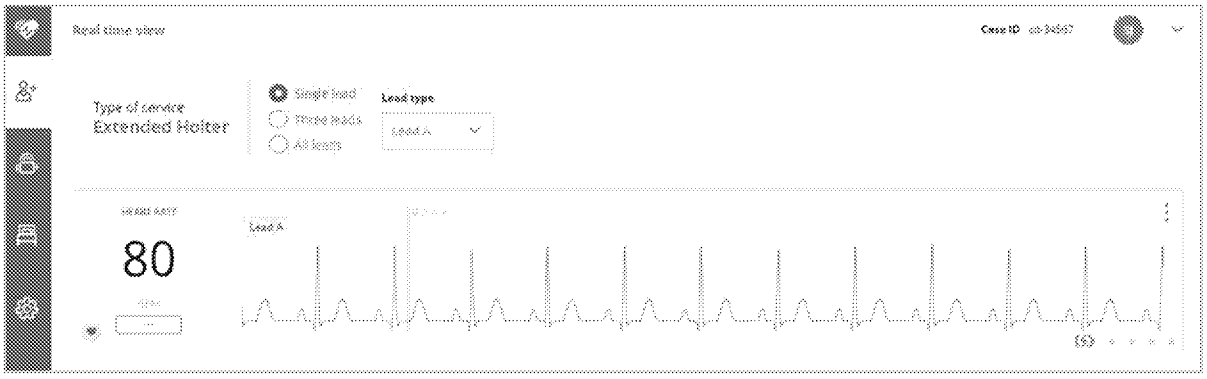
Real Time View

Once the patient's name is selected, their "Real Time View" is displayed. At that time, if you are not taken directly to the patient's real time view, on the left main menu select "Real time view" as pictured below.

NOTE: When you view a new different patient, you may be prompted to select "GO TO REAL TIME VIEW"





The following section will discuss all information shown and functionality available on this screen in detail.

At the top right of this screen, Case ID and patient initials are shown. When you pass the mouse over this information, there is a dropdown menu listing options for interaction with this patient's data as shown below.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHB@fda.hhs.gov or 301-796-8118

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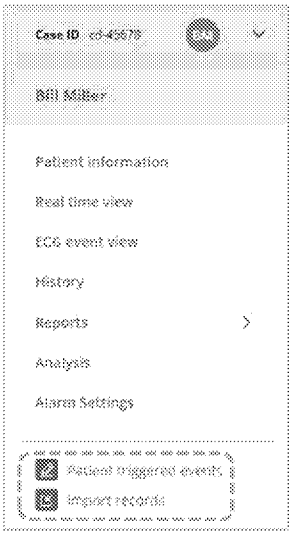
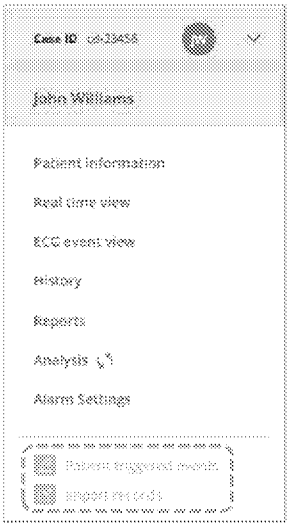
From this patient real time view page, you can view and manage “Patient triggered events” and “Import records”.

- “Patient triggered events” and “Import records” can also be accessed from Patient information, ECG event view, History, Reports, Analysis, and Alarm Settings.

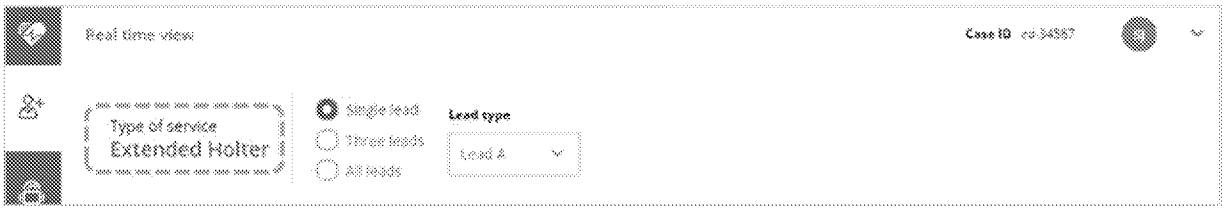


- If Analysis is in process “Patient triggered events” and “Import records” is not available and shaded in grey.



Type of Service Display

The “Type of service” selected to monitor the patient is shown in the upper left side of the screen (Holter, Extended Holter, Events, or Mobile Cardiac Telemetry). Detailed information about each type of service and how to make that selection is on page 26.



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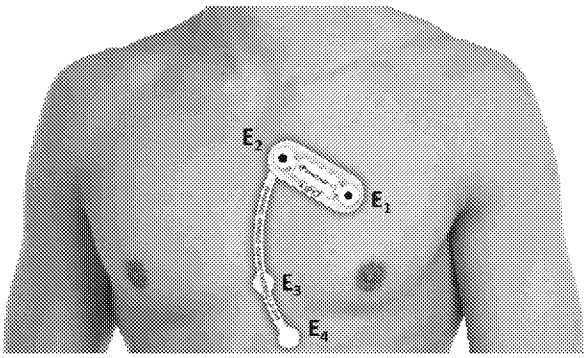
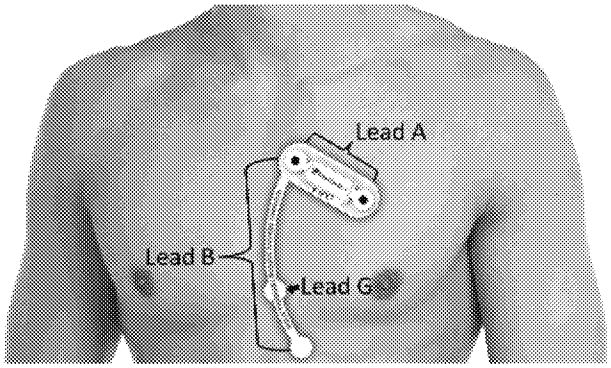
ECG Lead Display

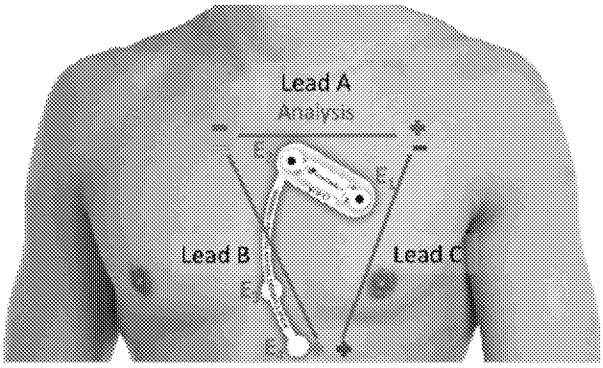
The four electrodes in the *7L Patch* transmit three vectors of ECG.
Seven ECG leads are computed and displayed (Leads A, B, C, D, E, F, G).
NOTE: Analysis is done on Lead A only.



ECG electrode identification



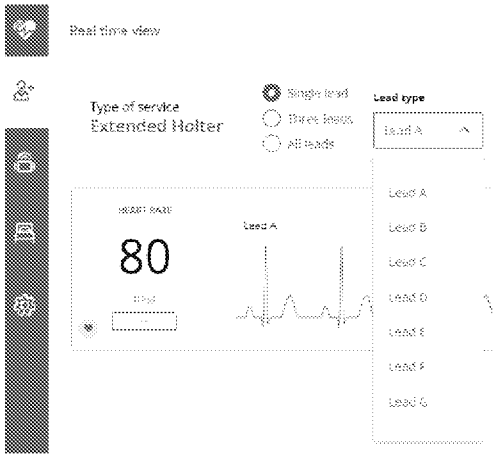
ECG channels transmitted



Polarity of measurements

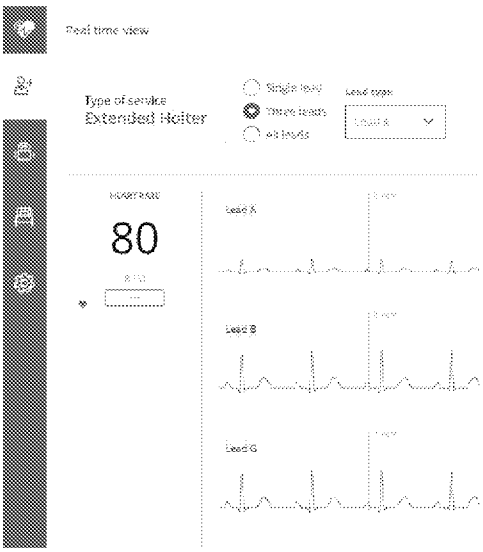
The ECG lead display format options are selected using a radio button. The choices of lead options available to view include:

- Single lead - you can select either A, B, C, D, E, F, or G. Use scroll bar to select all available leads.

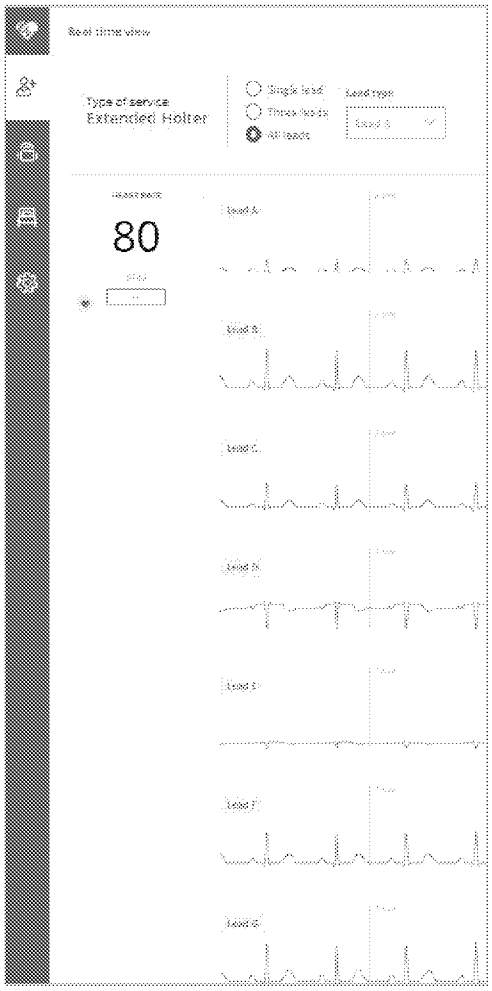


Questions? Contact FDAACDRH/OCE/DHB at CDRH-PolStaff@fda.hhs.gov or 301-796-8118

- Three leads - A, B, and G



- All seven leads - A, B, C, D, E, F, and G (Scroll down on the screen to view all leads)



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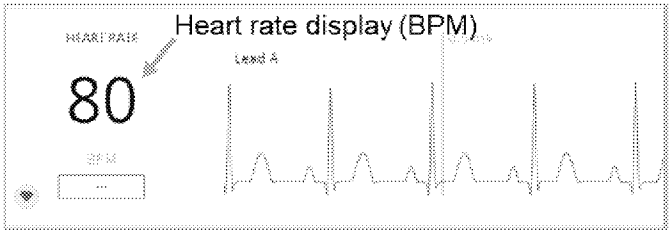
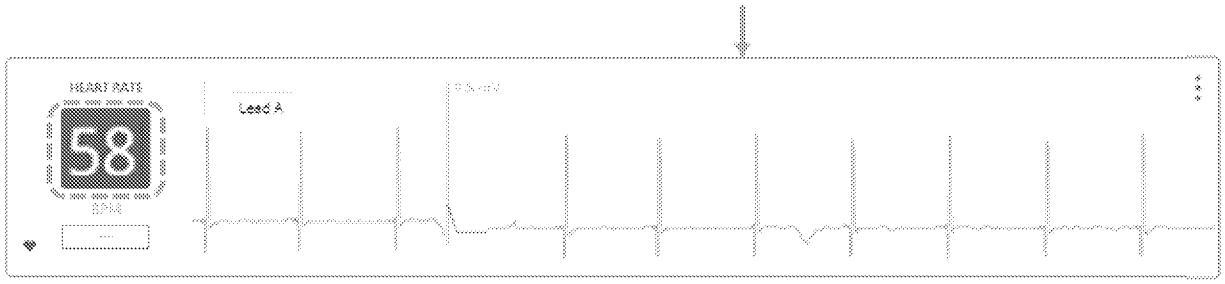
ECG Display

The lower section of the screen shows the real-time ECG. The number of leads and the specific leads selected are displayed.

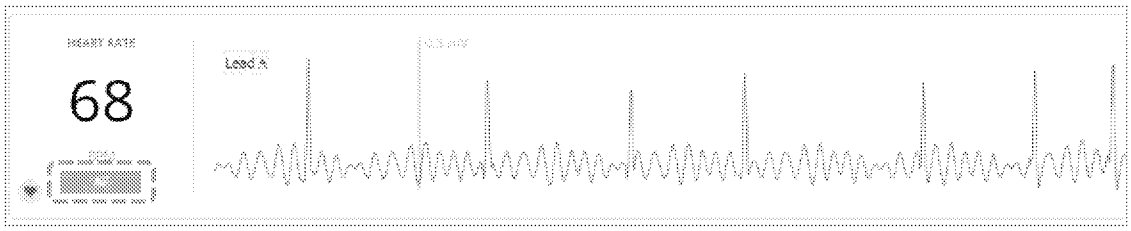
Heart rate (BPM) on the left



When the patient's heart rate is outside the set alarm limits, the patient tile is outlined in red, and the numerical heart rate box is shaded in red, and the high priority audio alarm sounds. In the example below, the patient's heart rate is outside the heart rate alarm limit setting. The patient tile is outlined in red, numerical heart rate display box shaded in red, and the high priority alarm sounds. See Alarms and Alarm Management section page 35 for additional information.

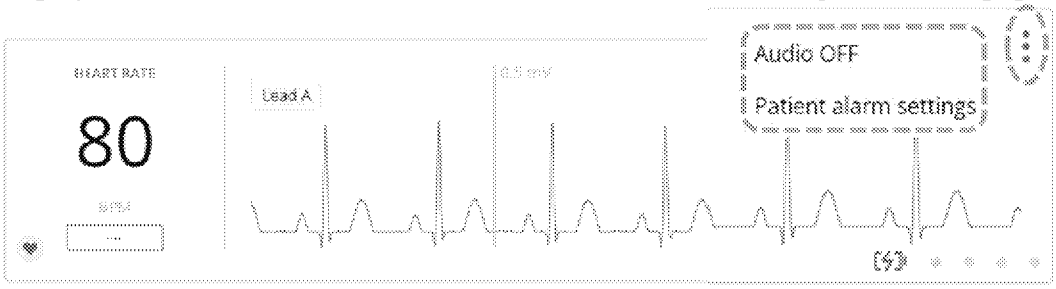


A visual alarm will be displayed in the case of atrial fibrillation. The following real time ECG view is an example of atrial fibrillation.



Navigation using Short Cut

A navigation shortcut using the three dots in the right upper corner of the ECG rhythm strip display selects "Audio OFF/Audio ON" or "Patient alarm settings" from the pop-up box.



Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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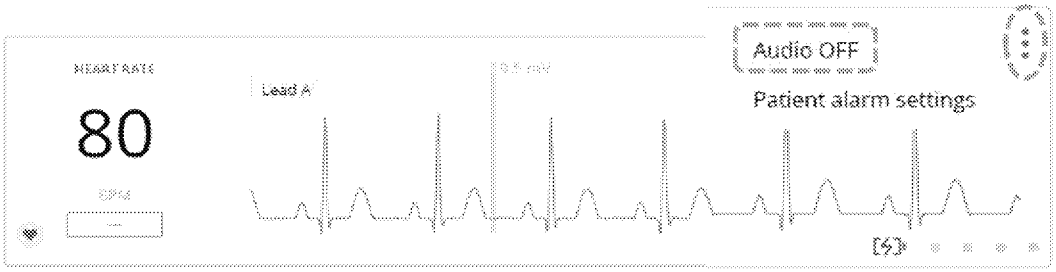
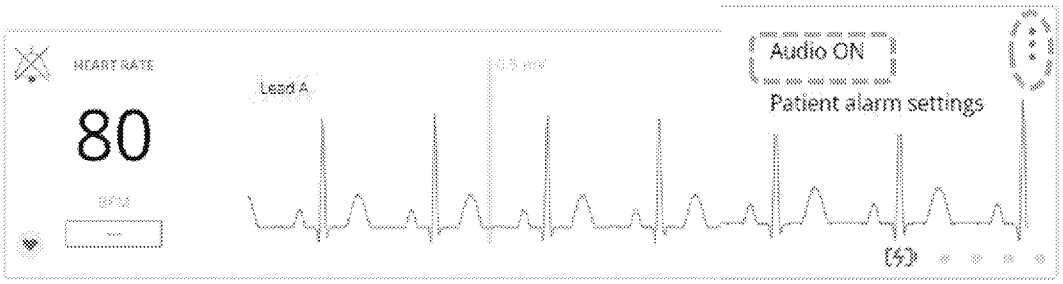
Short cut Audio OFF and Audio ON

In the right upper corner of the ECG rhythm strip display, clicking on the three dots brings up a pop-up box to select the alarm “Audio OFF” or “Audio ON” depending on the current audio alarm setting for the patient. In the strip below, the audio alarm is on and active. Therefore, the only option available to select is “Audio OFF” to turn off all audible alarms for this patient. Selecting “Audio OFF” for the patient, all auditory alarm sounds for that patient are turned off for five minutes



Audio OFF is indicated by a red “crossed bell” in the upper left corner of the patient tile. After five minutes of audio OFF, alarm audio turns ON automatically.



⚠	**WARNING: When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**

The SmartCardia 7L Platform checks the volume setting on the personal computer. If the volume is OFF or on Mute, a message will be shown in the top of the display.

If the volume is too low, the message will read "Low volume detected, please increase the volume of the computer".

Unmute and increase the volume of the computer to ensure auditory alarm signals can be heard.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118

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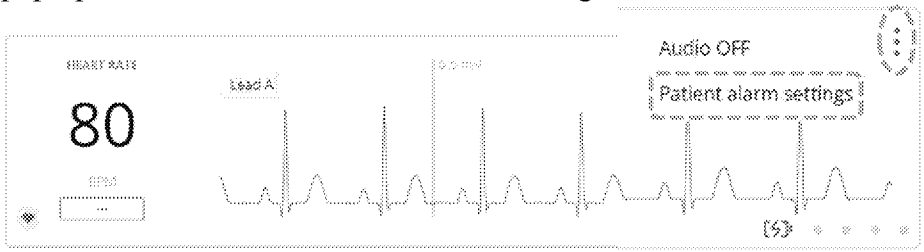
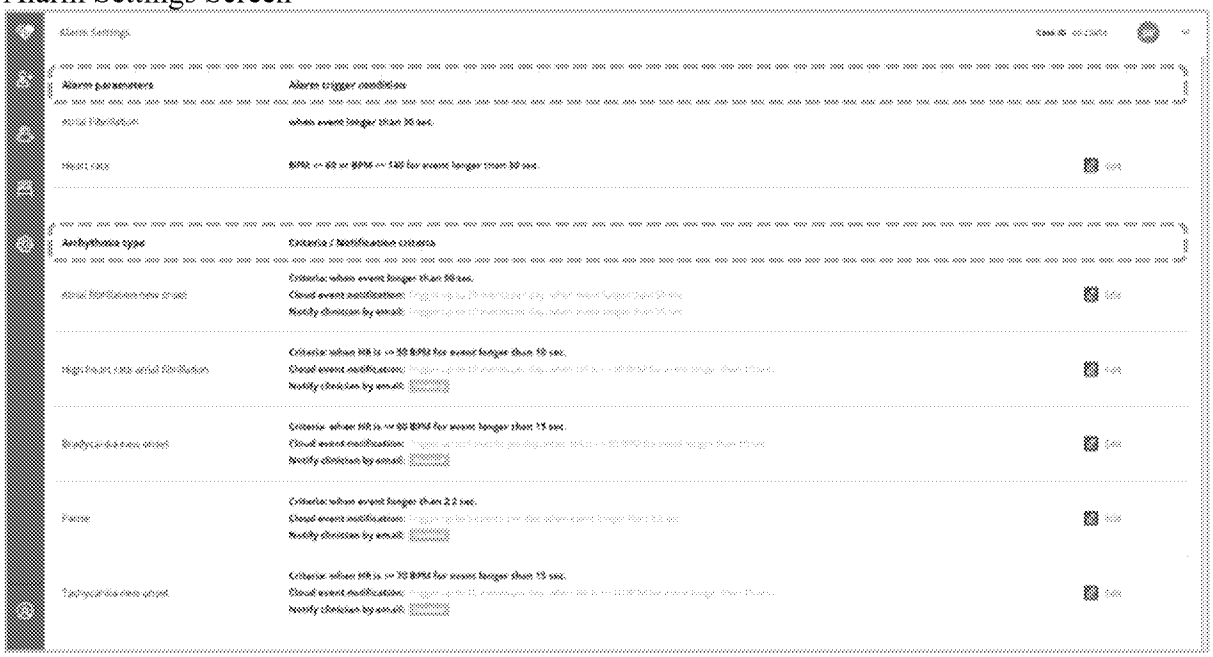
Short Cut to Patient Alarm Settings

In the right upper corner of the ECG rhythm strip display, clicking on the three dots brings up a pop-up box to select the “Patient alarm settings”.



Selecting “Patient alarm settings” takes you to the screen to adjust patient alarm parameters and arrhythmia notifications as shown below.

Alarm Settings Screen



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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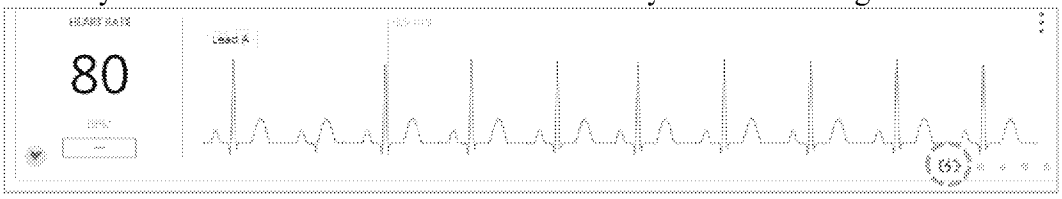
Battery Level Indicator

The device battery level of the *7L Patch / 7L Sensor* (device) worn by the patient is shown in the lower right corner of the ECG rhythm strip display. In the example below, the battery is critically low with 10% or less of the device battery level remaining.



Device battery is fully charged (100%)	
Device battery has 75% remaining	
Device battery has 50% remaining	
Device battery has 25% remaining	
Device battery level is critically low with less than 10% strength remaining	

NOTE: If the patient still needs monitoring, the patient should be contacted regarding direction to attach a new *7L Patch* according to facility protocol.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATTA@fda.hhs.gov or 301-796-8118

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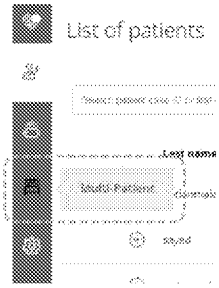
Multi-Patient View

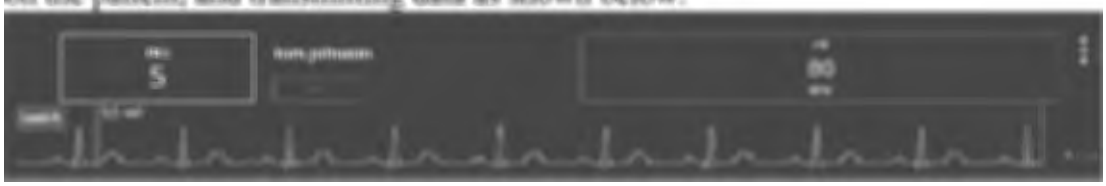
Multiple patient tiles can be viewed at one time. In this view, the clinician can view up to 12 patients at once on a single display screen. The data of many patients can be seen in a more detailed and comprehensive manner, similar to a hospital central monitoring unit. When a new patient is added they are automatically placed in a patient tile.
NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display.



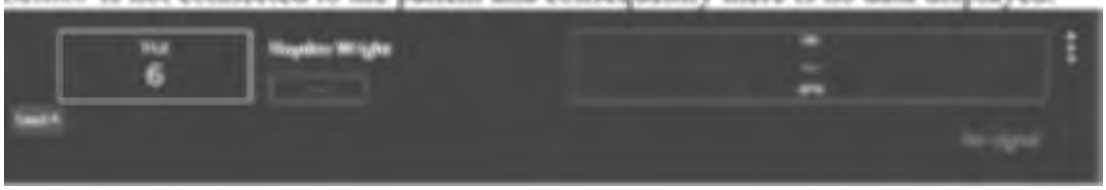
Select "Multi-Patient" on the left navigation menu to view all patients currently assigned to a patient tile.

In the Multi-Patient view, there are three variations of the patient tile screen display.

- The view when a patient is assigned to a patient tile, the *7L Patch* with the *7L Sensor* is on the patient, and transmitting data as shown below.



- This screen display below shows a patient is assigned to the patient tile but the *7L Sensor* is not connected to the patient and consequently there is no data displayed.



- This patient tile does not have a patient assigned.

	WARNING: When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.

Questions? Contact FDA/CDRH/OSEL/DAB at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118
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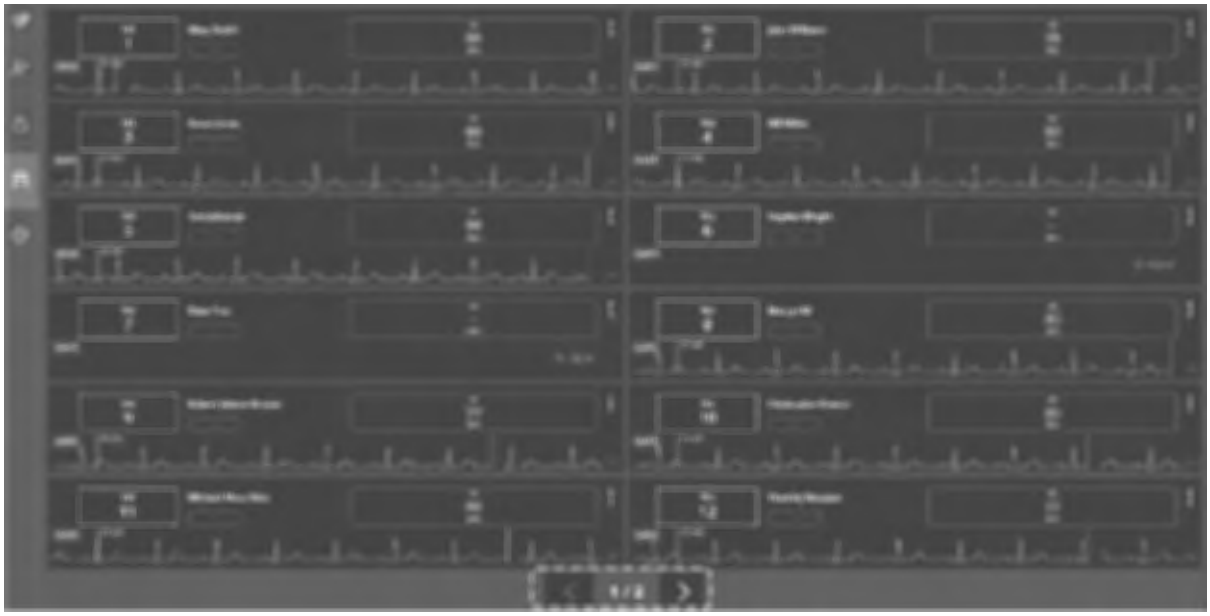
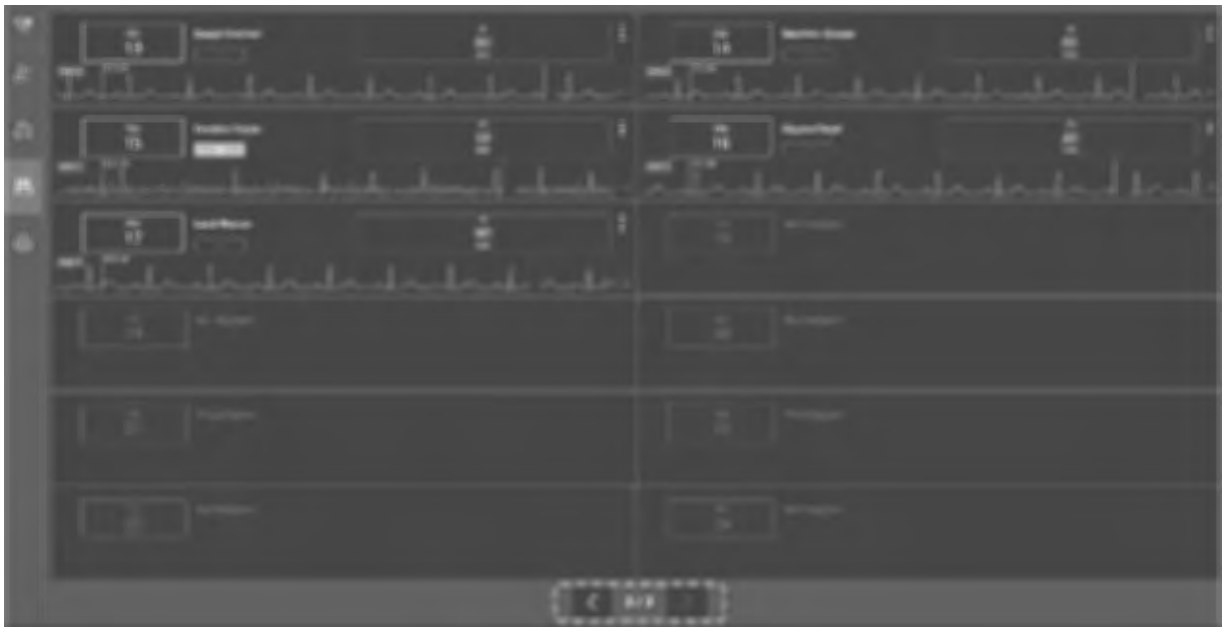
Multi-Patient View- using Multiple Displays

When monitoring more than 12 patients, ensure all patients are viewed at all times by opening another instance of the 7L Web Browser on additional displays.



Multi-Patient View- First instance of 7L Web Browser showing page one.
Display shows patient tiles 1-12



Multi-Patient View- Second instance of 7L Web Browser showing page two.
Display shows patient tiles 13-24

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATTS@fda.hhs.gov or 301-796-8118

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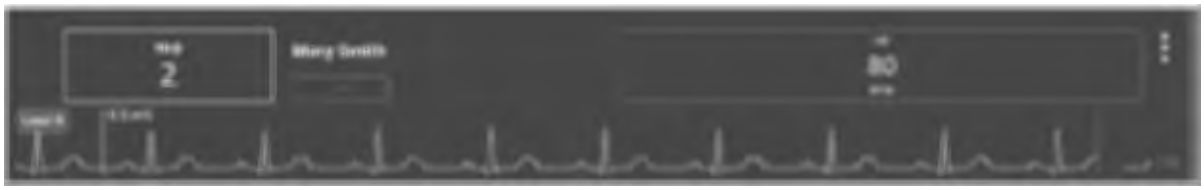
Patient Tile Display

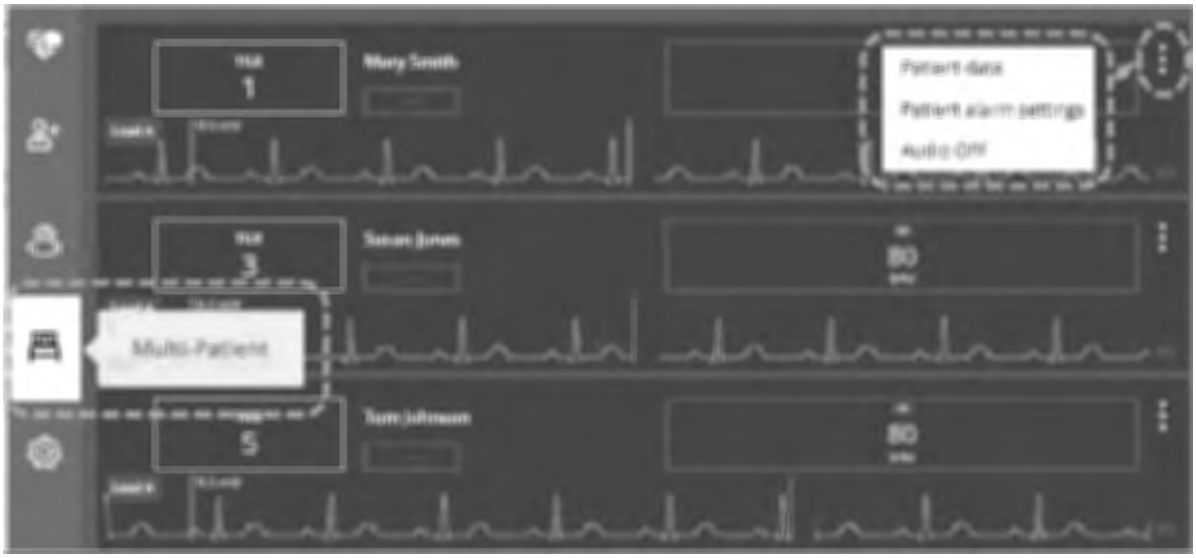
When a patient is assigned to a patient tile and the device is sending information in real time, the following information is displayed:

- Tile number
- Patient first and last name
- ECG signal
- Lead displayed
- Calibration pulse
- Heart rate beats per minute (BPM)



Navigation using Short Cut

There is a navigation shortcut using the three dots in the right upper corner of the patient tile display to select Patient data, Patient alarm settings, or Audio OFF/Audio ON.



Short Cut to Patient Data

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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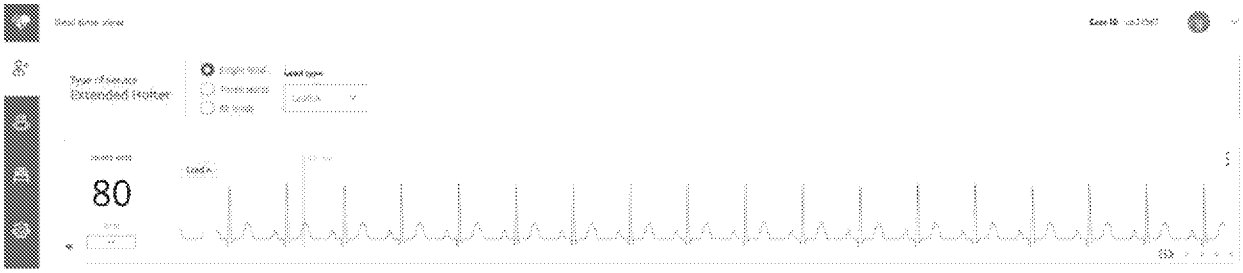
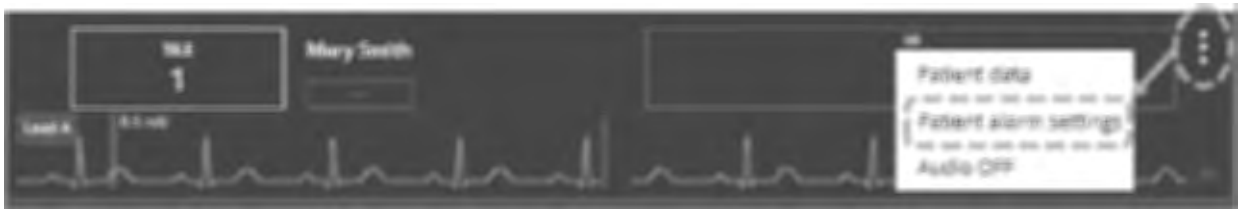
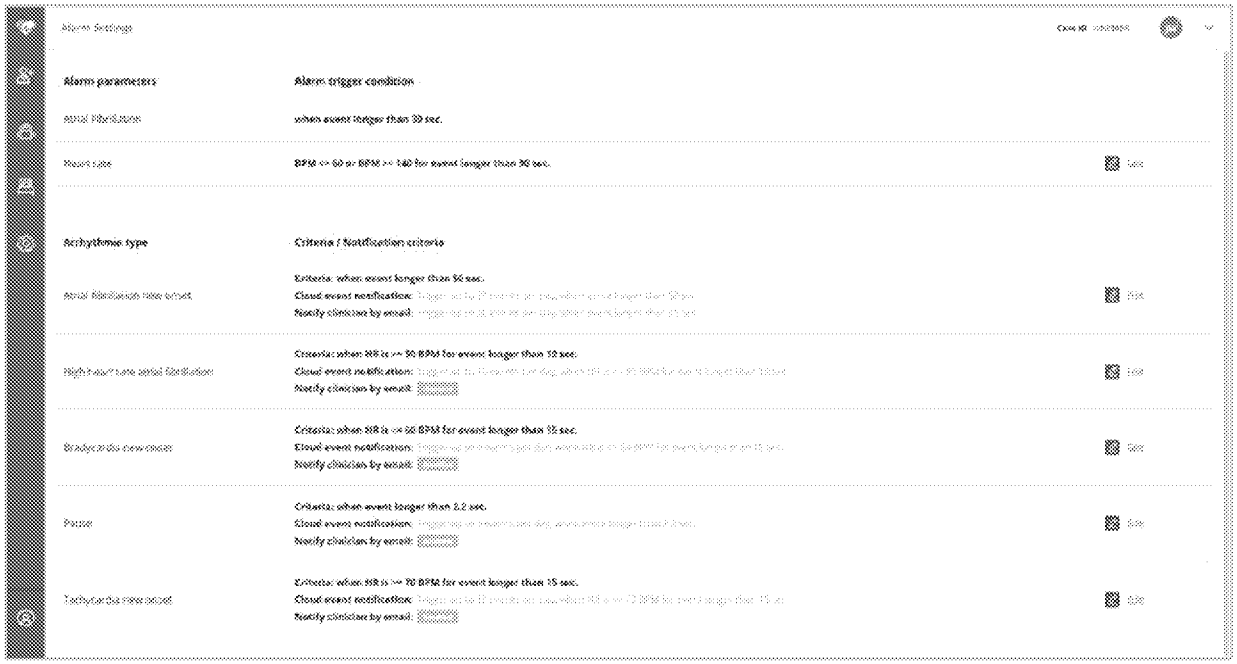
When you select “Patient data” the main patient information window opens displaying their “Real time view” of ECG. See page 43 for detailed information the patient’s real time view screen.



Short Cut to Patient Alarm Settings



Selecting “Patient alarm settings” takes you to Alarm Settings. Patient alarm and arrhythmia conditions and notifications can be adjusted as shown below. See Alarms and Alarm Management section on page 35 and Arrhythmia Event Notifications section on page 38 for additional information.



Questions? Contact FDA/CDRH/OCE/DHT8 at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118
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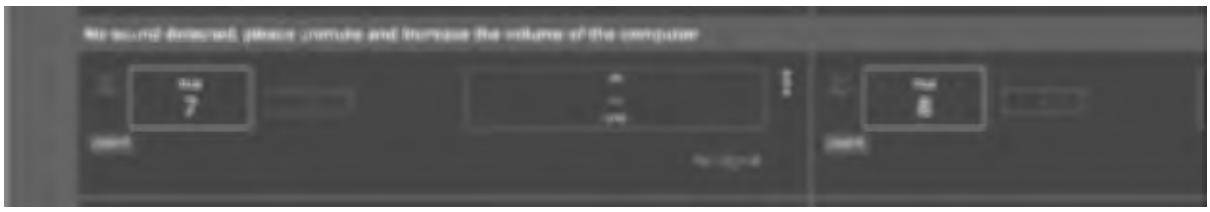
When you select “Audio OFF” all auditory alarm sounds are turned OFF for the selected patient. This is indicated by a red “crossed bell” in the upper left corner of the patient tile.

When Audio OFF is selected, the next time the menu is opened, it will show as Audio ON to turn on the auditory sound for all alarms. See page 49 for additional information.

⚠	**WARNING: When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**

The SmartCardia 7L Platform checks the volume setting on the personal computer. If the volume is OFF or on Mute, a message will be shown in the center of the display.



If the volume is too low, the message will read "Low volume detected, please increase the volume of the computer".

Unmute and increase the volume of the computer to ensure auditory alarm signals can be heard.

Battery Level Indicator

When the battery level of the *7L Patch /7L Sensor* worn by the patient has less than 10% charge remaining the battery icon is shown in red on the lower right side of the patient tile. If the patient still needs monitoring, the patient should be contacted regarding direction to attach a new *7L Patch* according to facility protocol.

Questions? Contact FDA/CDRH/OCE/DHT9 at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118
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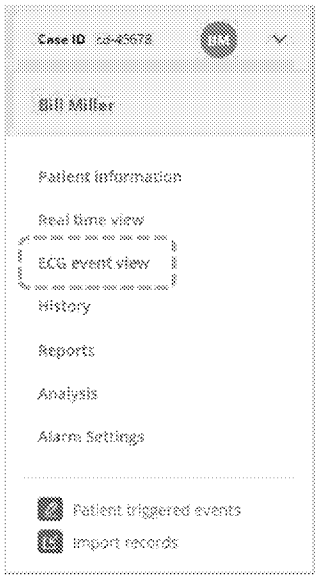
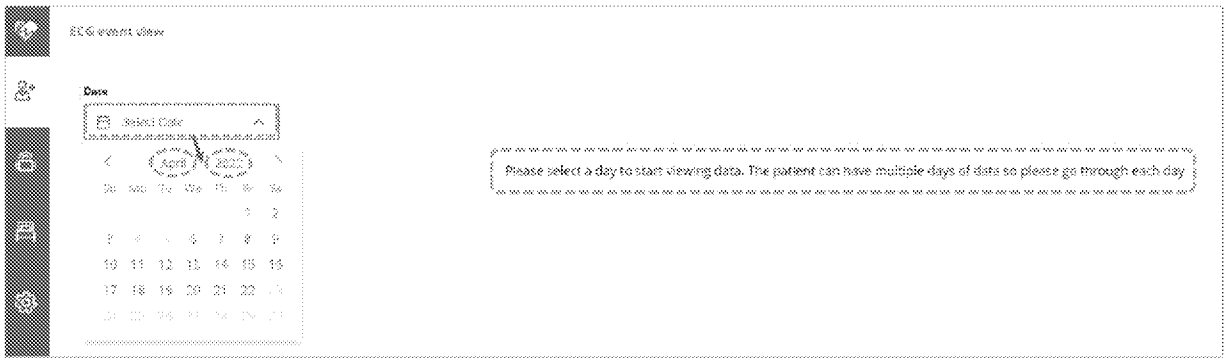
ECG Event View

On the patient page, select “ECG event view” on the expanded menu on the upper right side of the screen.



A screen will open to the calendar in the upper left corner and the message to select a day to start viewing data as shown below. The days where data is available are marked in black text, days when data is not available is grey text, and the current date is bold text. Use the calendar to enter the date to start viewing the data (to enter the year, select the year displayed then scroll to the one desired and select it. To enter the month, select the month displayed, then scroll to the appropriate one and select it.)



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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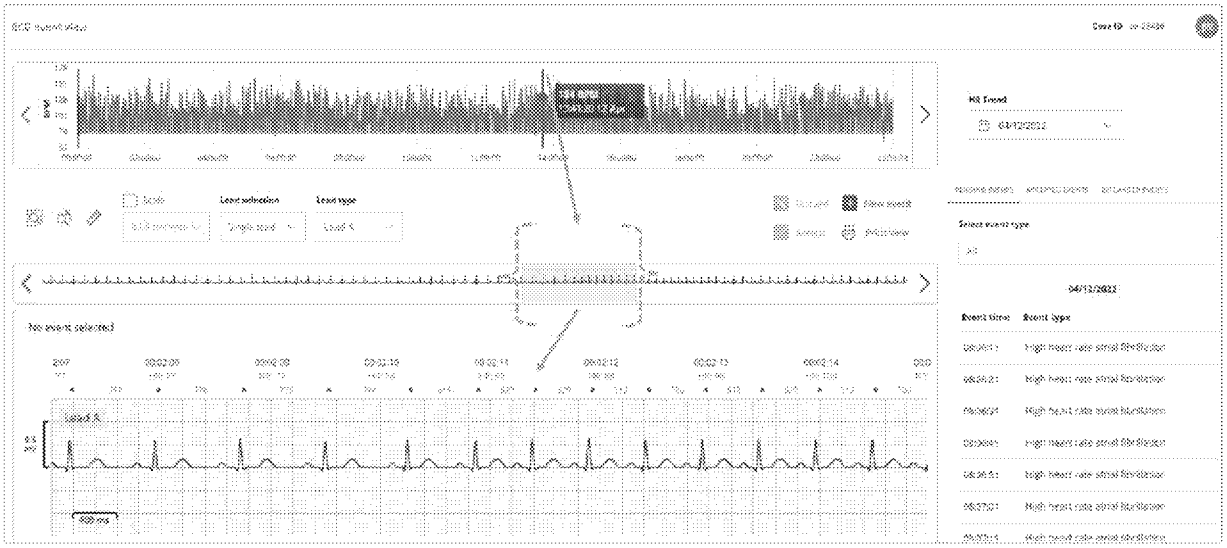
If there is available data, an image is shown as below.

Heart Rate Trend Display

At the top of the screen, there is a display of the heart rate trend shown over a 24-hour period. Clicking on any point in time there is data will show that selected section in the full disclosure bar display below and the rhythm strip from that point in time selected is also shown. The arrow keys on each side of the summary and full disclosure display provide scrolling backward or forward in time.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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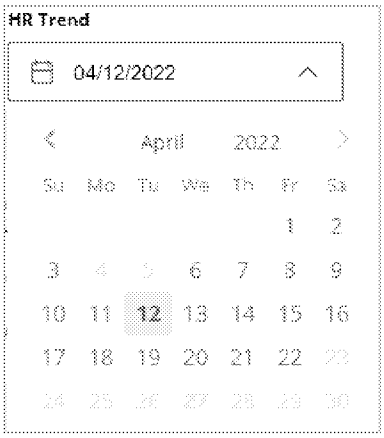
In this view with the data displayed, the calendar is in the upper right side of the screen. When the date box is clicked, a calendar appears. The days where data is available are marked in black text, days when data is not available is grey text, and the date currently being viewed is shaded in blue.



Review of Rhythm Strip

The tools below the HR Trend graph can be used to review and analyze the selected rhythm strip.

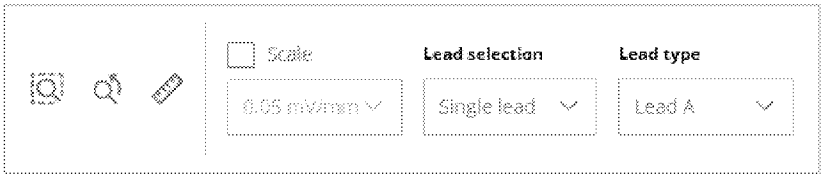
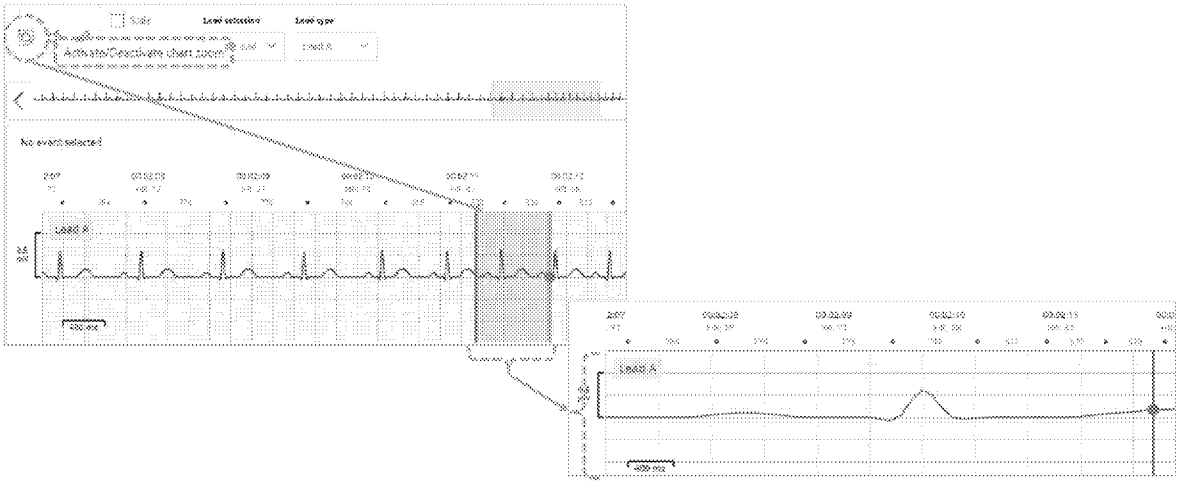


Chart Zoom

When Activate/Deactivate chart zoom is selected the icon turns red showing the tool is ready to use. On the rhythm strip, use a left mouse click at the beginning of the segment to enlarge and drag it over the area then left click to end. The zoomed in segment will display so that visual inspection can take place.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTAFF2@fda.hhs.gov or 301-796-8118

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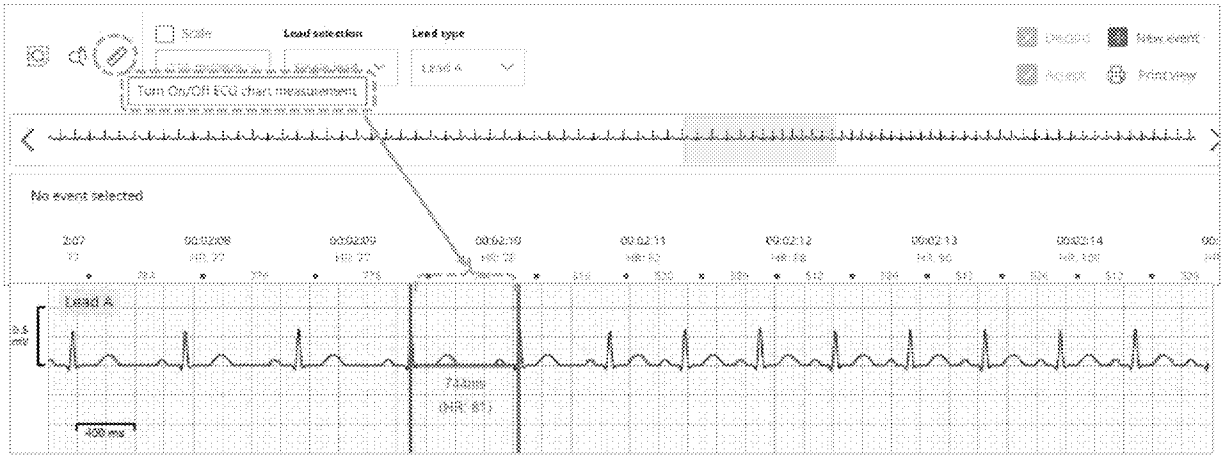
To return to the normal view, select the activate/deactivate chart zoom button again or select the restore chart zoom button.

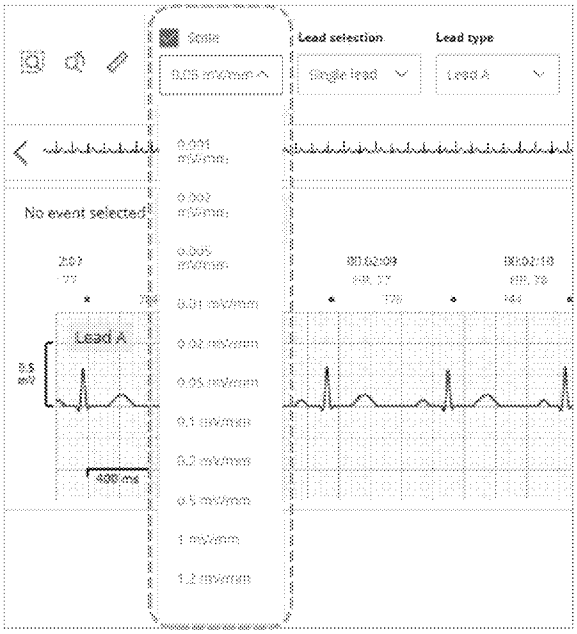
Measure



Heart rate can only be measured over one R-R interval. If you move the calipers to two R-R intervals, the heart rate will be one-half the actual rate.

Scale

The scale of each ECG graph is measured in millivolts per millimeter on the Y-axis. It is calculated automatically, but it can be changed by selecting the “Scale” box then choose the desired setting.



Questions? Contact FDA/CDRH/OHT5/DHP at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118

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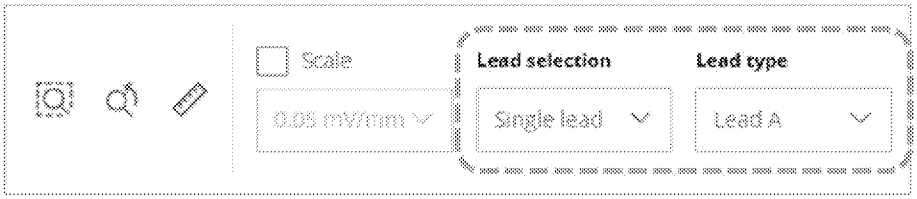
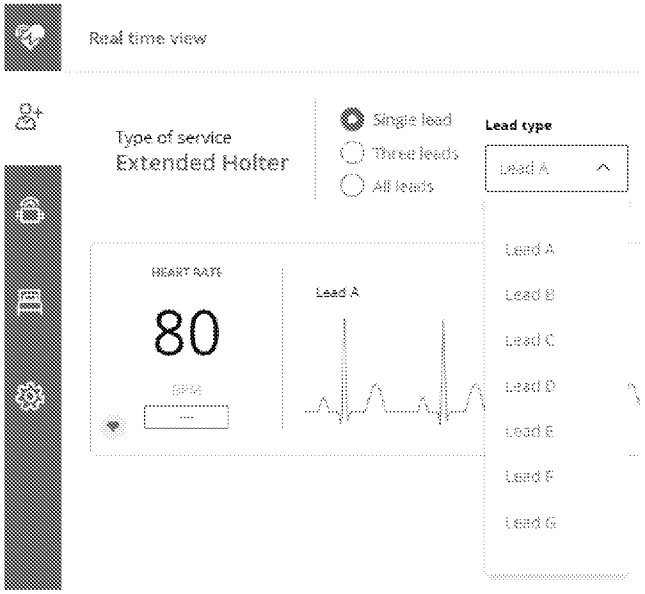
ECG Lead Display

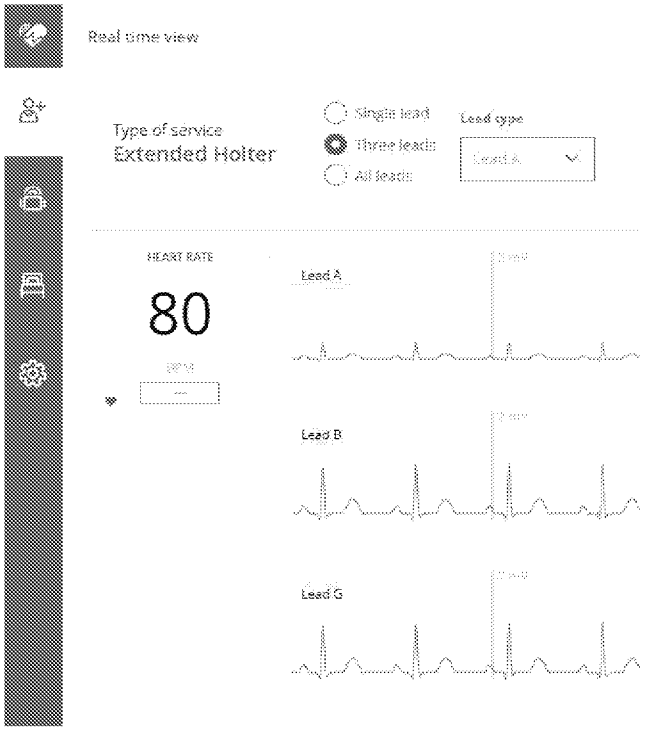
The ECG lead display format options are selected using a radio button.



- Single lead - you can select either A, B, C, D, E, F, or G



- Three leads -A, B, and G



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118

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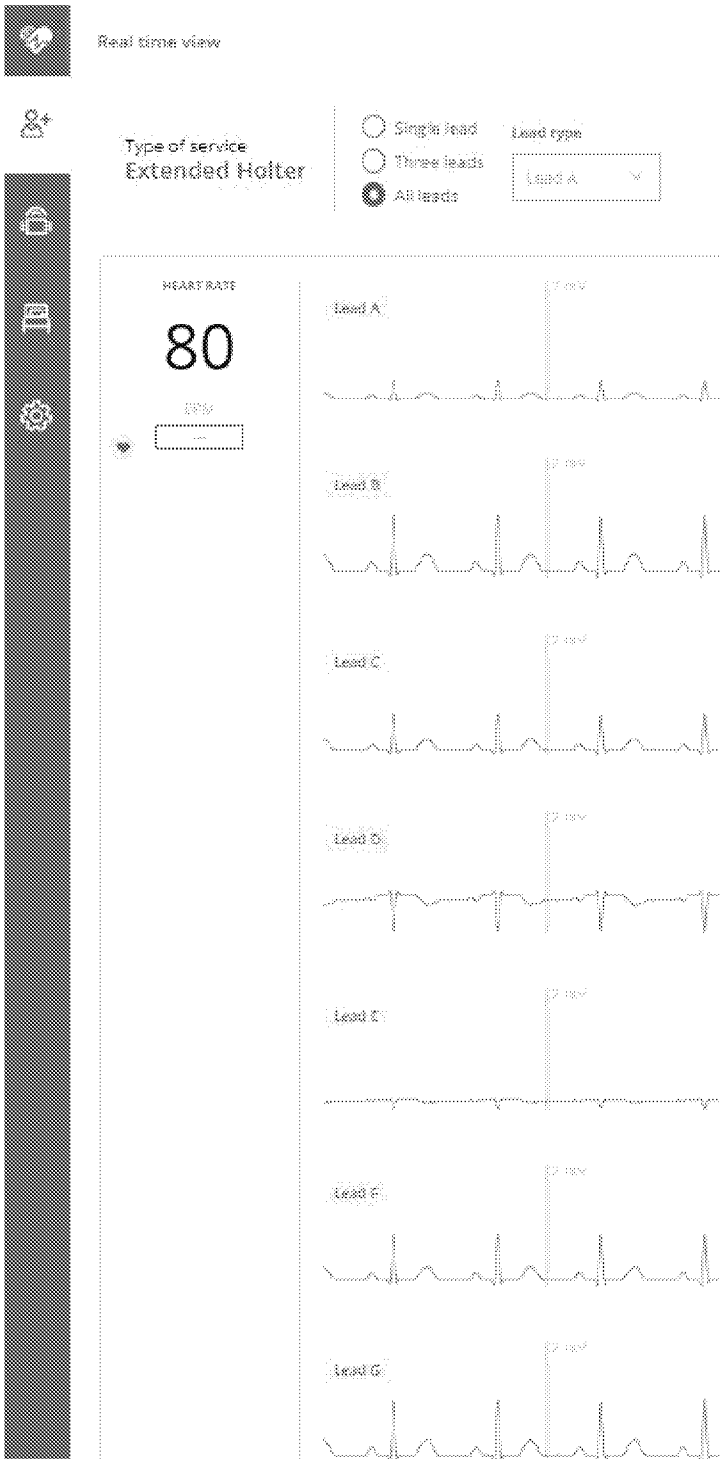
- All seven leads - A, B, C, D, E, F, and G (Scroll down on the screen to view all leads)



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118

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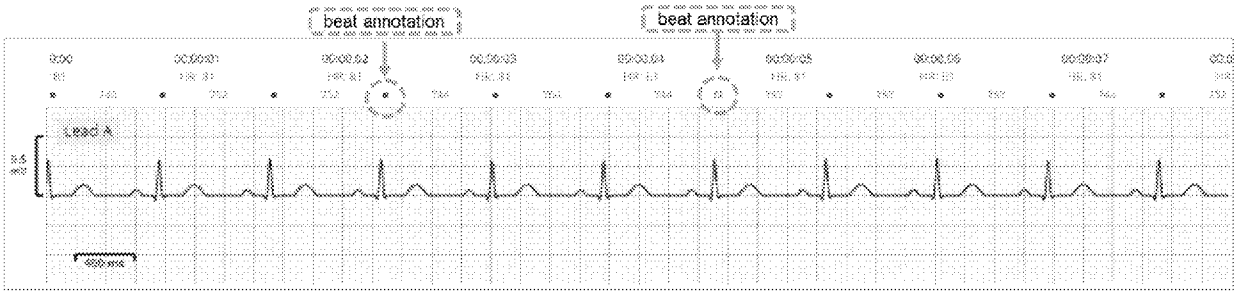
Beat Identification

The beat annotation is displayed as " ● " when a beat is detected by the 7L Sensor. Once Analysis processing is completed by the analysis service, beat types N, V, and SV are automatically detected by the analysis tool and labeled on the ECG. If the user wants to indicate the presence of a heartbeat that was not previously located, this new heartbeat must belong to one class. If the class cannot be determined, but the presence of the heartbeat must be explicitly indicated, the user can use the 'Indeterminate' class, which describes the beats that cannot be labeled clearly. The following table shows the list of heartbeats that can be marked on the ECG graph.

Label	Description	Definition
?	Unknown beat type	Clinician must always indicate a label classification Automatic annotation by SmartCardia analysis tool
N	Normal shape beat	Normal beat Automatic annotation by SmartCardia analysis tool
V	Ventricular Extrasystole	QRS complex arising from an ectopic focus in the ventricles of abnormal shape and duration. Also used to mark premature ventricular contractions (PVCs) Automatic annotation by SmartCardia analysis tool
SV	Supraventricular Extrasystole	Premature contraction arising from an ectopic focus above the bundle branches (includes the SA node, atria, and AV junction) Automatic annotation by SmartCardia analysis tool
I	Indeterminate Single Beat	Abnormal beat that cannot be identified

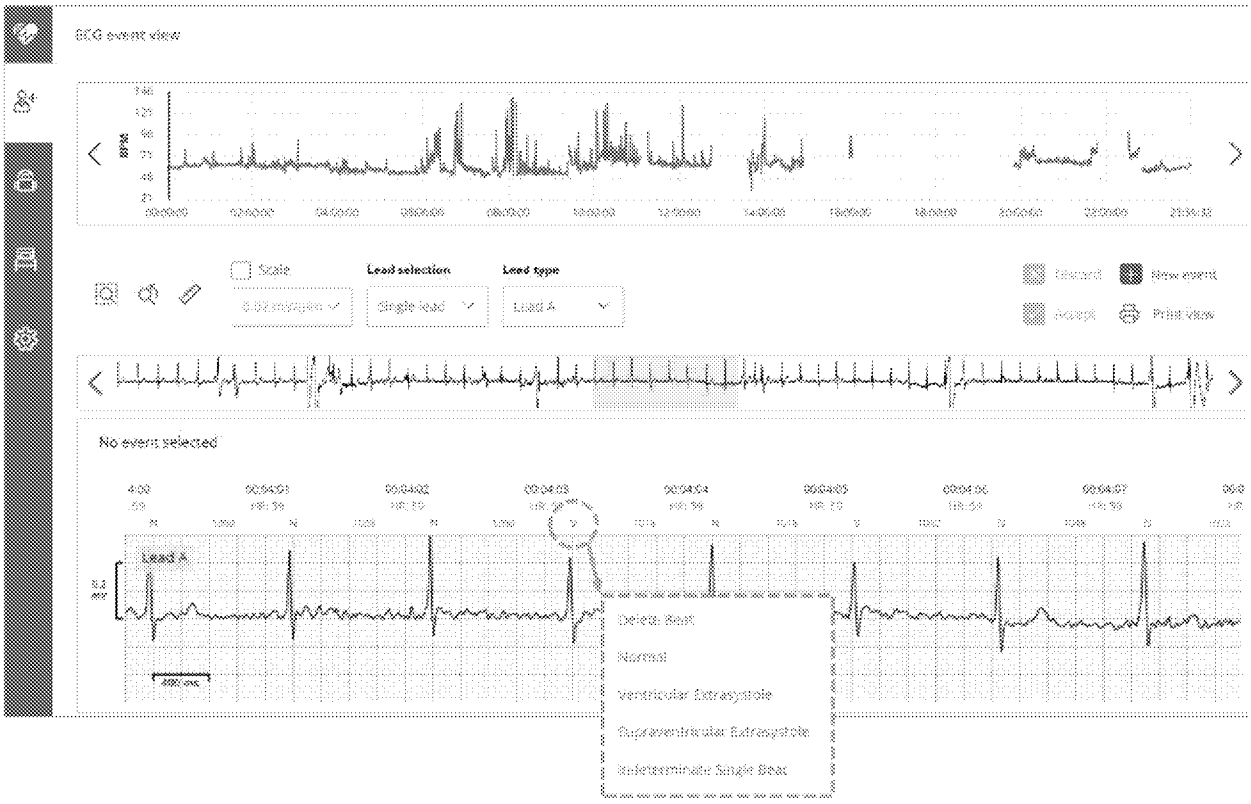
Beat Annotation

In one lead, three leads, and seven lead ECG views, the annotation for each beat is located at the top of the ECG graph. The annotation is either a letter label such as ?, N, V, SV, I, or " ● ".

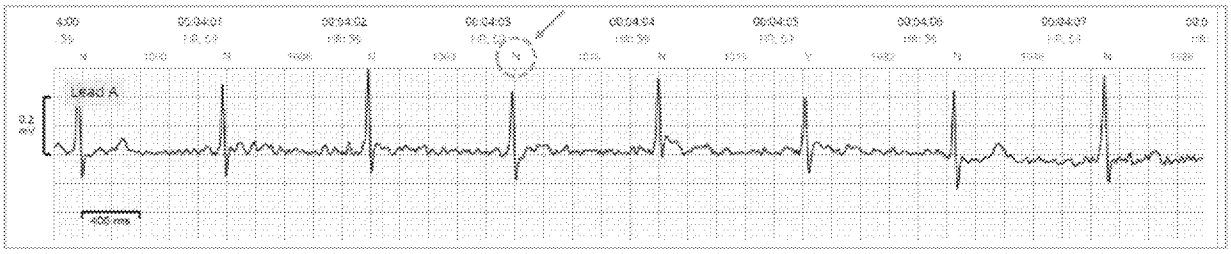


Clicking the mouse on any annotation brings up a pop-up box to delete or change the annotation for that beat. Choices include Delete Beat, Normal (N), Ventricular Extrasystole (V), Supraventricular Extrasystole (SV), and Indeterminate Single Beat (I).

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118



Once the new annotation is selected it replaces the one that was previously shown.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATHB@fda.hhs.gov or 301-796-8118

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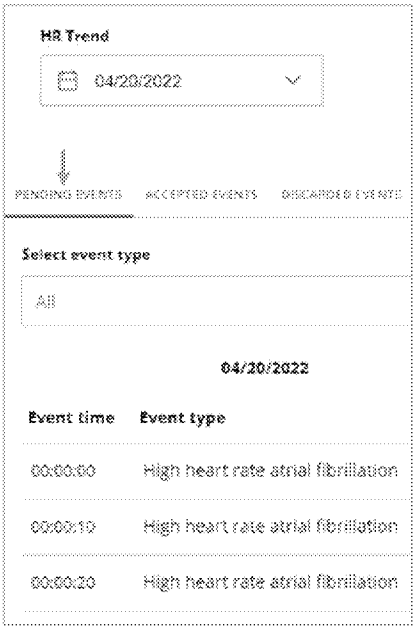
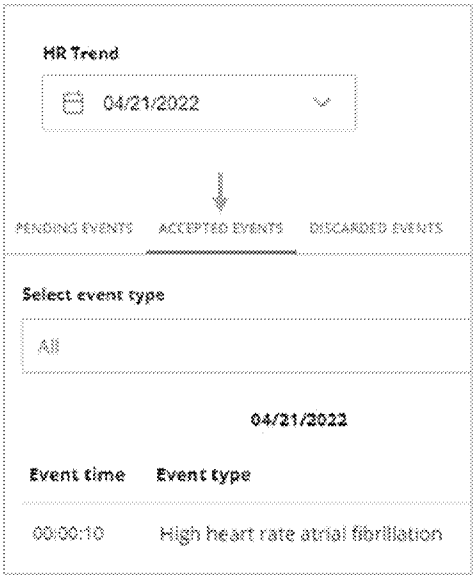
List of ECG Events

On the right-hand side of the screen is the list of events. The event date, time, and type of event are listed. There are tabs to view PENDING EVENTS, ACCEPTED EVENTS, and DISGARDED EVENTS. Select each one to view the respective list of events. Click on the box below “Select event type” to bring up the drop-down list of various arrhythmia events to filter the events listed.

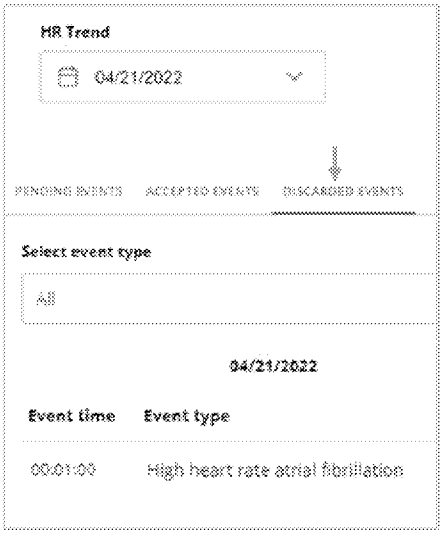
PENDING EVENTS



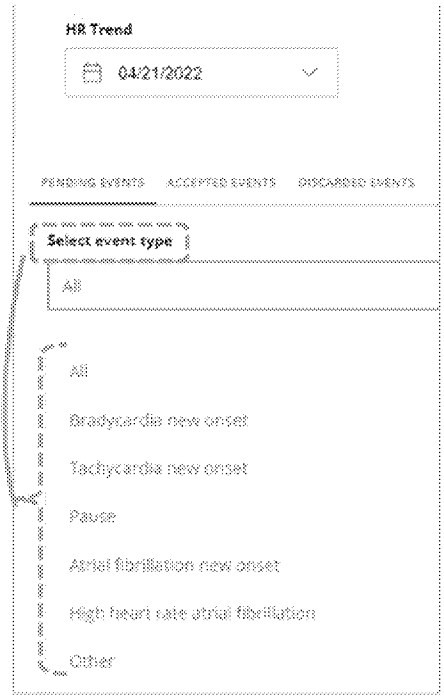
ACCEPTED EVENTS



DISCARDED EVENTS



Select event type to view



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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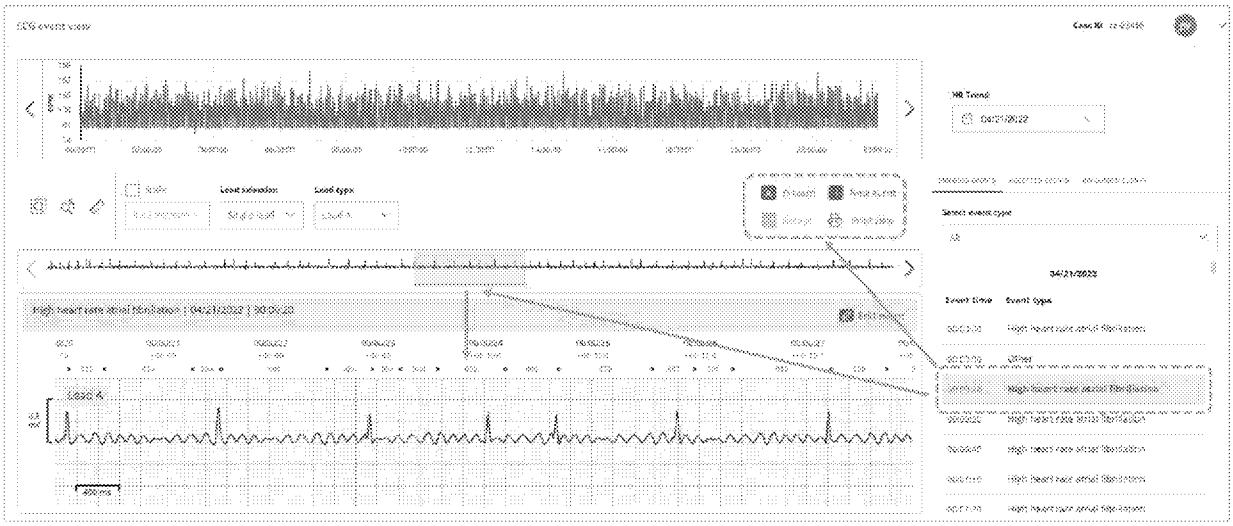
Select the event to review, analyze, and change any annotated beats. The event selected is shaded in blue. Notice the red line under the selected segment in the full disclosure bar indicating this is a listed event.



When an event first occurs, it is pending. After review of the event, it is either accepted or discarded by selecting the appropriate button.

In the following list of events, the red bell indicates that the clinician was notified of that event by email.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118

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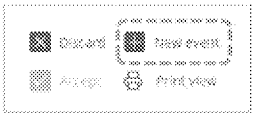
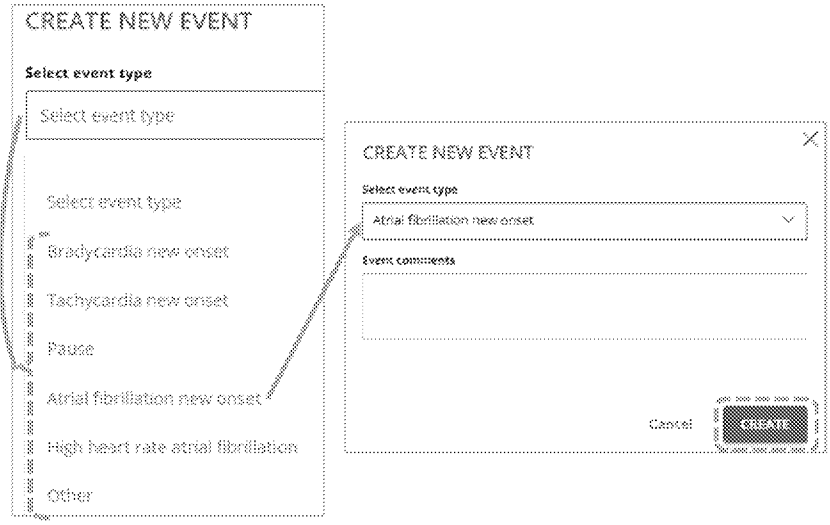
Create New Event

To document a new ECG event, select the “New event”.

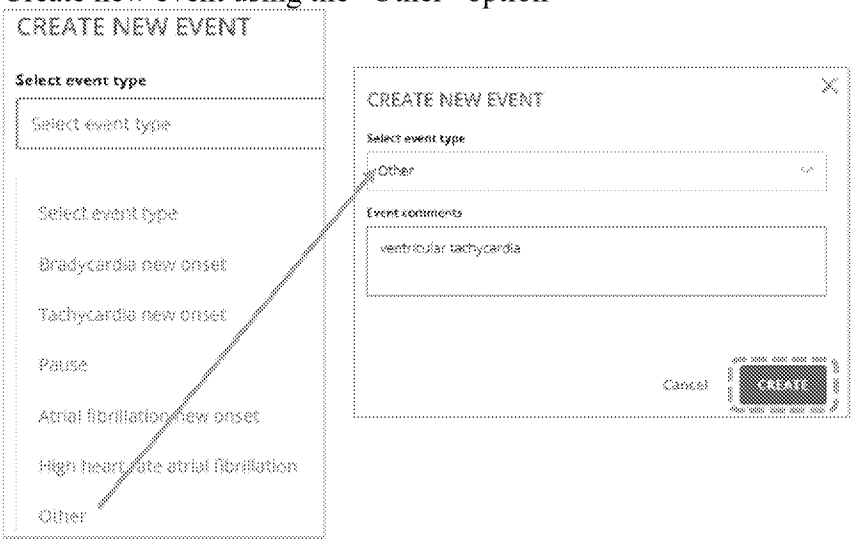


Select event type from drop-down menu and add any comments, then select “CREATE”. This new event will be listed under PENDING EVENTS. It can be reviewed and analyzed then either accepted or discarded.

Create new event from list of arrhythmia types



Create new event using the “Other” option



Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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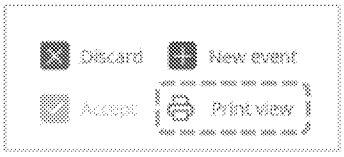
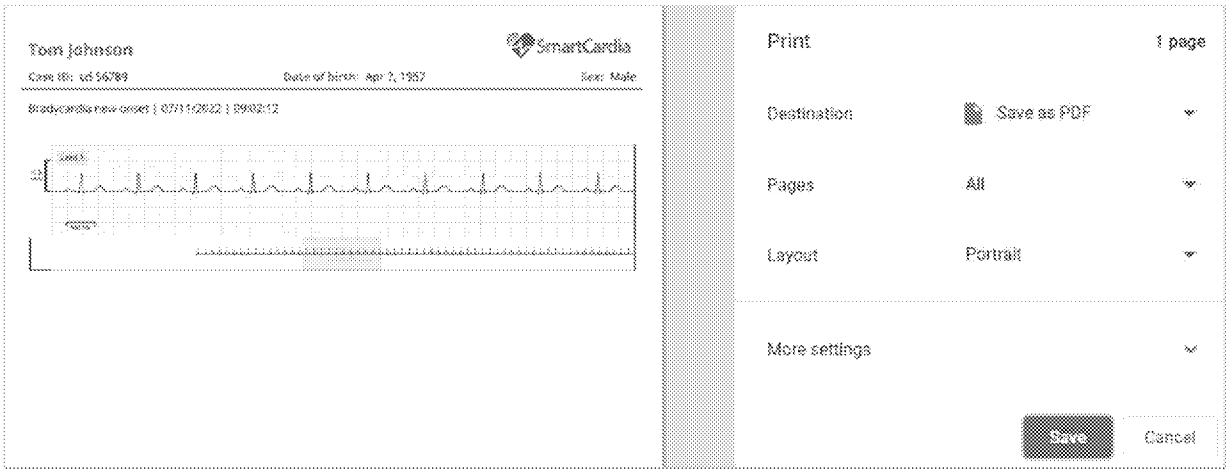
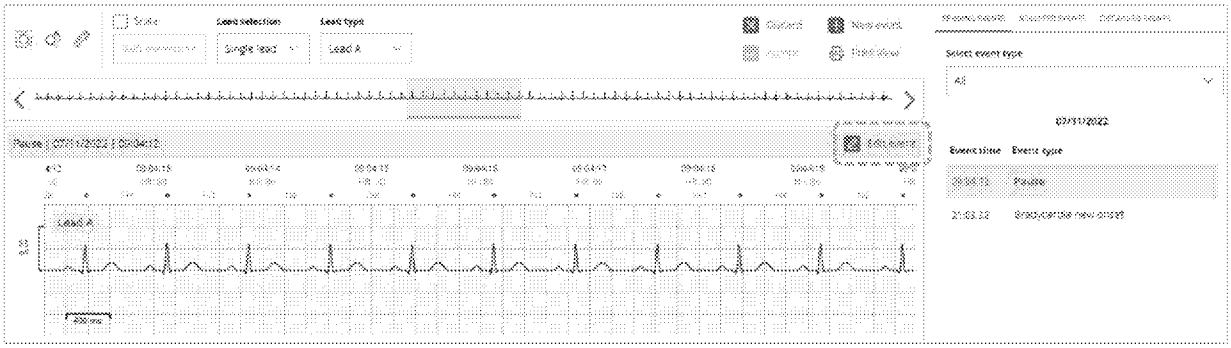
Print View

Print view can be selected and print the copy or cancel print

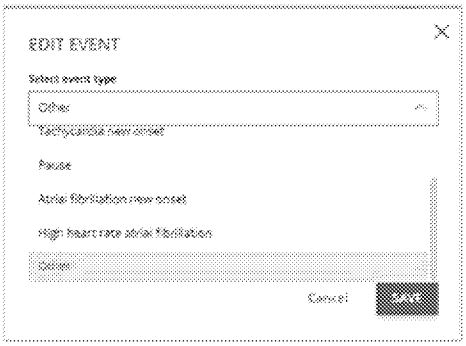


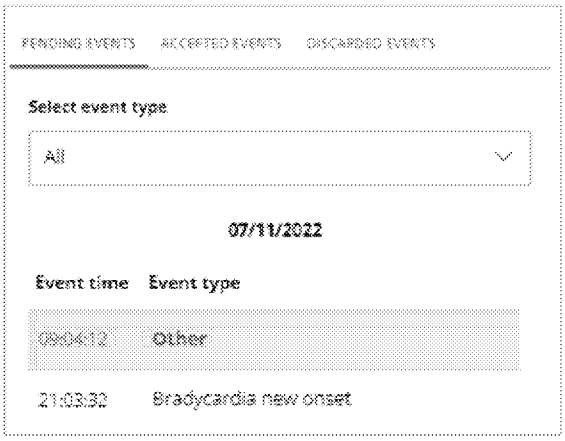


Edit Event



Select Edit event, choose the event type, and SAVE to complete the edit.





Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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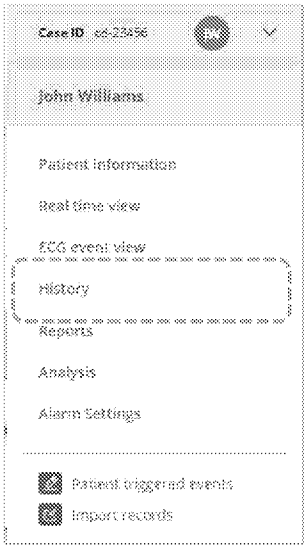
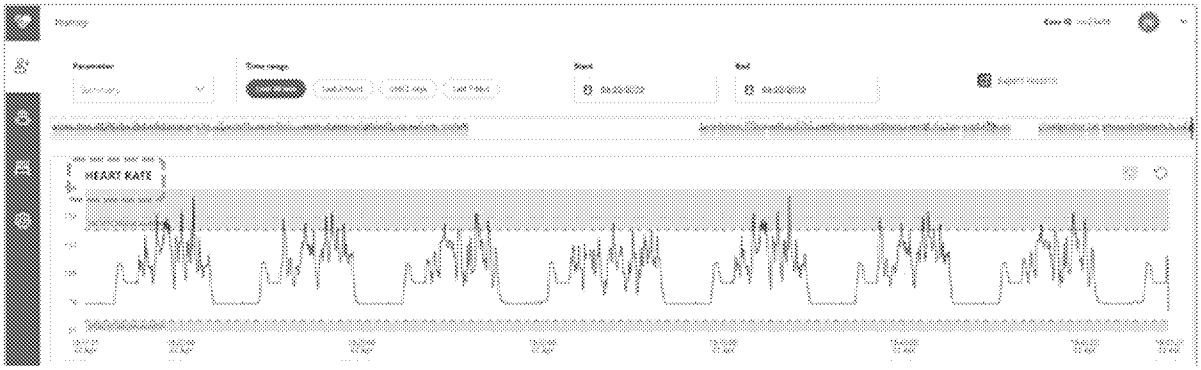
History

On the patient page, select “History” on the expanded menu on the upper right side of the screen.



The summary view displays heart rate when data is available.



Parameter and time range are two sections in the header at the top of the screen. In addition, the start and end date to review can be selected.

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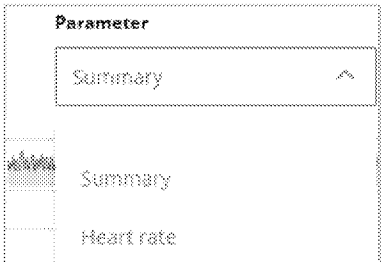
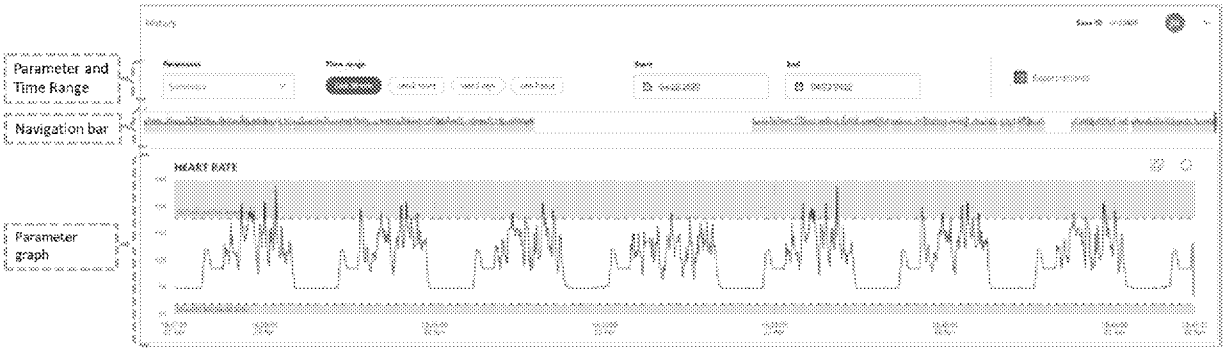
Parameter

At the top of the list is the summary option which displays heart rate graphs all in one view. Selecting the parameter box provides the option to view only the heart rate graph.



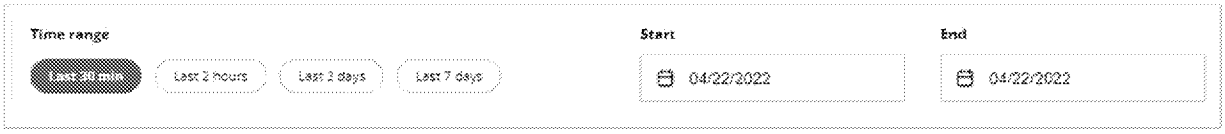
The summary and parameter page contains three elements:

- Header with the sections of parameter, time range, start and end date
- Navigation bar that displays the time of data
- Parameter graph



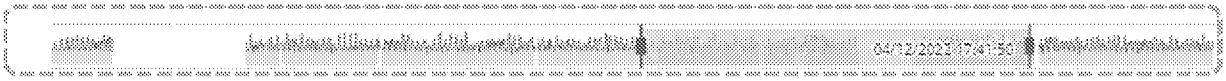
Time Range

In the time range section, data can be displayed for the last 30 minutes, 2 hours, 2 days, or 7 days. The calendar can also be used to select the start and the end dates of the data to display.



Navigation Bar

The bar shown just below symbolizes the graph of heart rate values in the period of the patient's stored data. The section appears blank if there is no data and shaded in gray when there is data. Sliding the blue bars can adjust the time of the data displayed.



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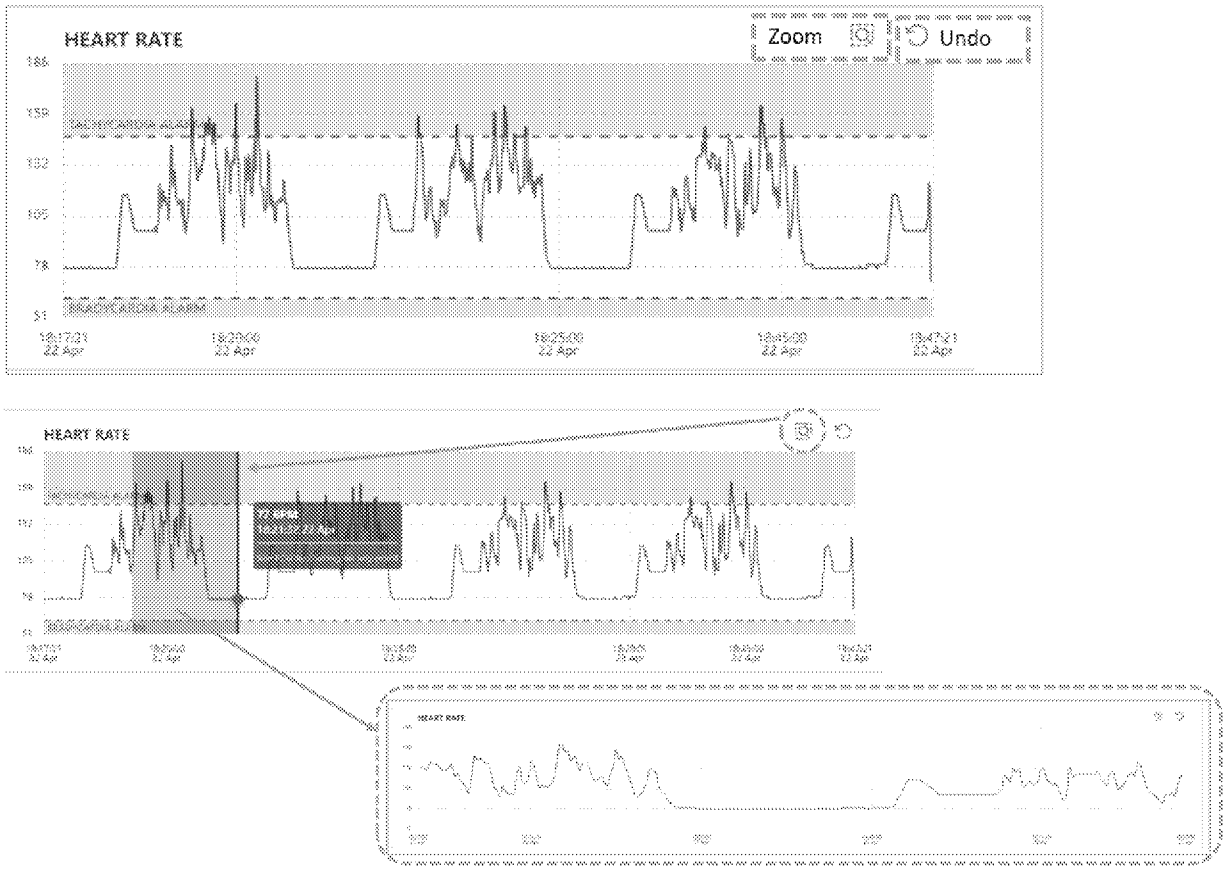
Parameter Graph

The summary view includes a parameter graph of the heart rate graph all in one view. In the graph, the x-axis shows the dates, and the y-axis shows the units of the parameter. If there is no data, the graph is blank. When data is available and inside the set limits, it is displayed in gray and data outside of the set limits is red. The threshold limits for the parameter are marked in the graph.

Chart Zoom

The parameter graph has the same format with the tools to review the graph in detail at the top right corner (Zoom, Undo, and Restore). The user can zoom in on an area of interest by activating the "Zoom" function (icon turns from grey to blue). Once it is active mark a point on the graph and drag it to the desired place. The undo function returns to the original time.



In the history summary, the graph displays a line, when the user moves the mouse over it, the line indicates the point of time in the plot. Moreover, if the user clicks in the plot, a pop-up window appears where the user can see 30 seconds of ECG centered at the click point.

When the user passes the mouse over the graph, the following information is observed:

- Heart rate
- Time and date

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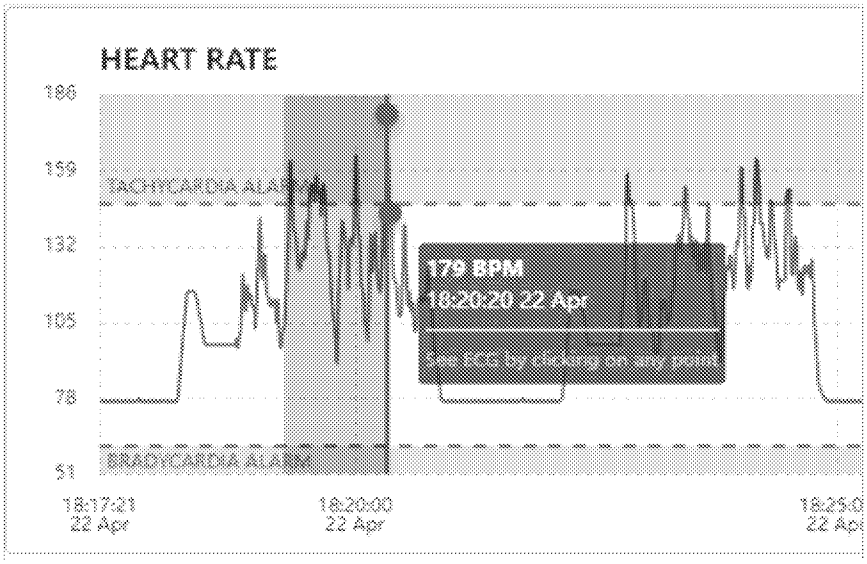
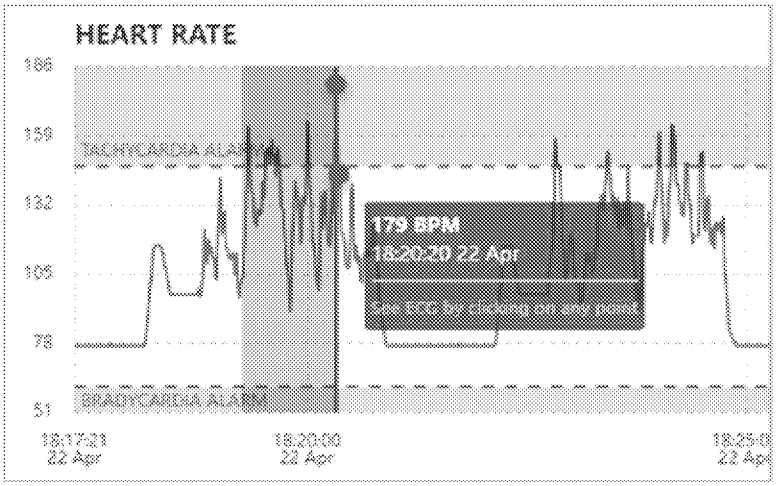
The heart rate graph is displayed in beats per minute (BPM). The red dotted line indicates the thresholds for tachycardia and bradycardia, respectively. The area above is shaded in red, indicating tachycardia alarm. Similarly, the area below is shaded in red indicating bradycardia. When the mouse is moved over the graph, the information box displays the heart rate value at that time with the date and time listed.



Clicking on one of the blue circles in the graph or on the bar line in the picture below, brings up the ECG graph observed at that precise moment and is displayed in the following picture below the summary graph.



The blue line in the middle of the rhythm strip indicates the exact time selected on the parameter graph. Selecting the arrows on either side of the displayed rhythm move forward or backward in time to review the ECG data.

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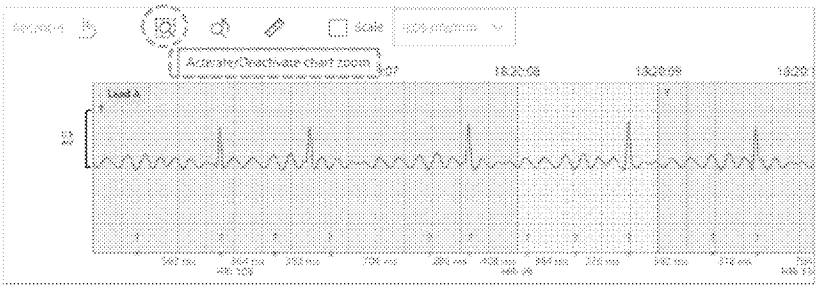
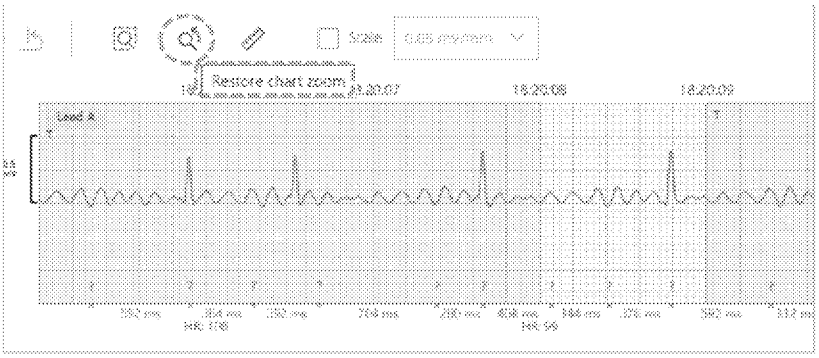
The yellow shading indicates an alarm condition is present. When two or more alarm conditions occur, the yellow shading is darker. The section at the end of the strip that is not highlighted indicates the ECG is within set thresholds and no alarm occurred.

The following functions found in the upper left corner are available to review the ECG rhythm strip:

- Activate/deactivate chart zoom



- Restore chart zoom



Questions? Contact FDAACDRHOCE@fda.hhs.gov or 301-796-8118
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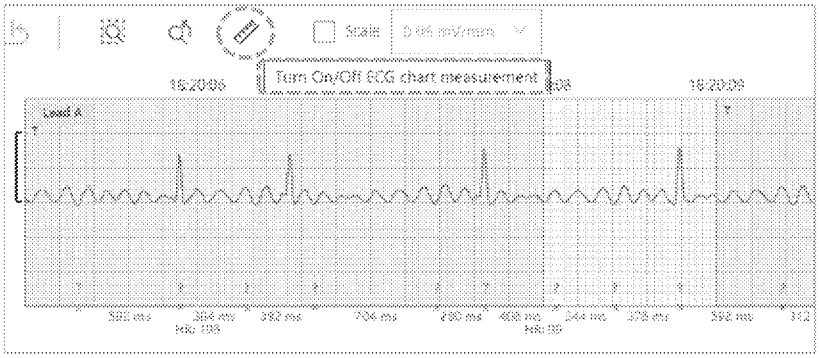
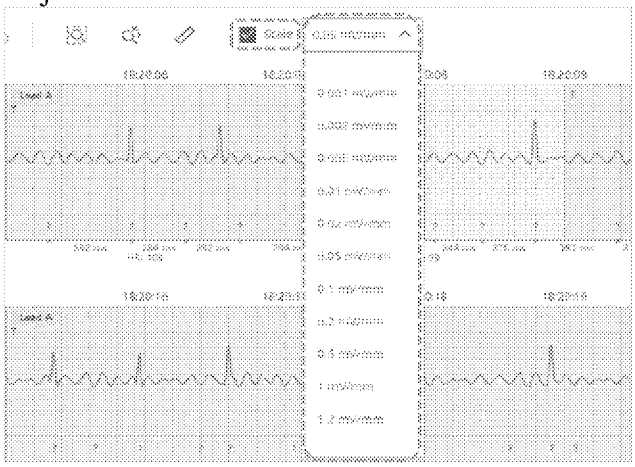
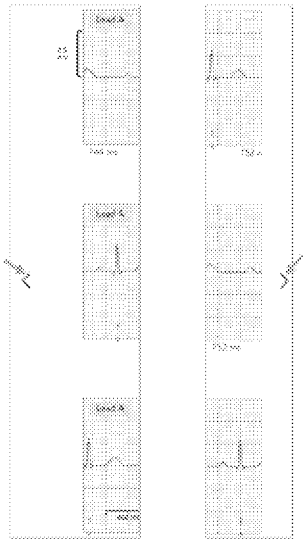
- Turn on/off ECG chart measurement



- Adjust scale as needed



To view more data scroll through the ECG using the arrow keys.



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118
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The “Recentre” (Recenter) button in the upper left corner can be used to return instantly where previously clicked.

At the top left corner of the rhythm strip the rhythm is identified with AFIB or an initial for the rhythm type.

Rhythm Types

The following chart lists the rhythm labels, description, and any related notes. Unless stated in the "Note" column, the rhythm is not automatically marked by the 7L Platform and can only be manually marked by a clinician/technician.

Label	Description	Note
NSR	Normal Sinus Rhythm	
A	Artifact or Noise	Extra spikes, waves, or complexes in signal
AFIB	Atrial Fibrillation	Automatic annotation by SmartCardia analysis tool
VFIB	Ventricular Fibrillation	
AFL	Atrial Flutter	
VFL	Ventricular Flutter	
MAT	Multi-focal Atrial Tachycardia	

Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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Label	Description	Note
VT	Ventricular Tachycardia	Automatic annotation by SmartCardia analysis tool
T	Tachycardia	Automatic annotation by SmartCardia analysis tool
Vx1	Isolated Ventricular Heartbeat	Also called VEB Automatic annotation by SmartCardia analysis tool
Vx2	Ventricular Couplet	Also called V Couplet Automatic annotation by SmartCardia analysis tool
Vx3	Ventricular Triplet	Also called V Triplet Automatic annotation by SmartCardia analysis tool
VRUN	Ventricular Run	Run of 4 or more VEBs. Automatic annotation by SmartCardia analysis tool
V2	Ventricular Bigeminy	Automatic annotation by SmartCardia analysis tool
V3	Ventricular Trigeminy	Automatic annotation by SmartCardia analysis tool
SVx1	Isolated Supraventricular Heartbeat	Also called SVEB Automatic annotation by SmartCardia analysis tool
SVx2	Supraventricular Couplet	Also called SV Couplet Automatic annotation by SmartCardia analysis tool
SVx3	Supraventricular Triplet	Also called SV Triplet Automatic annotation by SmartCardia analysis tool
SVRUN	Supraventricular Run	Run of 4 or more SVEBs. Automatic annotation by SmartCardia analysis tool
SV2	Supraventricular Bigeminy	Automatic annotation by SmartCardia analysis tool
SV3	Supraventricular Trigeminy	Automatic annotation by SmartCardia analysis tool
AV1	AV Block (First degree)	
AV2	AV Block (Second degree)	
AV3	AV Block (Third degree)	
P	Pause	Automatic annotation by SmartCardia analysis tool
B	Bradycardia	Automatic annotation by SmartCardia analysis tool
ASYS	Asystole	
PM	Pacemaker Rhythm	
MaxHR	Maximum HR	*Meta-label* to indicate that the segment contains an example of maximum heart rate of the recording Automatic annotation by SmartCardia analysis tool
MinHR	Minimum HR	*Meta-label* to indicate that the segment contains an example of minimum heart rate of the recording Automatic annotation by SmartCardia analysis tool
REPORT	Printable Strip	*Meta-label* denoting that this strip is of interest for a report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118
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Heartbeat Types

The type of heartbeat is shown in blue in the lower line of the graph. The red x indicates a beat was detected.

The beat types N, V, SV, and ? are automatically detected by the analysis tool, while the user can manually add /edit the rest. If the user wants to indicate the presence of a heartbeat that was not previously located, this new heartbeat must belong to one class. If the class cannot be determined but the presence of the heartbeat must be explicitly indicated, the user can use the 'Indeterminate' class, which describes the beats that cannot be labeled clearly. The following table shows the list of heartbeats that can be marked on the ECG graph.

Label	Description	Definition
?	Unknown beat type	Clinician must always indicate a label classification Automatic annotation by SmartCardia analysis tool
N	Normal shape beat	Normal beat Automatic annotation by SmartCardia analysis tool
V	Ventricular Extrasystole	QRS complex arising from an ectopic focus in the ventricles of abnormal shape and duration. Also used to mark premature ventricular contractions (PVCs) Automatic annotation by SmartCardia analysis tool
SV	Supraventricular Extrasystole	Premature contraction arising from an ectopic focus above the bundle branches (includes the SA node, atria, and AV junction) Automatic annotation by SmartCardia analysis tool

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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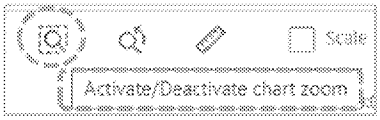
Label	Description	Definition
M	Missing QRS. This occurs in a heartbeat when the QRS complex is not present or not visible.	QRS complex is not present or not visible for a heartbeat
P	Paced beat	Beat from artificial pacemaker
F_V	Ventricular Fusion Beat	More than one electrical impulse fires at the same time in the ventricles causing the resulting complex to be varied in configuration and height
F_A	Atrial Fusion Beat	More than one electrical impulse fires at the same time in the atria with the resulting complex varied in configuration and height
X	Phantom Beat	Unclassified beat
I	Indeterminate Single Beat	Abnormal beat that cannot be identified

Chart Zoom

The chart zoom function can be activated and deactivated using these tools.

- Activate/Deactivate chart zoom



- Restore chart zoom

In the example below, the chart zoom icon is red indicating it is activated. The darker yellow shaded area was selected by placing the mouse cursor on the beginning point to review and dragging it to the last point to review.

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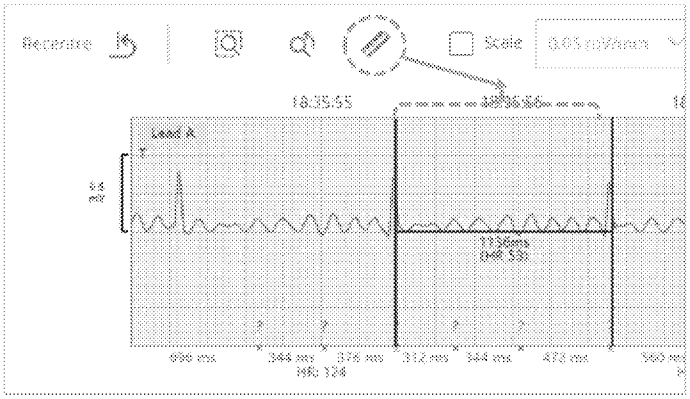
The example below shows the top strip with the highlighted beats using the zoom function. The second strip shown, is the normal view which can also be expanded using the zoom function if desired.

ECG Chart Measurement

ECG chart measurement can be turned on to analyze the ECG in more detail. The gray icon indicates the measurement function is off and red shows measurement is on as pictured below. The location of R peaks and the time between consecutive R peaks can be measured in milliseconds and heart rate is shown. The amplitude can also be measured in mV and displayed in the information box.



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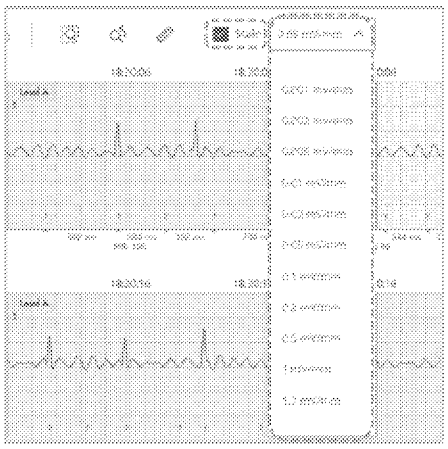
Scale for Display

The scale for rhythm display can be adjusted as desired.



After review of the detailed ECG chart view use the X to exit this screen to return to the graph view.

Export Records

From this view in “History”, clinicians can export the signals of a patient in the SmartCardia files’ format (*.SC). These files can be uploaded (imported) again to the same patient.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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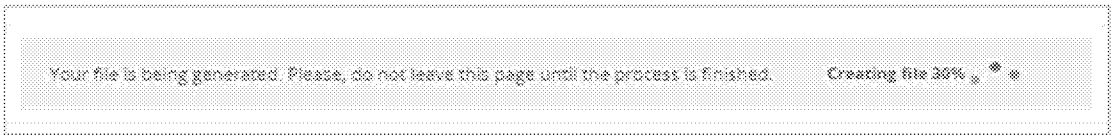
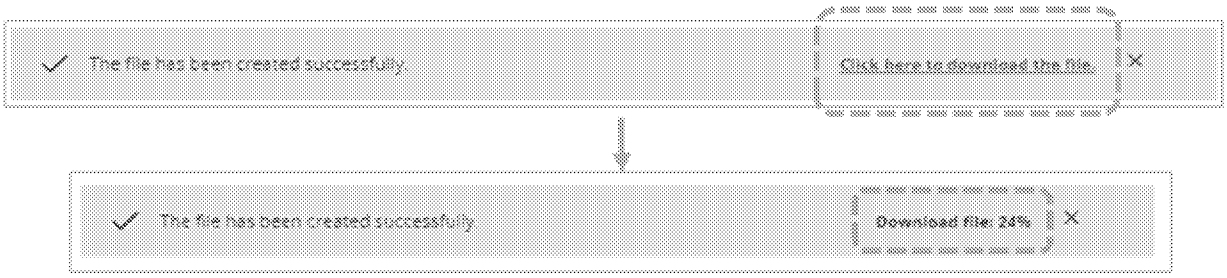
To create a *.SC file with the signals of a patient, a clinician must select the time range using the navigation bar. They can also use the buttons at the top-left corner to select one of the pre-defined options (last 30 minutes, last 2 hours, last 2 days and last 7 days with data). Select “Export records”

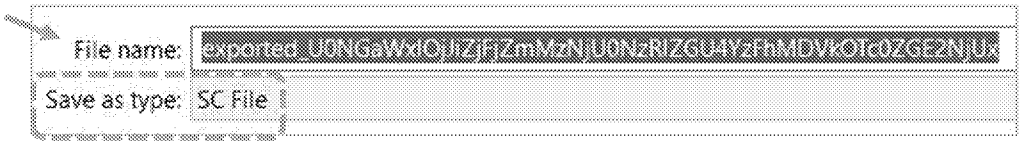
When selecting a large amount of data, the following message will show the progress of file generation and reminder to not leave this page until the process is finished.



Once the process finishes and the file is ready to be downloaded, the user will see a notification with a link. Clicking on that link will start the download process. A message will state the progress of the file download.



Clinicians must select the path and the name of the recording, and the file will be downloaded.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118
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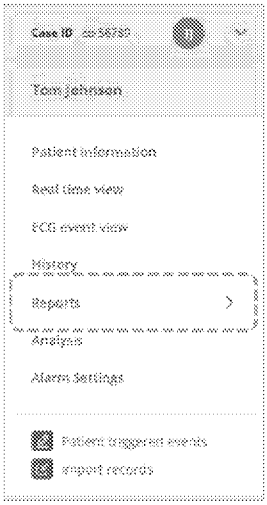
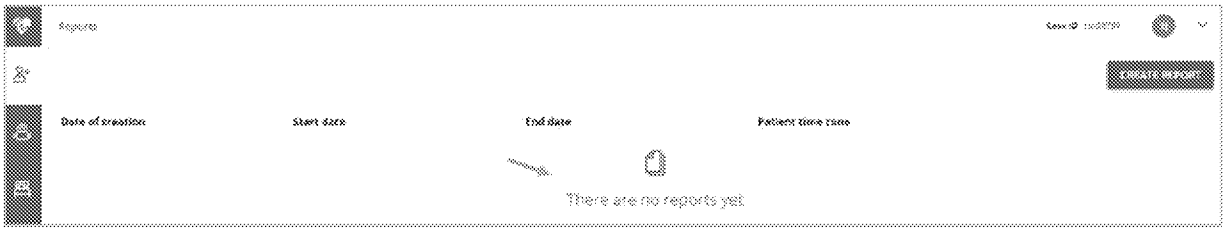
Reports

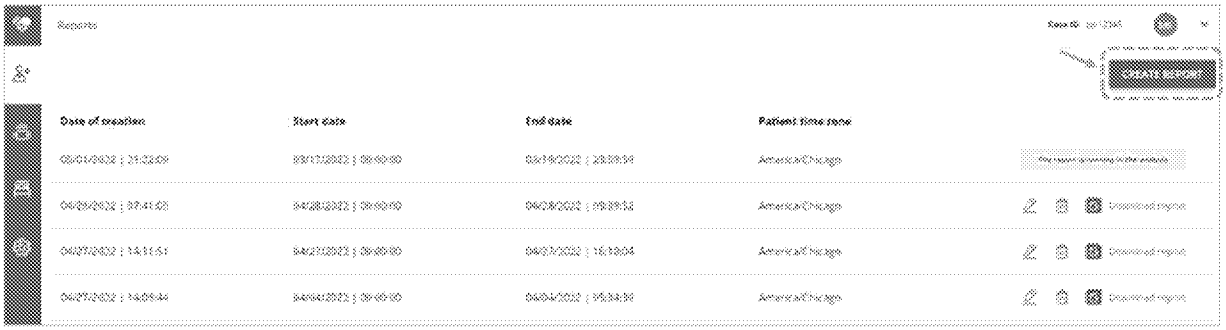
Reports of Analysis done for a patient can be managed by selecting “Reports” from the expanded menu on the upper right side of the screen.



If there are no reports available for the patient, there is a statement on the list of reports page that says, ‘There are no reports yet’.



This page below displays the list of reports that have been generated for the patient.
To generate a new report, select “CREATE REPORT”.



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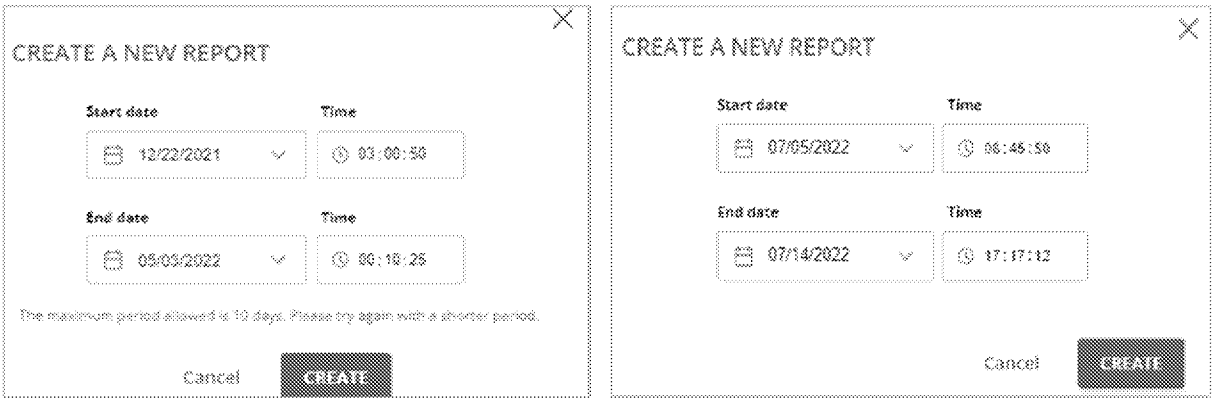
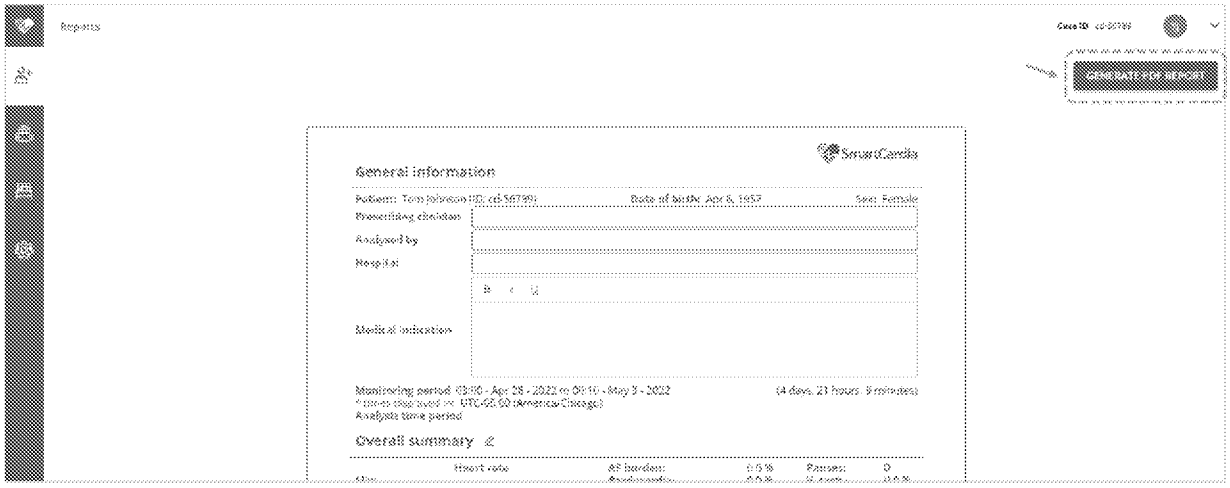
In the pop-up box, enter the start date and time along with the end date and time. Ten days is the maximum number of days possible for the report time period.

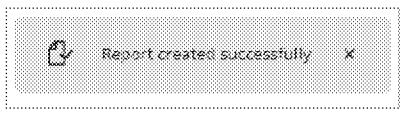
NOTE: The first screen shot below is an example when you try to enter more than ten days for the report time period. Once the date information is corrected the “CREATE” button changes color from gray to blue and is active.



Once “CREATE” is selected the report is created and displayed with the option to “Generate PDF Report”.



The report was created successfully, and the report is now added to the list of reports.



NOTE: If a long period of time is requested, it will take longer to create the report.

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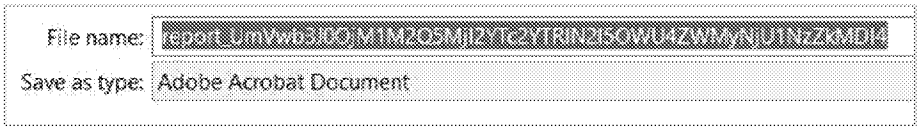
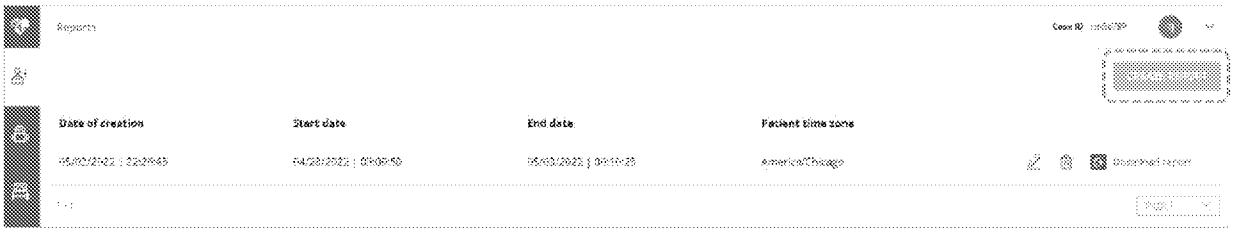
The report list has column headers of the creation date, the selected start and end date of the report, and patient time zone. For each report listed, there is a button to edit, delete, or download the report.

The edit function provides the ability to add and edit a comment on each report. Once edits are complete, select “GENERATE PDF REPORT”.

The report can be deleted or download as a PDF file.



NOTE: The “CREATE REPORT” button is shaded in gray and not active while Analysis is in process for the patient, as shown in the example below. During that time, the only function available is to work with an available report.



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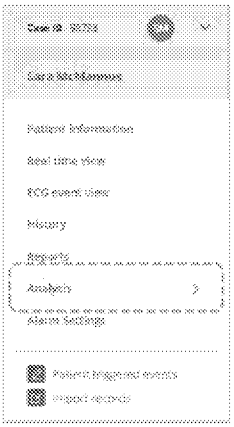
Analysis

Selecting Analysis provides a software tool to perform marking of long electrocardiogram (ECG / EKG) recordings. This was created with special emphasis on the ease of use for the clinician. The application has been developed to mark ECG recordings sampled at different resolutions and voltage levels, enabling the marking of heartbeat types, the underlying rhythm as well as episodic rhythm changes and artifacts. Analysis also provides processing functionalities to perform semi-automatic detection of different abnormalities aiding the marking process.

There are two ways to get to the Analysis function.

- From the "PATIENTS" list, select the patient's name that you want to perform analysis.



- From the "Multi-Patient" view, on the patient tile of the patient that you want to perform analysis, click on the three dots in the upper right corner of the patient tile.

Select Patient data in the pop-up window, then go to the options for that patient in the upper right side of the screen and select "Analysis".

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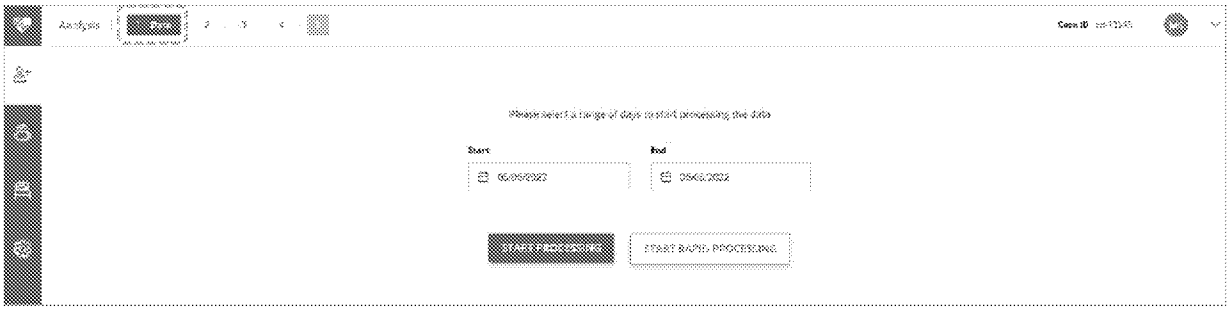
Holter Report Preparation- Standard Processing

Processing the data is done in five steps

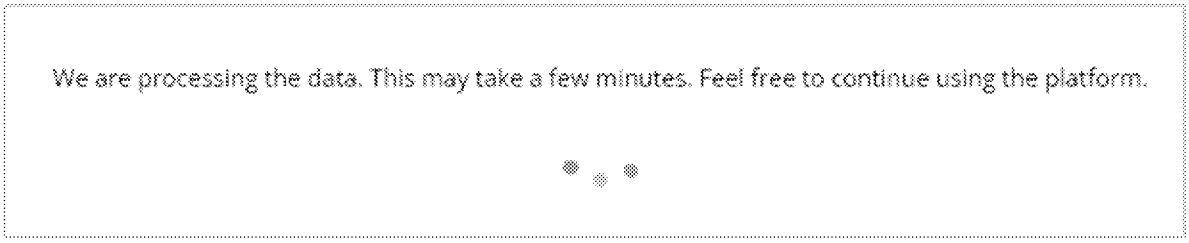
Step 1 Date

- Select the range of days to start processing the data. Use the calendar to set the start and end dates.
- Click on “START PROCESSING” or “START RAPID PROCESSING”



If analysis was done previously a pop-up asks if you want to do a new analysis.

If YES is selected in this case, data processing begins.



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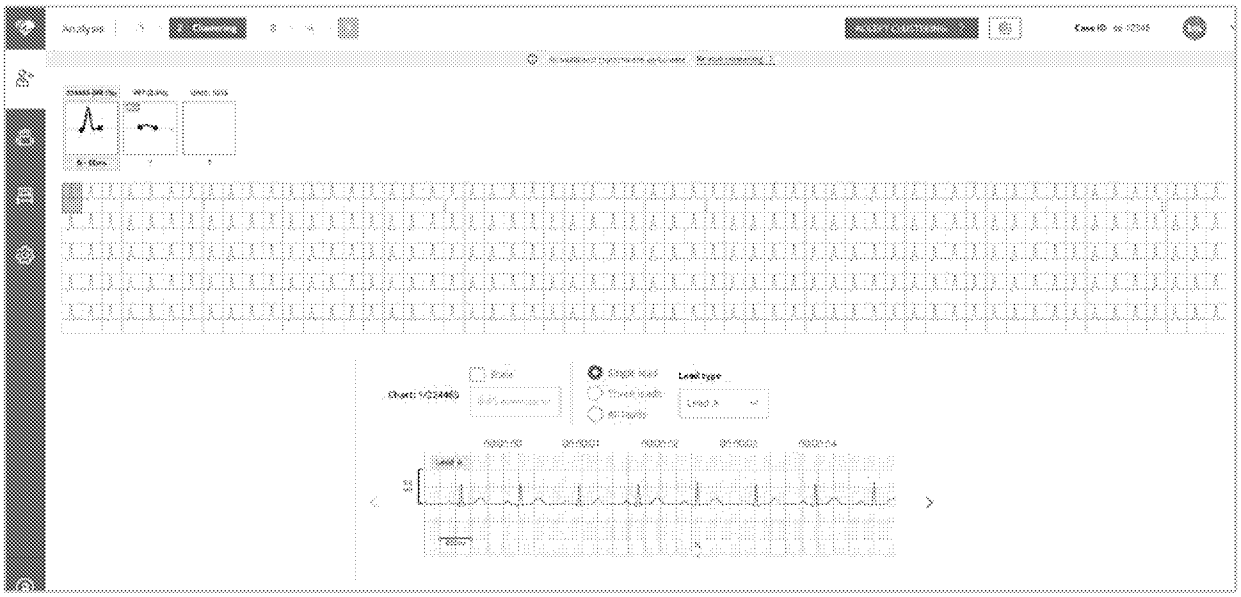
Step 2 Clustering-Beat clustering analysis



Reviewing the heartbeat clusters

Each cluster represents a group of heartbeats (QRS complexes) that are similar in morphology. The clusters are presented in descending order according to the number of heartbeats belonging to the cluster.

The template of each morphology is shown in a square.

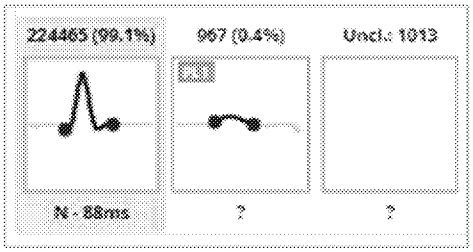
Above the cluster square is displayed:

- Number of the same morphology QRS beats
- Percentage of their occurrence

If a cluster has premature QRS complexes, the relative degree of prematurity will be shown in the upper left corner. The prematurity of the beats inside the cluster is indicated in three levels:

- Premature (PL1)
- Very premature (PL2)
- Extremely premature (PL3)

Below the cluster square is an estimation of the QRS length of the template as well as a tentative suggestion for the label to apply to the cluster.



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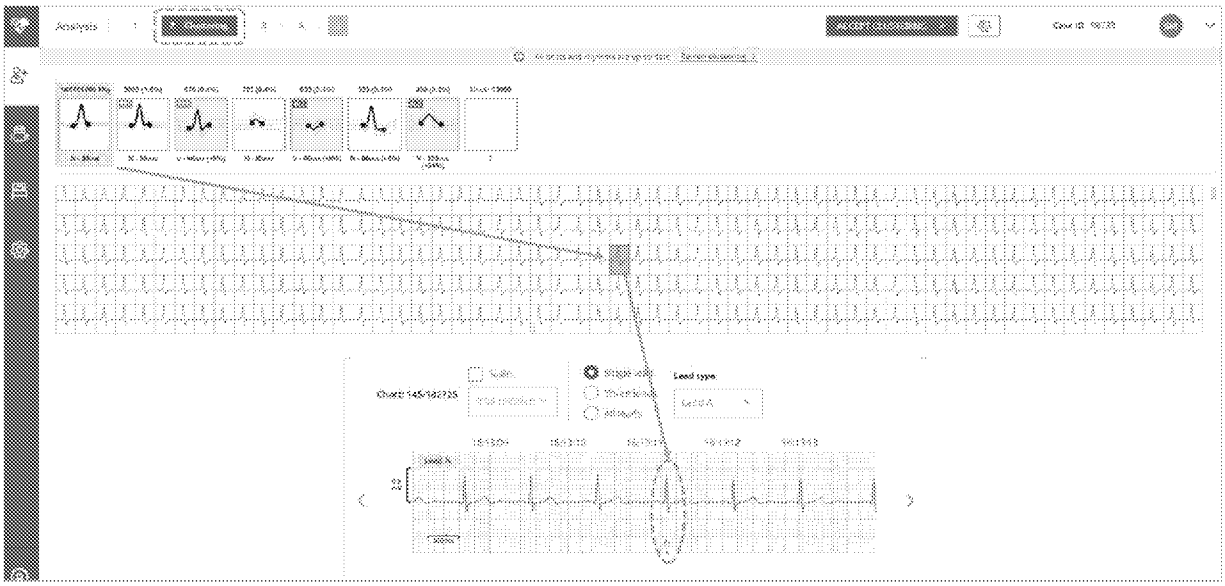
The background of each template is color coded:

- Green for Normal clusters (denoted with the label 'N')
- Yellow for any other type
- White for clusters of unknown type (denoted with the label "?")

QRS and ECG Preview

For each cluster, the individual heartbeats can be reviewed in greater detail.



ECG Time and Voltage Scales

As in a standard ECG rhythm strip, on the horizontal dimension (time axis), each 1mm box corresponds to 0.04 seconds (40 milliseconds) and each 5mm box corresponds to 0.2 seconds (200 milliseconds). In other words, the ECG is displayed at 25 mm per second. On the vertical dimension (voltage axis), the tool adapts the scale to optimally display the ECG signal. This ratio is expressed in millivolts per millimeter (mV/mm) and is indicated in the Scale pop-up selector.

While the tool automatically adapts this scale when changing from signal to signal (e.g., after loading a new file), the ratio can be manually changed by the user selecting the desired value using the pop-up selector for scale.

ECG preview leads

The ECG lead display format options are selected using a radio button. The choices of lead options available to view include:

- Single lead - you can select either lead A, B, C, D, E, F, or G

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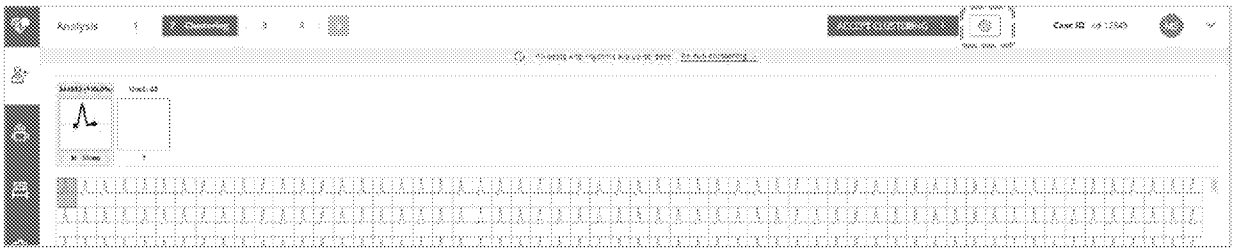
- Three leads - A, B, G
- All seven leads - A, B, C, D, E, F, or G (Scroll down to view all leads)

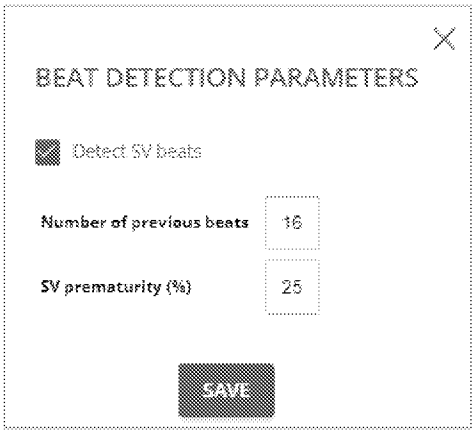
Beat detection parameters

Adjustments can be made to the parameters for beat detection.

- Click on the gear icon at the top right of the screen to the right of ACCEPT CLUSTERING

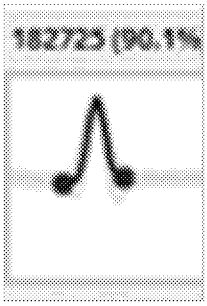


In the "pop up" box, BEAT DETECTION PARAMETERS make any adjustments to detect SV beats, number of previous beats and SV prematurity %. And "SAVE" changes.



Navigation through heartbeat clusters

Click on the square of the desired heartbeat (QRS) cluster to look at in detail. A blue box will outline the cluster.



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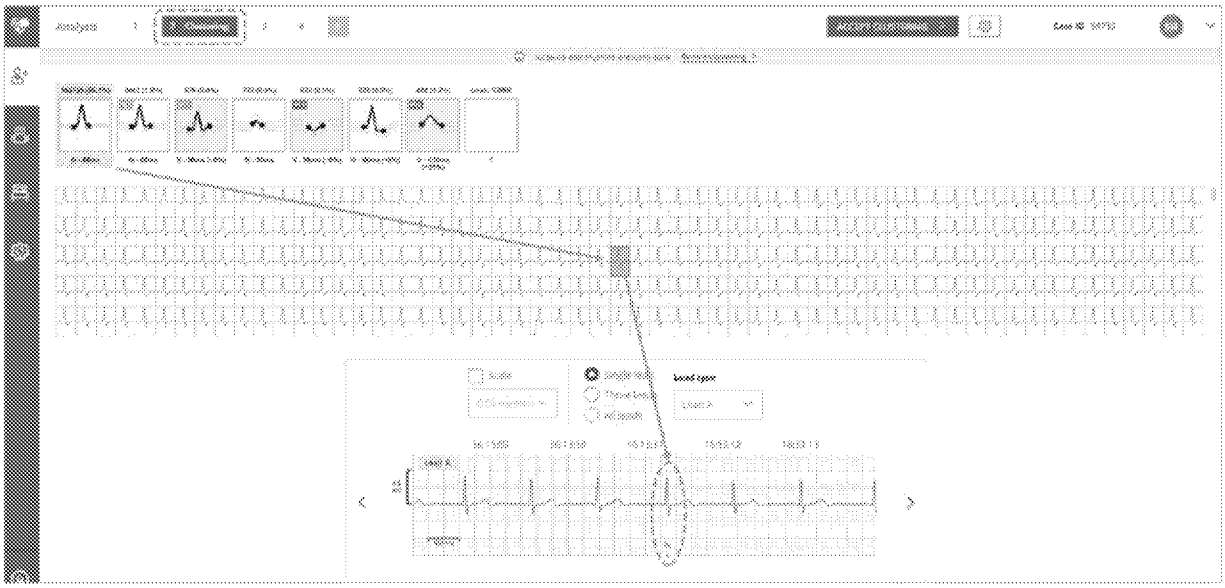
The first heartbeat of the recording belonging to this group will be highlighted on the top of the full disclosure ECG view and on the enlarged rhythm strip. Heartbeats are sorted by how similar they are to the template of the clusters where they belong, rather than chronologically.



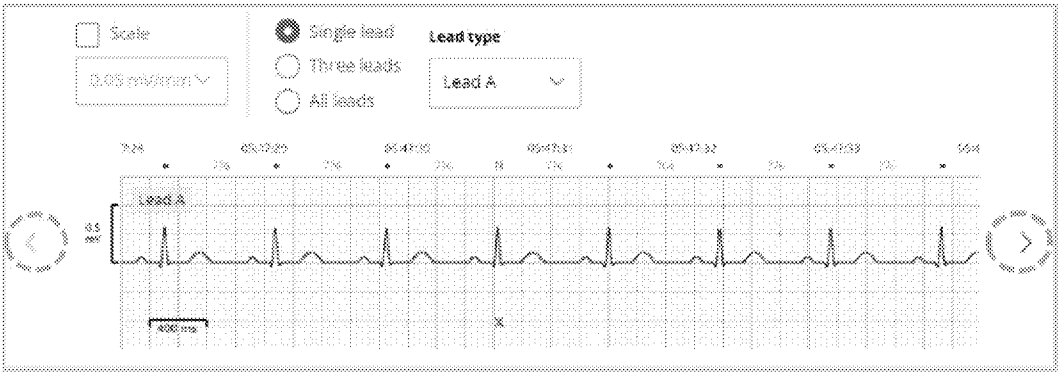
There are multiple ways to inspect the heartbeats belonging to a selected heartbeat cluster:

- Select the cluster to review
  - In the cluster screen, continue clicking on the selected heartbeat cluster to see each heartbeat in the ECG full disclosure and ECG preview strip
  - In the full disclosure ECG view (All complexes belonging to the cluster are displayed in the full disclosure view)
    - Click on any point to display that period of time in the rhythm strip view
    - Use the scroll bar on the right side of the screen to move through the ECG complexes

    NOTE: The beat highlighted in red on the full disclosure view is shown on the rhythm strip with the QRS complex beat annotation about the center of the strip.

OR

- On the rhythm strip, use the right/left arrow keys to move forward or go back in time



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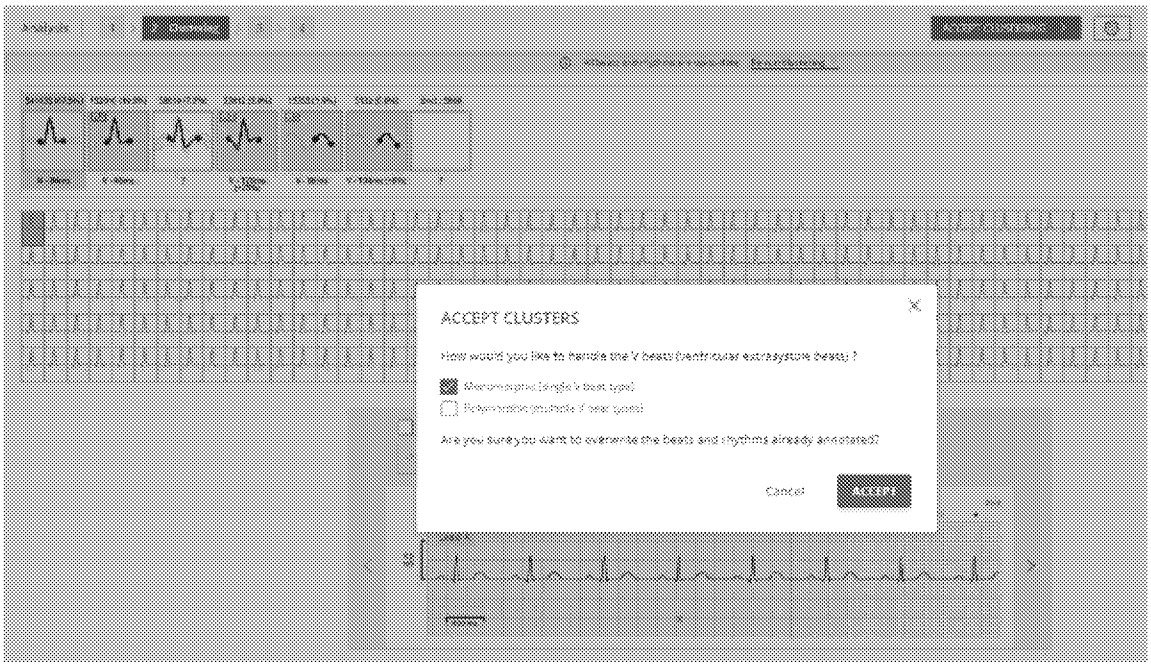
Accept Clustering

Select “ACCEPT CLUSTERING”.

In the “pop up” box, ACCEPT CLUSTERS choose how to handle the V beats (ventricular extrasystole beats)

- Monomorphic single (V beat type)- classify all V beats into one category/cluster
- Polymorphic multiple (V beat type)- classify V beats into more than one category/cluster



Step 3 Report selection

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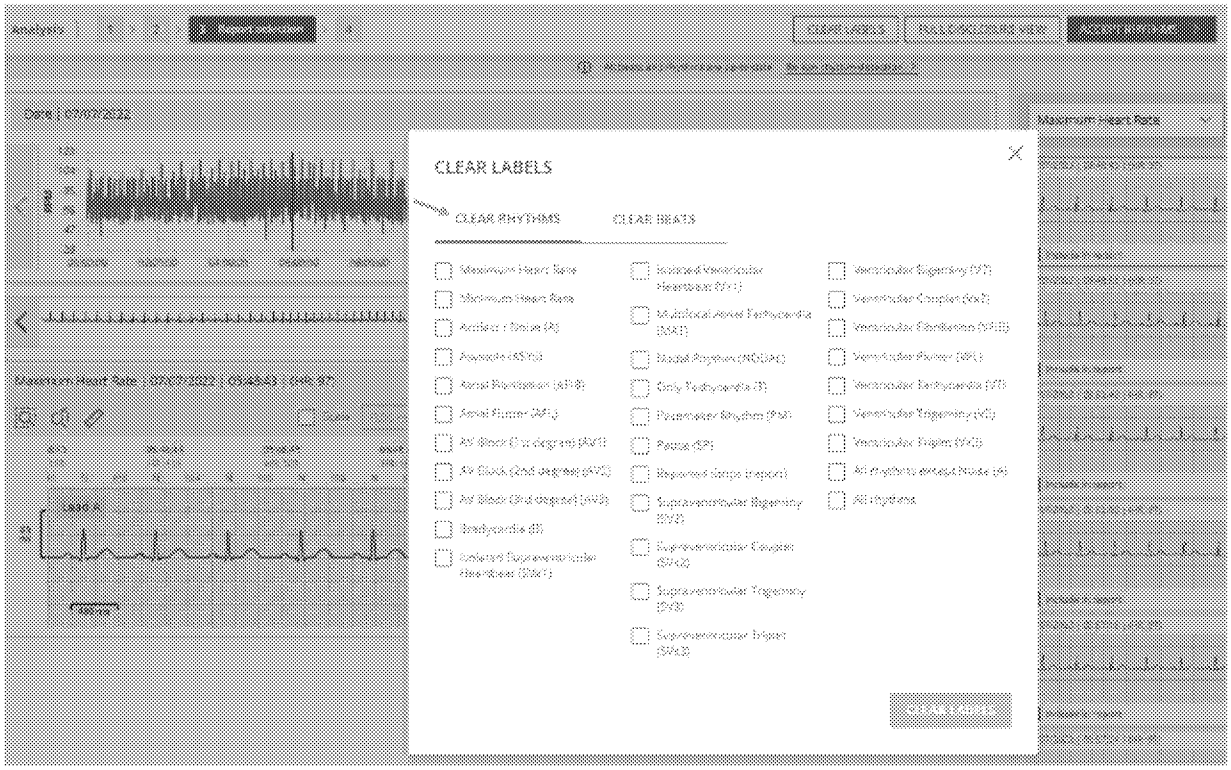
Rhythm detection can be repeated if needed. Select “Re-run rhythm detection” in the top middle of the screen.

Labels for rhythms and beats can be cleared by selecting “CLEAR LABELS” in the upper right corner.

In the pop-up box, select the item to delete which will be shaded in blue, then select “CLEAR LABELS”

CLEAR RHYTHMS



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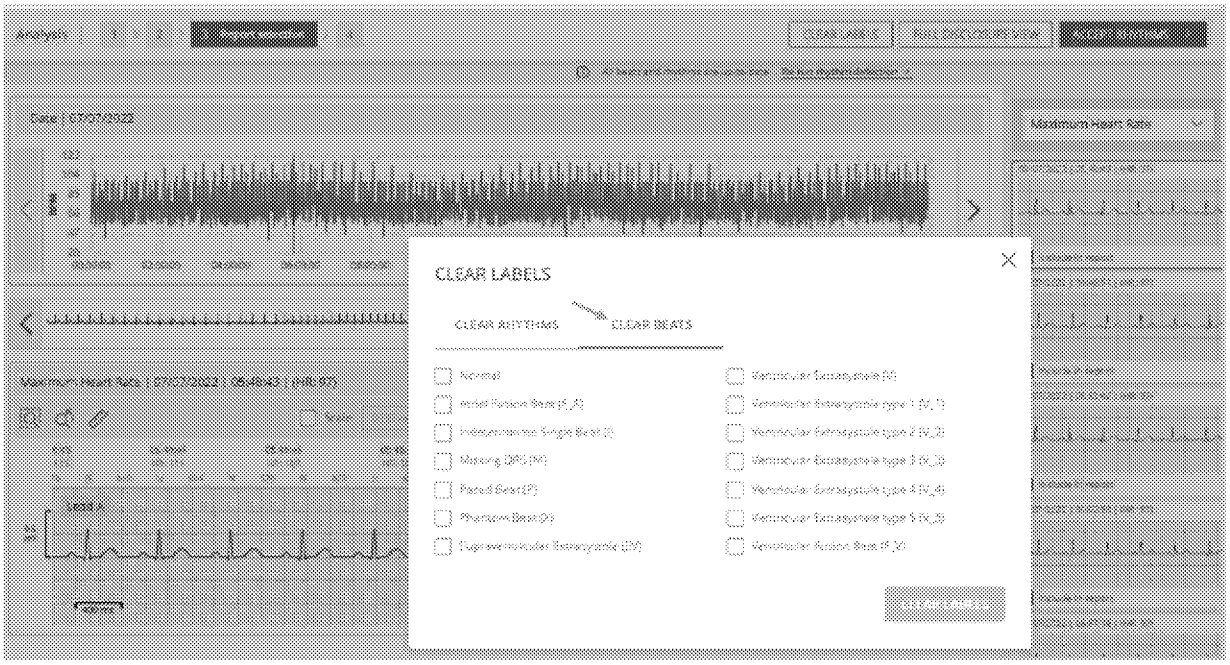
CLEAR BEATS



To view all available rhythms, use the scroll bar on the right side of the screen. In the various rhythm categories, there may be additional rhythms to view.

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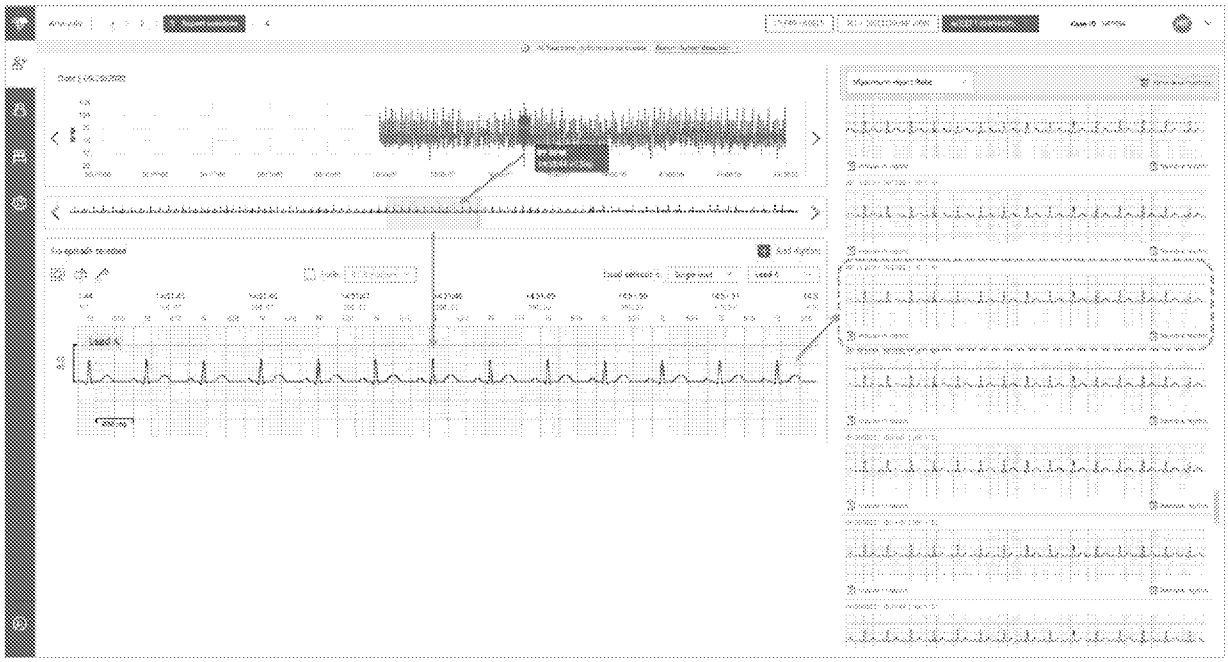

All rhythm strips can be removed from the report by selecting “Remove all rhythms”. Individual rhythm strips can be included or removed from the report using “Include in report” or “Remove rhythm”.

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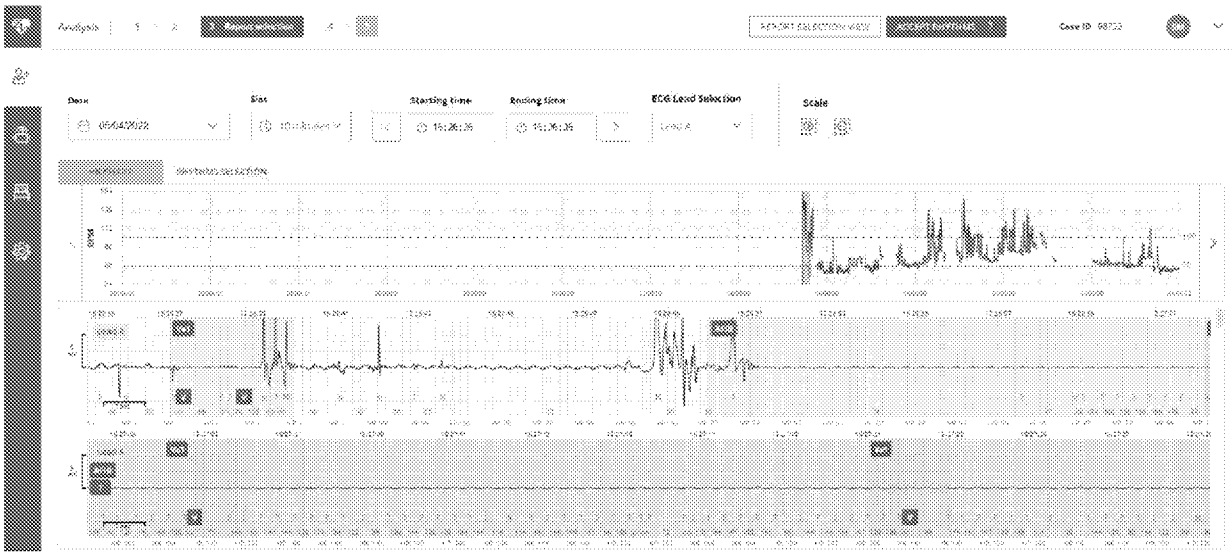
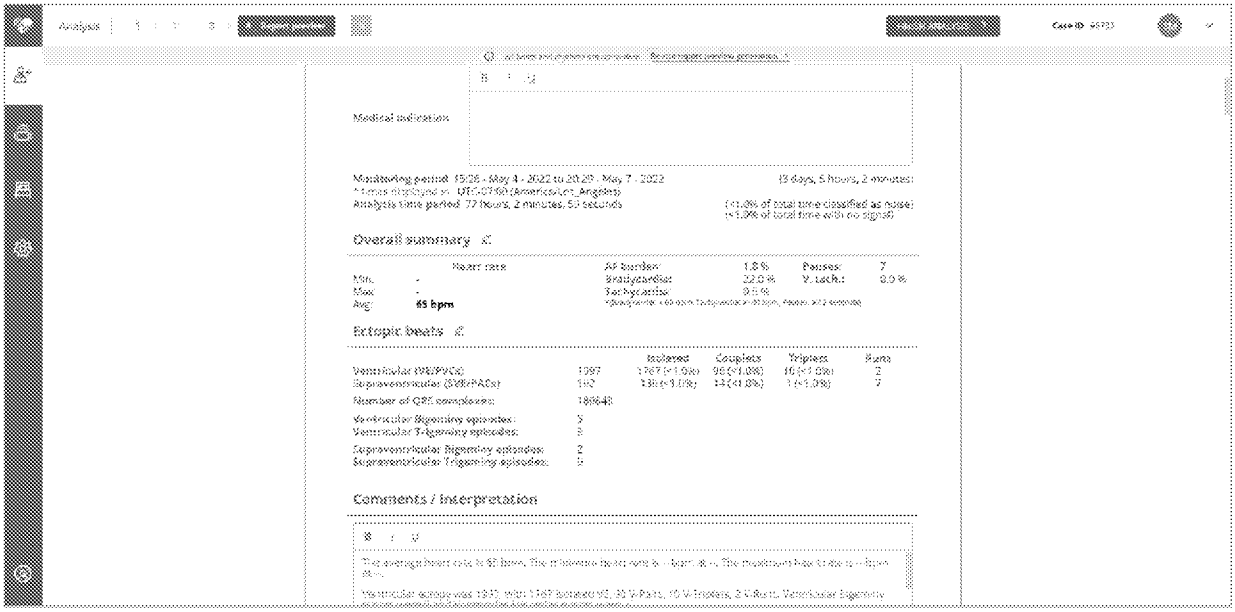
Full Disclosure View



When finished with review, select “ACCEPT RHYTHMS”

Step 4 Report preview

- The report is displayed, and you can scroll through all pages to review.
- Select “FINISH ANALYSIS”



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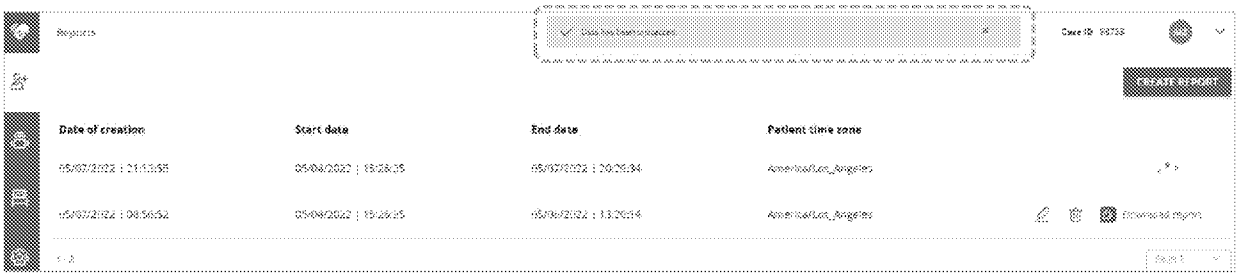
Step 5 Finished



Holter Report Preparation- Rapid Processing

Select “START RAPID PROCESSING” to begin analysis.

Using Rapid Processing skips user interaction in Step 2 Clustering-Beat clustering analysis and takes you directly to Step 3 Report selection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ.STATUS@fda.hhs.gov or 301-796-8118

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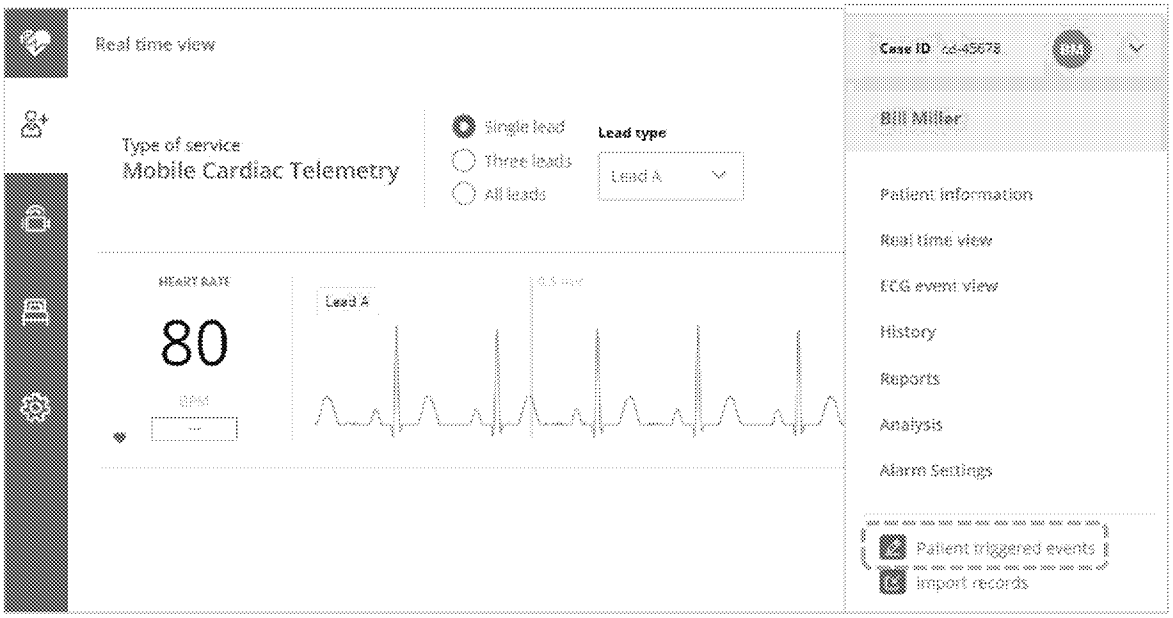
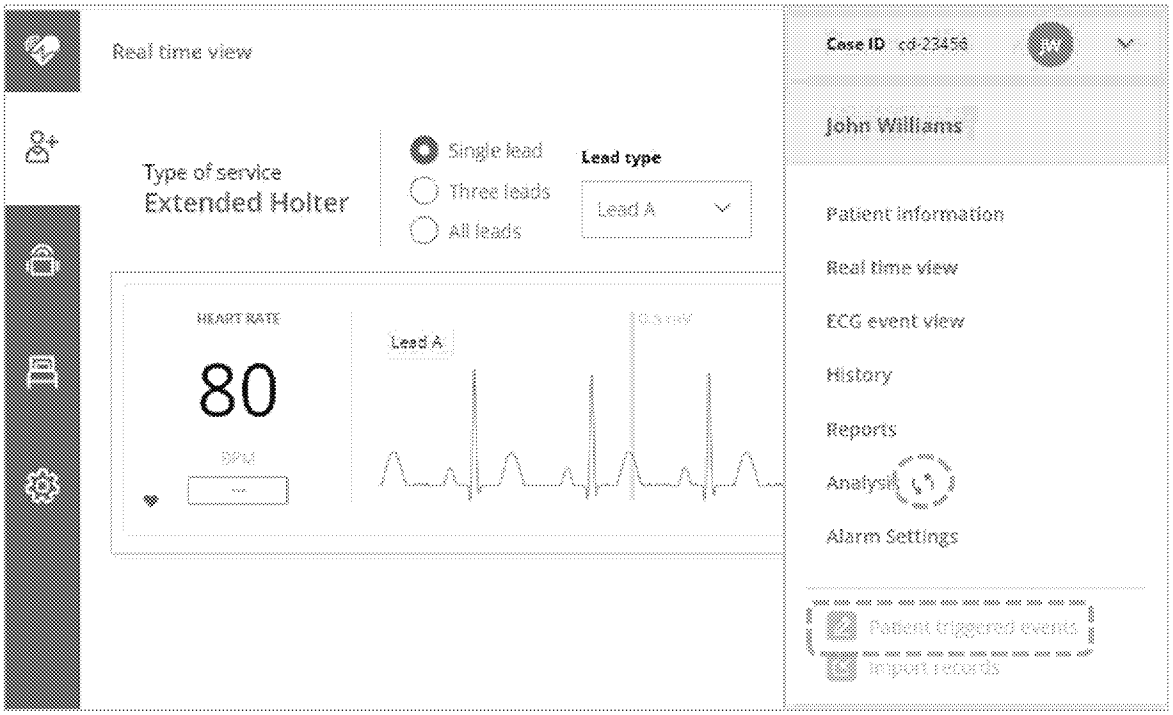
Patient Triggered Events

Patient triggered events can be reviewed from any individual patient page options (Patient information, Real time view, ECG event view, History, Reports, Analysis, and Alarm Settings).



If Analysis is in process “Patient triggered events” is not available and shaded in grey.



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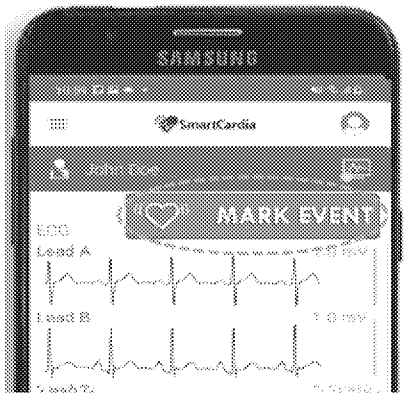
Patient triggered events can be added to the list by the patient or clinician

- The patient can select "MARK EVENT" on the SmartCardia *Phone* and select:
  - event duration
  - symptoms occurring

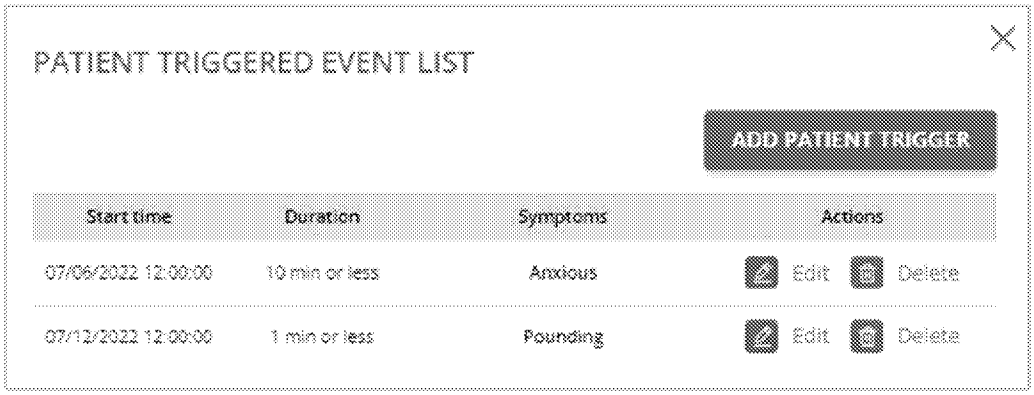


7L Web Browser

- This triggered event is automatically listed in "ACCEPTED EVENTS" in ECG event view
- All triggered events appear in the report

- Clinicians can manually add the patient triggered event information as shown in the two different patient triggered events list screens below

  - If the patient has triggered events, the event time, duration, and symptoms are listed. Triggered events on this event list can be edited or deleted.



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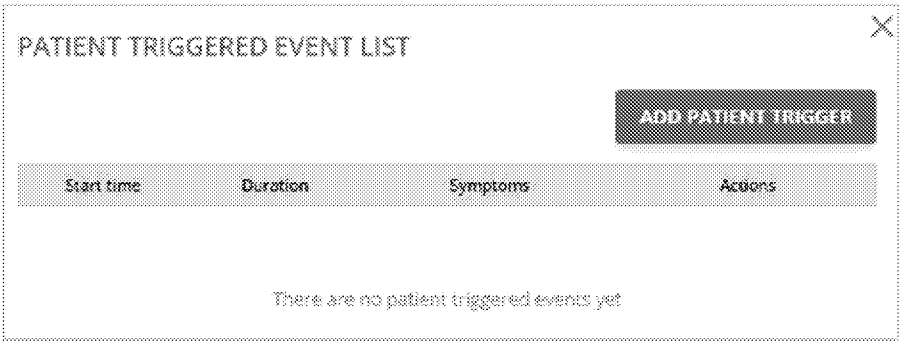
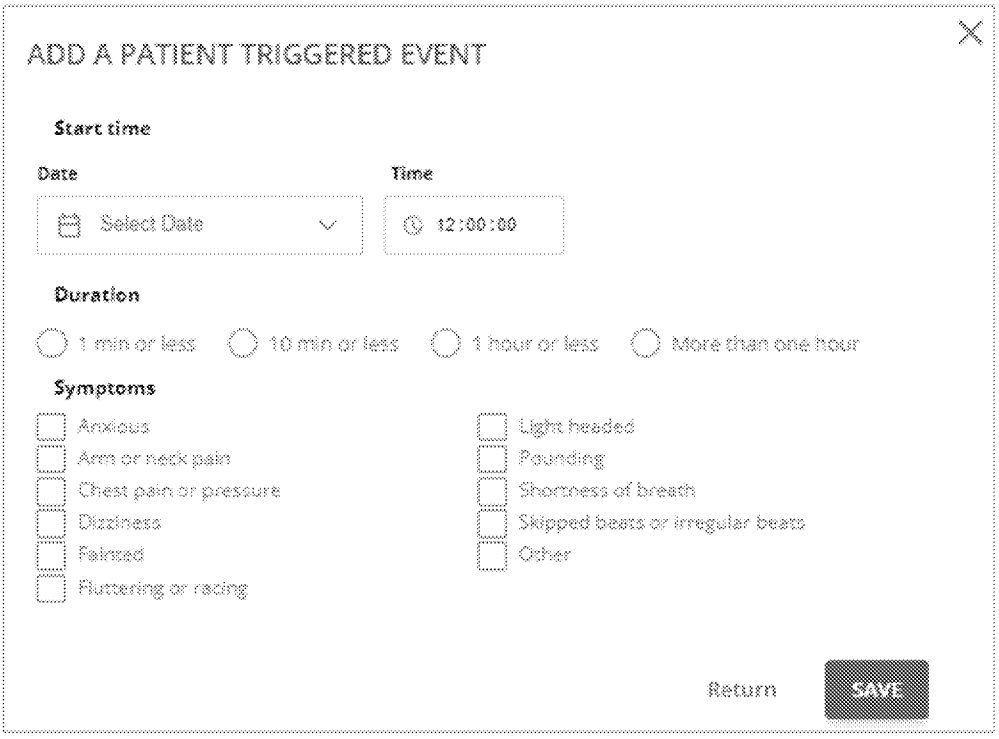
- If this patient has not marked any events or none have been added by the clinician, the list will be empty with the message “There are no patient triggered events yet”.



In both above situations if there are no patient triggered events yet or if events are listed, patient triggered events can be added.

Select “ADD PATIENT TRIGGER”

Enter all event information. Once the information is complete select “SAVE” and the event will be added to the list of triggered events for the patient.



Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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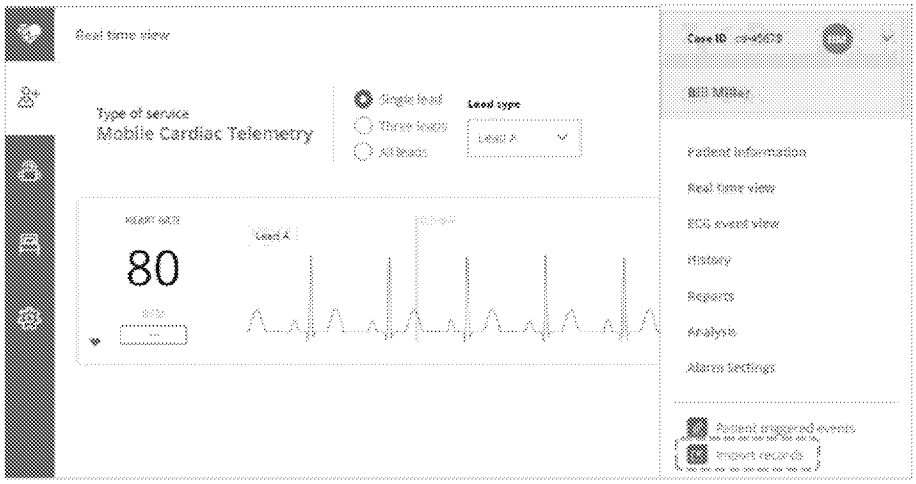
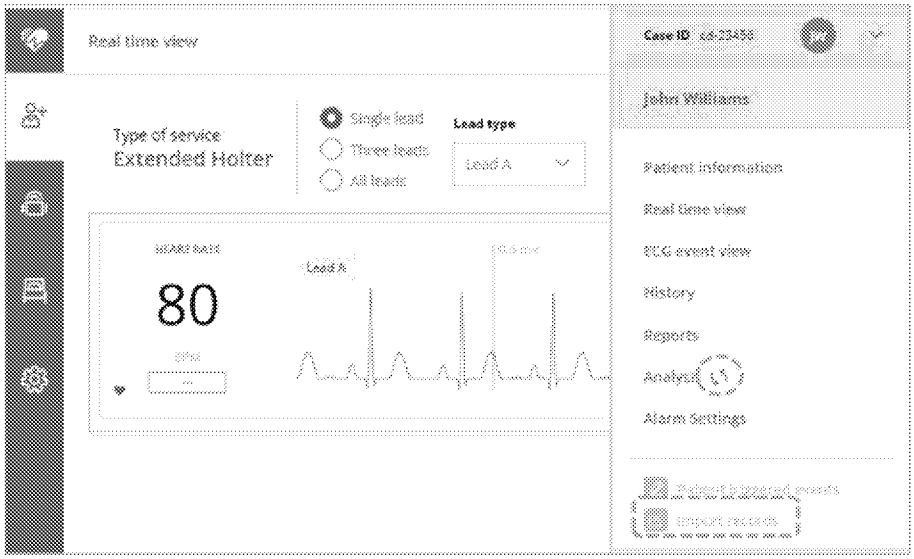
Import records

Import records can be done from any individual patient pages (Patient information, Real time view, ECG event view, History, Reports, Analysis, and Alarm Settings). Patient data can be added or combined with a record that already exists.



If Analysis is in process “Import records” is not available and shaded in grey.



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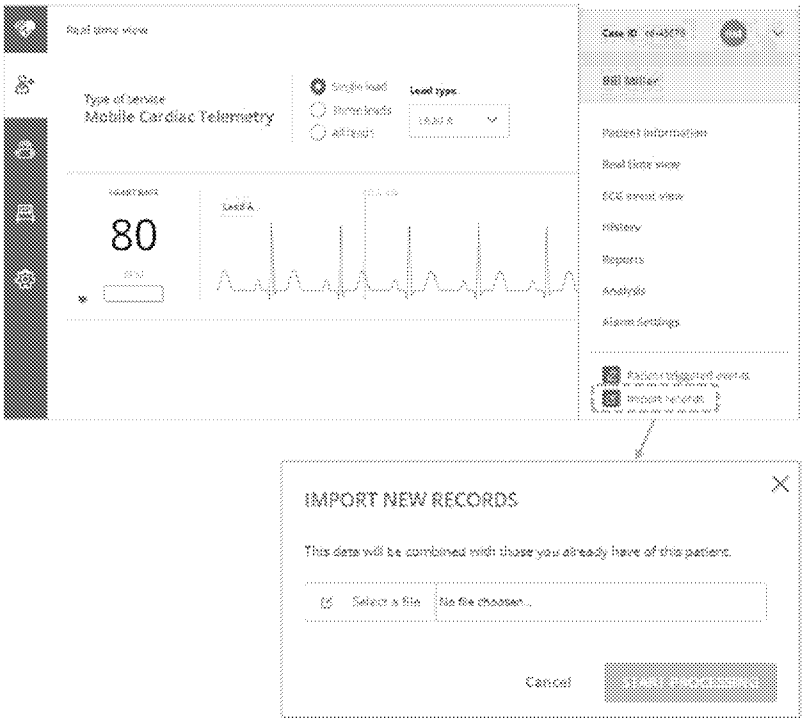
Select “Import records”



Click on the “Select a file” button to search for the file to add. **The file must have the extension “.sc”.** If a file is selected that does not have that extension, an error message is displayed.

Once the file is chosen, the file will begin uploading. The green line and digital information show the progress of the file upload.

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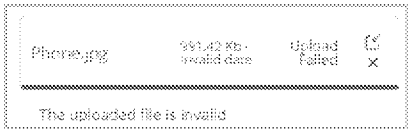
Steps when uploading the data file:

- Error
  A red message means there was an error in the operation with the message: “Upload Failed. The uploaded file is invalid.”
  NOTE: check file name and extension for correct format (.sc) See page 110.



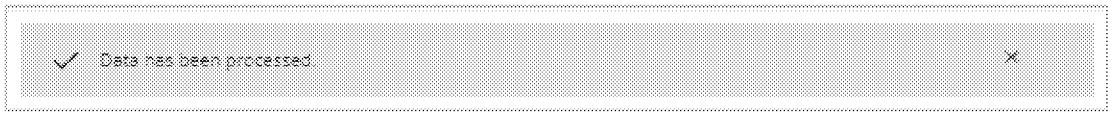
- Once upload is complete, record saved (name of record, file size/date/time, and complete with the option to delete) is displayed
- Select “START PROCESSING” Now ready to import additional new records

- In process

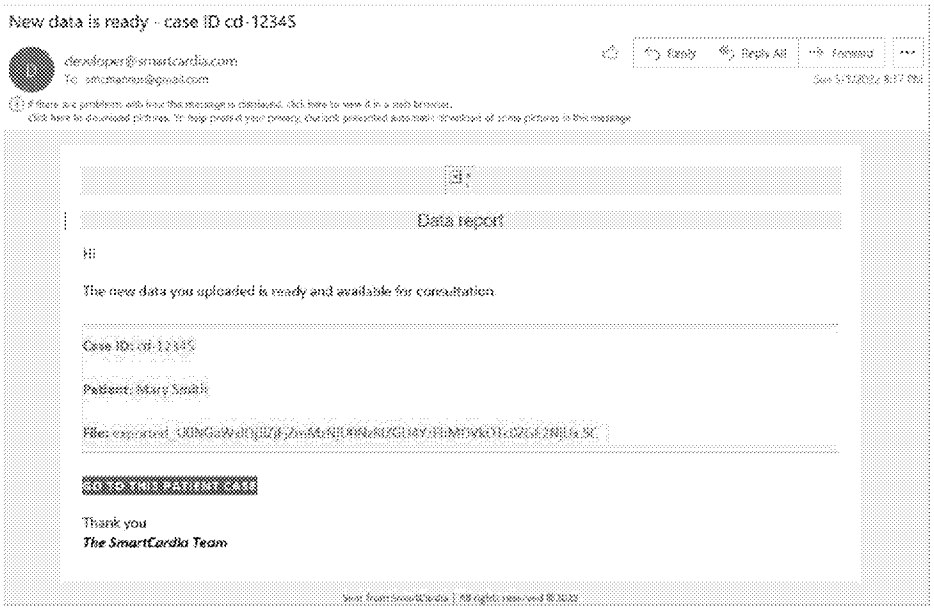
  The message in blue text, “Processing new data. Feel free to continue using the platform” indicates the operation is in process

- Successful import of record

  The message “Data has been processed” In the green box means the operation is successful



An email is sent to the clinician with notification the new data file is ready for import.



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Manage Devices

The Devices section of the *7L Web Browser* provides two functionalities for the clinician. They include review and editing the list of devices and to add a device.

List of Devices

This list has all *7L Sensors* currently in use or available to use for a new patient.

List of devices

The search bar allows the user to search for a device by MAC address or device name.

The following information is displayed and can be sorted:

- MAC address of the *7L Sensor*
- Name of the device
- Date of the last association with the patient
- Patient name which the device is assigned

Identification of the device location on the chest of the patient

The “Edit” button is used to change the name or MAC address of the *7L Sensor*

The “Delete” button removes the *7L Sensor* from the list of devices (only available for devices that are not assigned to a patient).

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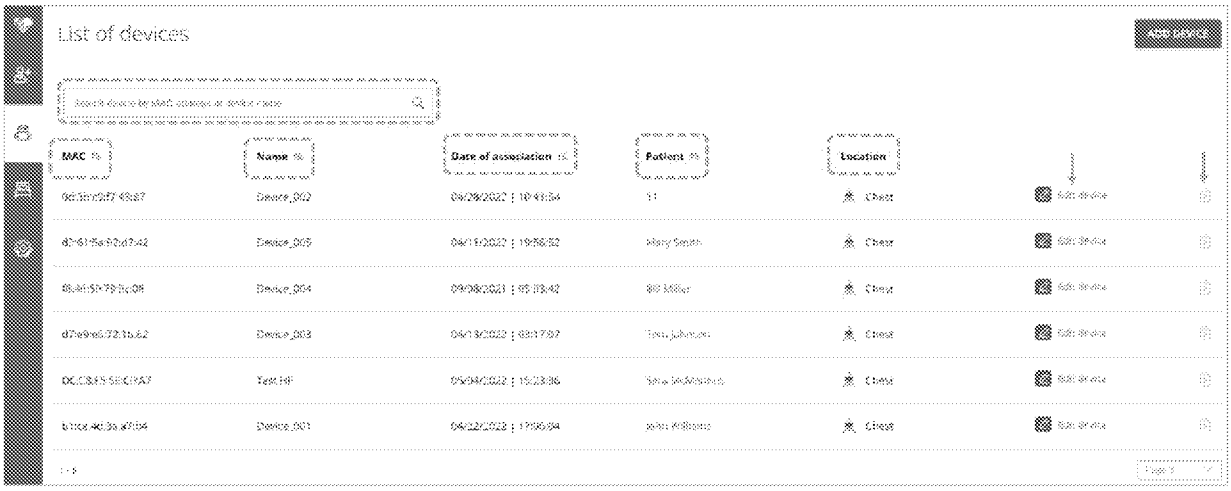
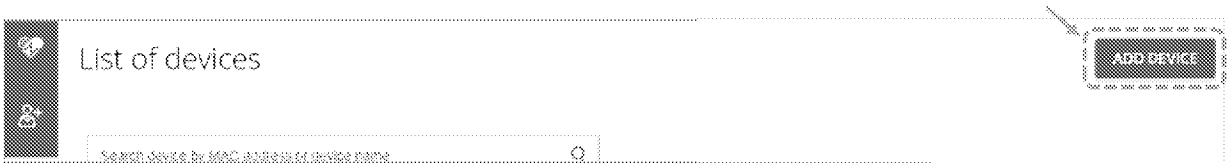


NOTE: To remove or add an association between a *7L Sensor* and a patient, the user must go the patient information page. Easily get there by selecting the patient's name on the list, select patient information and select "Assigned Devices" then "Unassign device" or "Assign device".

Add a New Device

If a new *7L Sensor* (device) needs to be added to the SmartCardia 7L Platform use the following process. Each *7L Sensor* has a unique MAC address that will be added along with the device name designated by your practice. For example, the device name could be CD01, CD02, etc.



Select the "ADD DEVICE" button in the upper right corner.

- Type the name for the new *7L Sensor* device (must not currently exist)
- Enter the MAC address that is found on the surface of the *7L Sensor* that is inserted into the *7L Patch*
- Select "SAVE"
- A notification is displayed with the message "Device added"
- The new device is now added to the list of devices and available for patient use

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Discontinuation of Monitoring

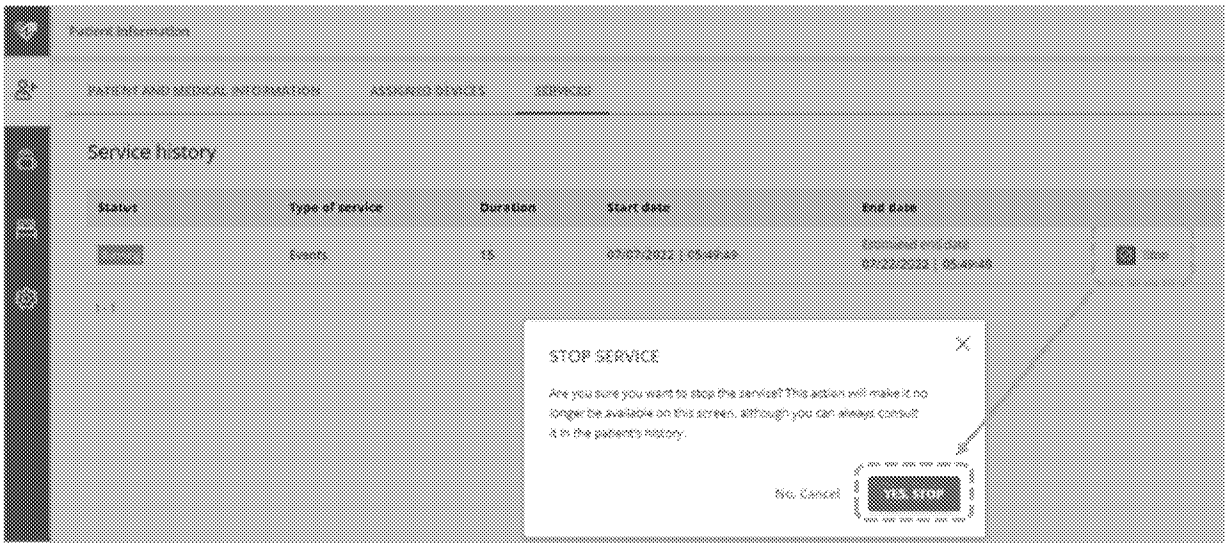
At the conclusion of the monitoring service, the patient returns the SmartCardia *7L Sensor*, *Phone*, and medical grade charger using the pre-addressed, pre-paid mailing envelope for reprocessing.

Follow the process of your practice to review, analyze, and prepare patient reports.

On the patient information page, select “SERVICES” tab.

Under Service history, for the current running service, select “Stop”.

In the confirmation pop-up box, select “YES, STOP”



The confirmation message, “Type of service has been stopped” is briefly displayed on the screen and status shows “Finished”.

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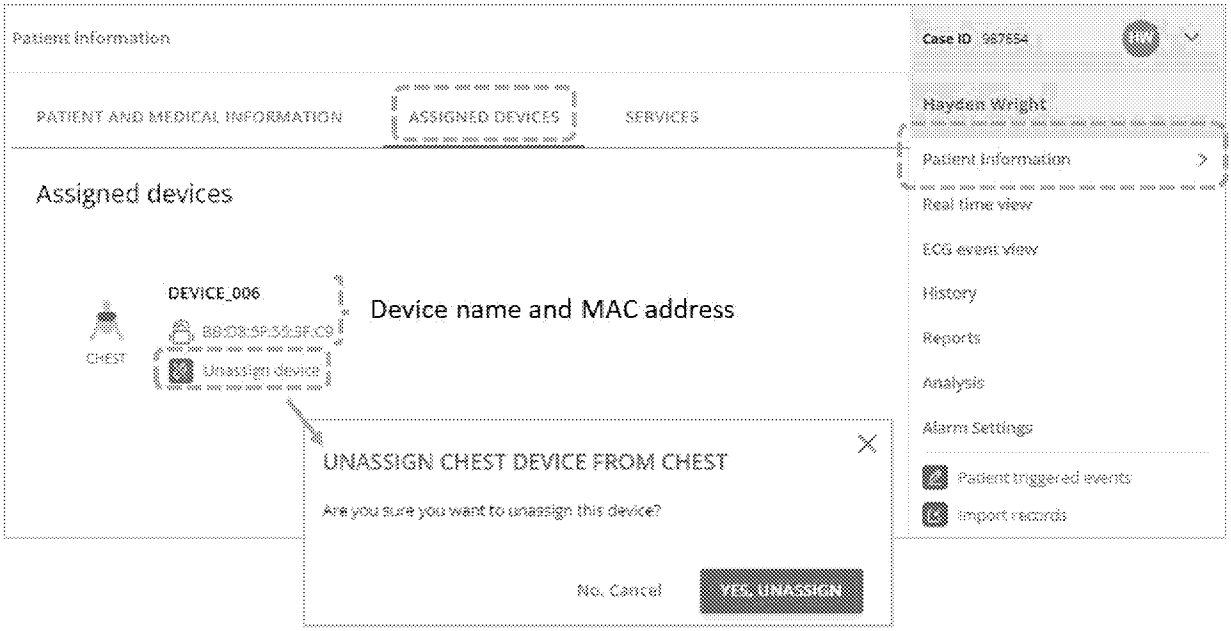
Next step is to unassign device.

On the patient information page, select “ASSIGNED DEVICES”, then select “Unassign device”.

In the pop-up box select “YES, UNASSIGN” to stop monitoring the patient.



A notification message is posted that the device was unassigned successfully.

NOTE: Monitoring is stopped for the patient. All patient information, data, and reports remain available in the practice data base.

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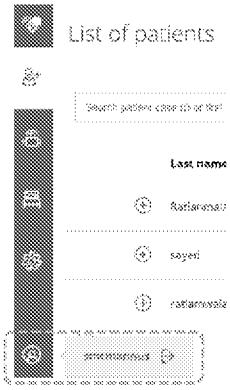
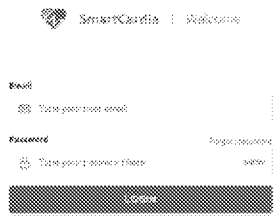
Clinician Logout

The last image of the main left navigation menu is the clinician logout option.



When “Logout” is selected the application closes and the SmartCardia Welcome LOGIN screen is displayed.



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Troubleshooting

7L Sensor, 7L Patch, and SmartCardia Phone

Problem	Cause	Correction
When logging into the SmartCardia *Phone* an error occurs	Unknown	Contact SmartCardia Customer Support
Problem	**Cause**	**Correction**
Related to the Bluetooth-ECG does not display on SmartCardia *Phone*	• *7L Patch* battery is low • *SmartCardia Phone is too far away from 7L Patch*	Always use new *7L Patch* (batteries are part of the *7L Patch*)
Problem	**Cause**	**Correction**
SmartCardia *Phone* is not connected to the SmartCardia backend server	• SmartCardia *Phone* lost its cellular connection or is out of range of cellular communication	Make sure the SmartCardia *Phone* has good cellular signal strength. Move location if necessary

7L Web Browser

Problem	Cause	Correction
Unable to login using the clinician's credentials (email and password)	• Clinician's account is not activated • Clinician's email is not correct • Clinician's password is not correct	Contact SmartCardia Customer Support team to: • Activate the account • Update the clinician's email • Set a new password
Problem	**Cause**	**Correction**
Invalid web certificate *7L Web Browser* says site is insecure, web certificate is invalid	The *7L Web Browser* has cached the old certificate	Remove the browser cache and reload the page

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Viewing Clinical Data

Problem	Cause	Correction
Missing functionality- Some of platform functions are not working properly. Artifacts are presented, problems with style, etc.	• User is not using supported Google Chrome browser (version 93 or higher) • Web browser has cached the old code	• Use Google Chrome version 93 or higher (do not use beta or alpha releases) • Remove browser cache and reload page
Problem	**Cause**	**Correction**
Real-time signals are not shown on clinical data page	• Patient is not connected to the server • Patient does not have the *7L Patch* on their chest	• Make sure the patient is connected and sending data to server • Confirm Bluetooth is activated on SmartCardia *Phone* • Verify no error is displayed on SmartCardia Mobile application • Put *7L Patch* on chest
Problem	**Cause**	**Correction**
Signal amplitude is too small, and signal cannot be visualized properly	Poorly positioned *7L Patch* High Body Mass Index (BMI)	• Reposition *7L Patch* • Manually change scale to smaller one so signal display will be higher amplitude
Problem	**Cause**	**Correction**
Text labels and controls overlap or appear partially	Screen size is too small, or resolution is too low	• *7L Web Browser* was designed to run in a system with minimum resolution of 1024x768 pixels • Use higher resolution in Operating System or use larger screen
Problem	**Cause**	**Correction**
Real-time signals are not shown on multi-patient view	Patient does not have the *7L Patch* on the chest	Put *7L Patch* on chest

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Reports

Problem	Cause	Correction
The generation of the reports never finishes	The server is processing other user's reports	Wait a few minutes until the server finishes processing the rest of the reports
Problem	**Cause**	**Correction**
Unable to download a PDF report	The browser is blocking the file downloads browser allows the file downloads	• Verify the report is being downloaded to a write-allowed location • Try to download the report to another location
Problem	**Cause**	**Correction**
Unable to open a PDF report	• PDF document is corrupted • User is trying to open document using a non-PDF reader application	• Open PDF report using PDF reader, like Adobe Acrobat Reader

Files

Problem	Cause	Correction
Unable to save a file	User does not have necessary write permissions	Make sure user has proper permissions to write to file and access directory where file is stored
Problem	**Cause**	**Correction**
Unable to upload a data file	The file does not have the extension ".sc". If a file is selected that does not have that extension, an error message is displayed.	Check file name and extension for correct format (.sc)

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Patient Use

Problem	Cause	Correction
Contact between skin and *7L Patch*- Quality of ECG signal is poor	• Skin was not cleaned well or *7L Patch* isn't attached correctly • Out-of-date *7L Patch* was used and no longer works well	Clean skin, clip or shave hair if needed, and attach new *7L Patch*
Problem	**Cause**	**Correction**
Quality of ECG signal is poor	Amplitude of ECG wave is small in Lead A, which is difficult for analysis	Reposition or replace *7L Patch*

We are here to help

Customer Support (800) 363-8151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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System Administrator Set-up for the Organization

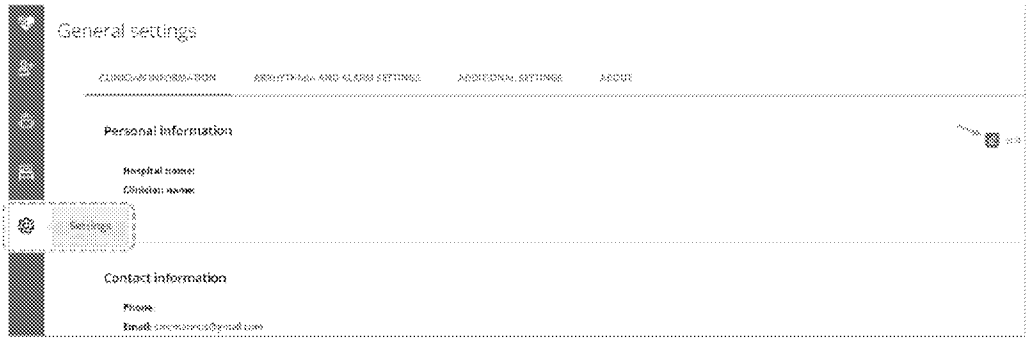
Initial Set-up for Clinician First Use

Registration of Clinicians on SmartCardia 7L Platform

- Contact SmartCardia Customer Support (800) 363-8151 to register clinicians to use the 7L Platform
- Viewing and report privileges for each clinician will be established

Settings

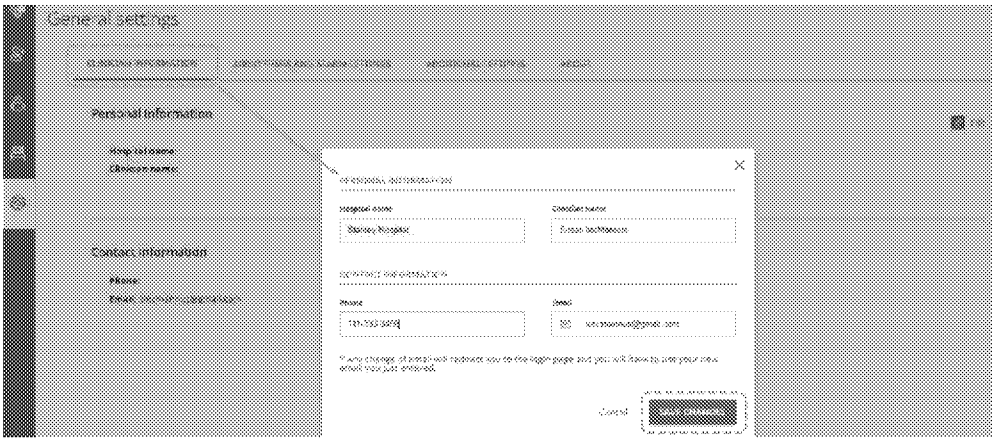
The administrator for each practice facility can edit the system general settings for their organization. On the left menu select the gear icon to access “Settings”.



Clinician Information

- Select the “Clinician Information” tab to edit clinician personal and contact information
- Select “Edit” on right side to make changes to hospital name, clinician name and phone
- Enter required information - Hospital name, Clinician name, and Phone. Email will be already entered. (Any change of email will redirect you to the login page and you will have to use your new email you just entered)
- Select “Save Changes” or “Cancel”

NOTE: To add new clinician, contact SmartCardia customer support at 800-363-8151



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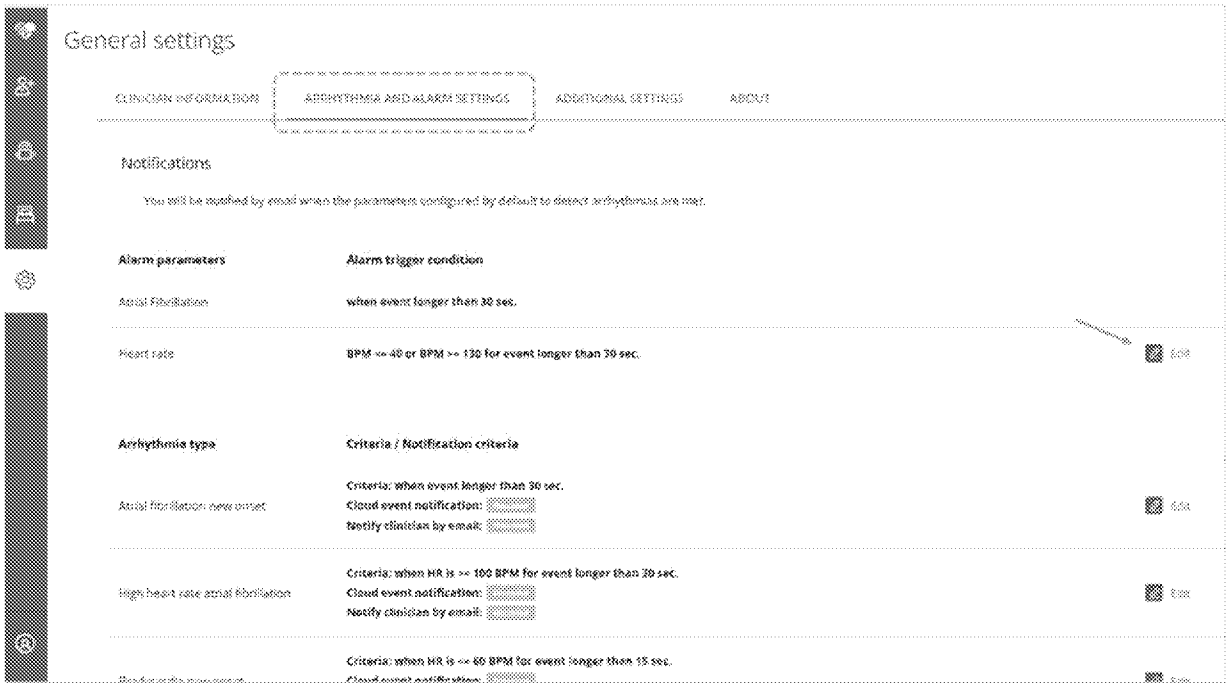
Configure Default Alarm and Arrhythmia Event Notification Settings for Organization

Alarms and arrhythmia event notifications are pre-set by the manufacturer and can be modified to meet the practice requirements. It is important to review settings and modify these to meet the practice requirements of the organization.

NOTE: Alarms and event notifications can be customized for individual patients based on their clinical condition and provider orders.

To set the hospital/practice alarm and notification settings:

- Select the "Arrhythmia and Alarm Settings" tab to adjust alarm, notification, and report settings
- See Alarms and Alarm Management page 35 and Arrhythmia Event Notification page 38 for detailed information



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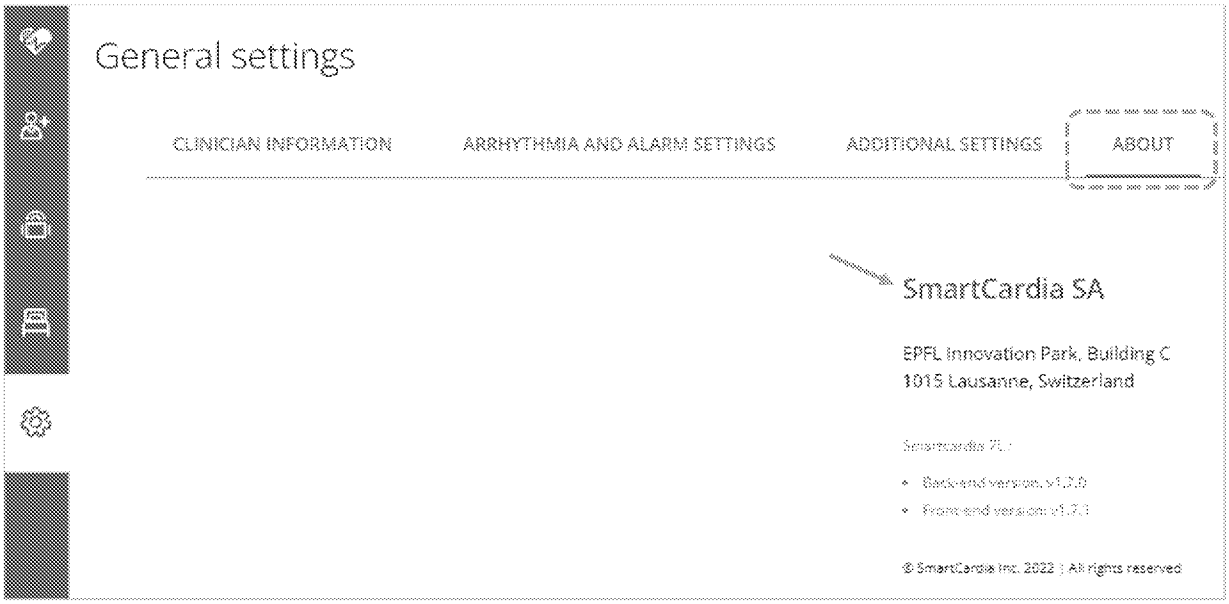
About

The About section provides SmartCardia SA corporate address and software version information.



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Product Specifications

Physical and Environmental

Physical and Environmental	
Size	7L Sensor: 1.97 x 1.18 x .39 inch; (50 x 30 x 10mm) 7L Patch (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14mm)
Weight	7L Sensor and 7L Patch: Less than 3.52oz. (100 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C)
	Operating: +41 to +104°F (+5 to + 45°C)
Humidity	Storage and transport: relative humidity up to 90%, non-condensing
	Operating: 10 to 95% at +41 to 95°F (+5 to +35°C) (non-condensing) / 700 – 1060 hPa
Safety	Type BF
Water Ingress	IPX7 (waterproof)
Battery Life	Up to 14 days, depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30 - 200	Beats per Minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Manufacturer Default Alarm Settings			
Parameter	Low Limit	High Limit	Alarm Delay
Heart Rate	40	130	0 seconds
Atrial Fibrillation	When event is longer than 30 sec.		NA

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Parameters

Body Measurements	Shown As	Range	Units	Accuracy	Comment
Heart Rate	HR	30 - 200	Beats per minute (BPM)	± 3 BPM	HR is computed every 2.048 seconds and the displayed value is updated every 2.048 seconds as the average of the last 6 beat-to-beat intervals
Atrial Fibrillation	AF	N/A	N/A	N/A	Computed every 10 seconds using last 30 seconds of ECG data

ECG Arrhythmia Definitions

Arrhythmia Definitions	
Normal Sinus Rhythm	Normal rhythm of the heart, originating in the sinoatrial (SA) node with a regular rhythm and heart rate of 60-100 beats per minute (BPM)
Bradycardia	Regular rhythm and heart rate below 60 BPM
Tachycardia	Regular rhythm and heart rate more than 100 BPM
Sinus Pause	SA node does not discharge an impulse for ≥ 2 seconds
Supraventricular Bigeminy	Every other beat is a premature supraventricular contraction
Supraventricular Trigeminy	Every other beat is a premature supraventricular contraction
Supraventricular Couplet	Two consecutive premature supraventricular beats
Supraventricular Triplet	Three consecutive premature supraventricular beats
Multi-focal Atrial Tachycardia (MAT)	Atrial tachycardia (heart rate greater than 100) originating in three or more different atrial ectopic pacemaker sites, P waves differ in size, shape, and direction
Nodal Rhythm	Regular rhythm arising from the atrioventricular (AV) node typically the QRS complexes are narrow
Atrial Fibrillation	Absence of P waves, with disorganized electrical activity in their place, and irregular R–R intervals due to irregular conduction of impulses to the ventricles.
Atrial Flutter	Absence of P waves, presence of characteristic "flutter waves". Individual flutter waves may be symmetrical, resembling p-waves, or maybe asymmetrical with a "sawtooth" shape.

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Ventricular Bigeminy	Every other beat is a premature ventricular contraction
Ventricular Trigeminy	Every third beat is a premature ventricular contraction
Ventricular Couplet	Two consecutive premature ventricular beats
Ventricular Triplet	Three consecutive premature ventricular beats
Ventricular Tachycardia	Originates in an ectopic pacemaker in the ventricles characterized as a wide complex (QRS duration greater than 120 milliseconds) and heart rate greater than 100 BPM
Monomorphic Ventricular Beat	QRS morphology is the same from beat to beat
Polymorphic Ventricular Beat	QRS morphology changes from beat to beat
Ventricular Flutter	Sinusoidal waveform without clear definition of QRS and T waves with loss of organized electrical activity with a rate over 250-350 BPM
Ventricular Fibrillation	Arrhythmia originating in multiple ectopic pacemakers in ventricles characterized by many fibrillatory waves and no QRS complexes
Asystole	Absence of any contractions
AV Block (First degree)	All normal P waves are followed by QRS complexes, but the PR interval is longer than normal (> 0.20 seconds)
AV Block (Second degree)	Some normal P waves are followed by QRS complexes, but some are not. Type I- PR interval progressively lengthens with each beat until atrial impulse is not conducted and QRS complex is dropped, AV nodal conduction resumes with next beat, and the sequence is repeated. Type II- PR interval remains constant with beats intermittently not conducted and QRS complexes dropped
AV Block (Third degree)	No relationship between P waves and QRS complexes (AV dissociation) the P wave rate is greater than the QRS rate
Pacemaker Rhythm	Arrythmia produced by an artificial pacemaker

Definitions from public source domain

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Attachment A: Alarm System Disclosures

Alarm System Description

The SmartCardia 7L Platform is a Distributed Information System (DIS) that communicates alarm conditions in real time for Heart Rate and Atrial Fibrillation. It provides alarm signals at a remote location but does not contain a mechanism for confirmation of receipt of the alarm signal.

	WARNING: The alarm system in the SmartCardia 7L Platform is a distributed information system and cannot be relied upon to indicate the clinician has received the alarm signals as there is no feedback mechanism for the clinician to acknowledge such receipt.

Alarm Conditions

The SmartCardia 7L Platform provides alarm signals for heart rate (upper and lower threshold violations) and Atrial Fibrillation. In addition, there are information signals for battery charge level and wireless communication status.

Alarm System Delay

The SmartCardia 7L Platform measures the ECG of a patient through a body worn sensor/patch (the source). The ECG waveform and heart rate are communicated via Bluetooth wireless communication to the SmartCardia Phone (the integrator) which acts as a gateway to the SmartCardia cloud-based backend server (the communicator). Alarm signals are communicated when the heart rate exceeds the alarm limit threshold (either upper or lower) or Atrial Fibrillation is detected for more than 30 seconds.

Delays from the 7L Sensor to the SmartCardia Phone to the SmartCardia backend and for presentation on the web browser are shown in Table 1. These were measured using a simulated signal and applying the alarm condition (High or Low HR, or Atrial Fibrillation) to the 7L Sensor and measuring the delay time to see the condition on the SmartCardia Phone, on the SmartCardia Backend server, and resultant display of the alarm signal on the SmartCardia Web Browser.

Table 1. Alarm Signal Delay

7L Sensor to SmartCardia Phone	SmartCardia Phone to SmartCardia Backend	SmartCardia Backend Server to Display on the SmartCardia Web Browser	Total Alarm Signal Delay (seconds)
Up to 100 msec.	Up to 1 sec.	User selectable 0, 4, 8 sec.	Based on user selection up to 9.1 sec.

Alarm signal delay is a user choice to reduce false alarm signals due to artifact or momentary violations of limit settings. Follow clinical practice guidelines for your institution when

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selecting an alarm delay. If no delay is desired, set to "0" and the alarm system delay will be approximately 1.1 seconds. However, this may result in multiple false alarm signals so take caution when making this selection.

Alarm System Presets

The SmartCardia 7L Platform contains one alarm preset for heart rate. This is set by the manufacturer to a lower heart rate value of 40 and an upper heart rate value of 130, either condition lasting longer than the user selectable alarm delay time of 0, 4, 8 seconds. The delay preset is at 0 seconds. . These alarm preset values are configured by the manufacturer and cannot be permanently modified.

These alarm preset values can only be changed by an operator with authorized credentials (username and password login) to ensure proper monitoring for a patient's clinical condition. These settings are automatically selected upon admitting a new patient.

Alarm Settings

In the event of a power failure or loss of power, whether momentarily or for up to 30 seconds, the alarm settings are not affected as these are stored in the SmartCardia cloud-based server. When power is restored to the viewing web browser computer, the alarm settings remain as they were prior to the power loss.

The SmartCardia 7L Platform does not continuously display the alarm limit settings but these are displayed through operation action by selecting "Patient Alarm Settings".
The SmartCardia 7L Platform does not incorporate "Intelligent Alarm System" as defined in the IEC 60601-1-8 standard, nor does it provide automatic setting of alarm limits. Customized alarm limit settings must be done through manual operator action.

To check the alarm system functionality, manually set an alarm limit below or above the current heart rate. The visual and auditory alarm signals should be present after the selected delay time.

Alarm Sounds

The SmartCardia 7L Platform provides alarm signals for heart rate (upper and lower threshold violations) and Atrial Fibrillation. Table 2 shows the alarm condition, alarm priority, alarm signal, and sound presented. The sound level is operator adjusted only, the SmartCardia 7L Platform does not incorporate dynamically algorithm-adjusted sound levels. The SmartCardia 7L Platform does not incorporate reminder signals as defined in the IEC 60601-8 Alarm Standard.

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Table 2. Alarm Signals and Sounds

Alarm Condition	Alarm Priority	Alarm Signal Displayed	Alarm Sound
Heart Rate lower than the low alarm limit setting	High	Patient tile outlined in red, Heart Rate numeric zone backfilled in Red and flashing, Heart Rate numeric in white text	High Priority pointer per IEC 60601-8 standard, Annex G, table G.3
Heart Rate higher than the high alarm limit setting	High	Patient tile outlined in red, Heart Rate numeric zone backfilled in Red and flashing, Heart Rate numeric in white text	High Priority pointer per IEC 60601-8 standard, Annex G, table G.3
Atrial Fibrillation detected for greater than 30 seconds	Medium	AF message displayed below the heart rate when in the single patient data view, below patient name in the multi-patient view. AF message is highlighted in yellow with 'AF' in white text and flashing.	Medium Priority pointer per IEC 60601-8 standard, Annex G, table G.3

The alarm signal auditory sound level is controlled by the speaker volume control on the personal computer that is presenting the SmartCardia *7L Web Browser*. Personal computers have the ability to turn the auditory sound completely OFF (Mute).

	WARNING: Do not try to turn the volume on the personal computer to OFF or Mute. Do not try to adjust the volume to such a low value that auditory alarm signals cannot be heard. The 7L Platform will indicate a waring on the display.

The SmartCardia 7L Platform enables auditory alarm sounds to be turned OFF for an individual patient for five minutes. At the expiration of the five minutes, the audio is turned ON automatically. This inactivation state only impacts the selected patient, other patient's audio remains ON unless they are individually inactivated.

This inactivation state is indicated in the patient tile using the audio off symbol.

Operator Position

For continuous monitoring, the operator should be located from one to four meters from the display of patient data to ensure they can identify alarm signals.

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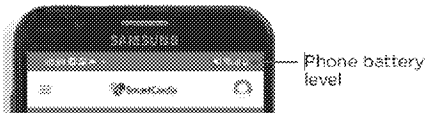
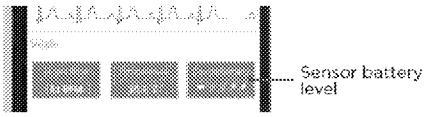
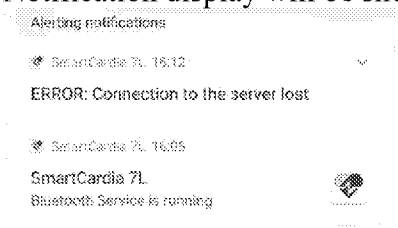
Information Signals

The SmartCardia 7L Platform displays information signals as shown in Table 3.

Table 3. Information Signals

Information Signal	**Meaning**	**Display**	**Sound**
Battery charge level in SmartCardia Phone	Charge level in SmartCardia Phone		Visual indicator
Battery charge level in the SmartCardia 7L Sensor green	Charge level at 100%, 75%, 50% 25%	 100% (4 green dots), 75% (3 green dots), 50% (2 green dots), 25% (1 green dot)	Visual indicator
Battery charge level in the SmartCardia 7L Sensor – red	Charge Level less than 10% remaining		Visual indicator
Bluetooth Connection	Bluetooth not connected between the SmartCardia 7L Sensor and the SmartCardia phone	Bluetooth ON icon located in the upper right of the top bar of the phone disappears, SmartCardia logo appears next to the time. In addition, a red banner "trying to re-connect Please wait" appears on mobile app display	Single notification sound
Cellular Connection	The SmartCardia Phone and the cloud service are not connected	The same SmartCardia logo will appear, and Wi-Fi icon will disappear. If you swipe down from top, the Alerting Notification display will be shown 	Single notification sound

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Alarm System Logging

The SmartCardia 7L Platform logs all alarm related data in a responsible organization log. There is no separate operator alarm system log. The alarm system log can only be accessed by SmartCardia authorized personnel. The alarm log is maintained in the SmartCardia cloud-based backend server. Powering down of the SmartCardia 7L Web Browser instance does not affect the alarm system log. The SmartCardia cloud-based server is maintained by Amazon Web Services and is redundant and automatically backed up. The alarm system will not experience a total loss of power; therefore, the alarm system log is not impacted.

The alarm system log is stored on the SmartCardia cloud-based backend server and has an unlimited capacity. In the event the log reaches maximum capacity, the oldest data stored are deleted and the newest data are saved.

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Attachment B Electromagnetic Compatibility

FCC ID: XOYNINAAB30
Medical electrical equipment can generate or receive electromagnetic energy or interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601-1-2:2020, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2:2015.
Product Essential Performance specified for EMC:

1. The Wireless EEG System shall not change operating modes, settings, or modify stored data during EMC immunity testing.
2. Within 30 s after exposure to transient electromagnetic phenomena, the device shall resume normal operation without operator intervention. The resumption to normal operation shall be without loss of any operator settings or stored data

Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to and when using the product.
Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of electrical medical equipment. If this device does cause harmful interference to other devices, you may need to do one of the following:
• Reorient or relocate the other device,
• Move the devices farther apart,
• Contact the device manufacturer for assistance.
Your service provider for RF communications equipment may have a minimum recommended separation distance between that equipment and the product.
Compliance is only claimed for sensors and accessories that are listed in documentation accompanying the product.

Warnings and Cautions

- The use of accessories, sensors, and cables other than those specified in the technical and user documentation can result in increased electromagnetic emissions or decreased immunity of the product.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Short-range radio communication is subject to interruption that may be caused by interference from other radio sources in the vicinity. This can include microwaves (microwave ovens), other Bluetooth devices, and cellular phones. Outside of the operating frequency and 5% above and below is the exclusion band according to IEC

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60601-1-2. The short-range radio connection is immune up to 10 V/m in the frequency range from 80MHz to 2.7 GHz. If the strength and duration of the radio interference is strong, the interruption may occur for an extended period.

- Always inspect the product before use. If the product appears damaged or out of sorts, do not use.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The SmartCardia 7L Platform is equipped with a wireless communication interface and intentionally receives RF electromagnetic energy for the purpose of its operation. Therefore, other equipment may cause interference, even if that other equipment complies with CISPR emission requirements.
- These guidelines may not apply in all situations. Electromagnetic energy is affected by the type of structures, objects, and people in the vicinity of the product.
- The SmartCardia 7L Platform should not be used in an aircraft.

To Reduce Electromagnetic Interference

The SmartCardia System and associated accessories can be susceptible to interference from other RF energy sources and continuous, repetitive, power line bursts.

Examples of other sources of RF interference are other medical electrical devices, cellular phone products, information technology equipment, microwave ovens, and radio/television transmission. If interference is encountered, as demonstrated by excessive artifact on the ECG or a sudden and dramatic change in measurement values, you should attempt to locate the source.

• Is the interference due to a misplaced or poorly applied SmartCardia 7L Sensor/7L Patch? If this is the case, check the installation to ensure it is properly installed or positioned and located correctly per the user instructions.

• Does the interference come and go or is it always present?

• Does the interference happen only when the SmartCardia 7L Sensor/7L Patch is in a specific place?

• Does the interference occur only when the SmartCardia 7L Sensor/7L Patch are near other medical or electrical equipment?

The first thing to do when the interference source is located is to reduce the interference as much as possible by moving as far from the source as possible. Do this prior to contacting your service representative to ensure you have taken necessary precautions.

Restrictions for Use

Artifact on ECG and other physiological waveforms caused by electromagnetic interference should be evaluated by a physician or physician-authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

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The SmartCardia 7L Platform environment of use is in a physician office, outpatient facility, or in the patient's home.

Electromagnetic Compatibility (EMC) Specifications
Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your equipment according to the EMC information provided in this manual. Portable and mobile radiofrequency (RF) communications equipment can affect medical electrical equipment.
Accessories Compliant with EMC Standards
Only accessories listed as accessories for the SmartCardia system comply, with the requirements of IEC 60601-1-2:2014.

Electromagnetic Emissions
Specification
The SmartCardia 7L Platform uses Bluetooth LE version 5 and includes an RF transmitter for Bluetooth Low Energy that transmits data in the 2.4 GHz frequency band (2.400 to 2.4835GHz)
using data rates of 2 Mbps

Guidance and manufacturers declaration – electromagnetic emissions		
The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Avoiding Electromagnetic Interference**
Radio Frequency (RF) emissions	Group 1	The SmartCardia System uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SmartCardia System is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Not Applicable	Device is powered by disposable battery only
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not Applicable	Device is powered by disposable battery only

Electromagnetic Immunity

Guidance and manufacturers declaration – electromagnetic immunity

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The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Comments**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ±8kV, ±15kV air	± 8 kV contact ± 2kV, ± 4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC61000-4-4 EFT/burst immunity	± 2 kV, 100 kHz burst frequency, coupling duration ≥ 60s, positive and negative polarity	± 2 kV, 100 kHz burst frequency, coupling duration ≥ 60s, positive and negative polarity	
IEC61000-4-5 Surge Immunity	± 0.5 kV, ± 1 kV differential mode source impedance, positive and negative polarity, phase angle at 0°, 90°, 180°, 270°, 60 sec repetition rate, 5 surges at each position	± 0.5 kV, ± 1 kV differential mode source impedance, positive and negative polarity, phase angle at 0°, 90°, 180°, 270°, 60 sec repetition rate, 5 surges at each position	AC Power Line Cable, unshielded, active status, 0.3 m in length
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz 60 s each axis (X, Y, Z)	30 A/m 50 Hz or 60 Hz 60 s each axis (X, Y, Z)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, home, and/or healthcare environment
IEC61000-4-11 Voltage dips	100% dip; 0.5 period, phase angle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 3 interruptions, 15s repetition	100% dip; 0.5 period, phase angle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 3 interruptions, 15s repetition	

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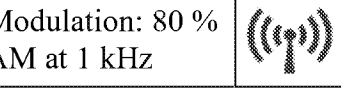
	100% dip; 1 period, phase angle at 180°, 3 interruptions, 15s repetition	100% dip; 1 period, phase angle at 180°, 3 interruptions, 15s repetition	
	30% dip; 30 periods (60 Hz), 180°, 3 interruptions, 15s repetition	30% dip; 30 periods (60 Hz), 180°, 3 interruptions, 15s repetition	
	100% dip; 300 periods (60 Hz), 180°, 3 interruptions, 15s repetition	100% dip; 300 periods (60 Hz), 180°, 3 interruptions, 15s repetition	
IEC61000-4-39 Immunity - Proximity Magnetic Fields	30 kHz, CW Modulation, 5 cm distance, 8 A/m	30 kHz, CW Modulation, 5 cm distance, 8 A/m	
	134.2 kHz, PM Modulation, 5 cm distance, 65 A/m	134.2 kHz, PM Modulation, 5 cm distance, 65 A/m	
	13.56 MHz, PM Modulation, 5 cm distance, 7.5 A/m	13.56 MHz, PM Modulation, 5 cm distance, 7.5 A/m	

Guidance and manufacturers declaration – RF Immunity

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform may use it in such an environment.

Immunity Test	**Immunity Test Levels**	**Compliance Levels**	**Electromagnetic Environment Guidance**
IEC 61000-4-6 Conducted Disturbances, Induced by RF Fields AC Power Line Cable, unshielded, active status, 0.3 m in length	3 Vrms 0.15 MHz – 80 MHz, 6 Vrms in ISM bands between 0.15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	3 Vrms 0.15 MHz – 80 MHz, 6 Vrms in ISM bands between 0.15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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IEC 61000-4-3 Radiated RF	10 V/m, Antenna Separation 2.5 m, 80 MHz – 1000 MHz, 1.0 GHz - 2.7 GHz, 80 % AM modulation at 1 kHz, 1% frequency step @ 3s dwell time	10 V/m, Antenna Separation 2.5 m, 80 MHz – 1000 MHz, 1.0 GHz - 2.7 GHz, 80 % AM modulation at 1 kHz, 1% frequency step @ 3s dwell time	
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartCardia 7L Platform is used exceeds the applicable RF compliance level above, the SmartCardia 7L Platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended Separation Distances

Guidance and manufacturers declaration – recommended separation distances between portable and mobile RF communications equipment and the SmartCardia 7L Platform

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter - W	**Separation distance according to frequency of transmitter m**		

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	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2√P	**d = 1.2√P**	**d = 2.3√P**
	Minimum Separation distance	**Minimum Separation distance**	**Minimum Separation distance**
0.01 W	0.1 m	0.1 m	0.2 m
0.1 W	0.4 m	0.4 m	0.7 m
1 W	1.2 m	1.3 m	2.3 m
10 W	3.8 m	3.8 m	7.3 m
100 W	12.0 m	12.0 m	23.0 m
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).			

Portable and mobile RF communications equipment should be used no closer to any part of the SmartCardia System, than these recommended separation distances that are calculated from the equation appropriate for the frequency of the transmission.

Enclosure Port Immunity

Guidance and manufacturers declaration – Proximity Fields from RF Wireless Communications Equipment

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.

Band (MHz)	Test frequency (Mhz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test level (V/m)
380 – 390	385	Pulse modulation 18 Hz	1.8	0.3	27
430 – 470	450	Pulse modulation 18 Hz	2	0.3	28
704 – 787	710	Pulse modulation 217 Hz	0.2	0.3	9
	745	Pulse modulation 217 Hz	0.2	0.3	9
	780	Pulse modulation 217 Hz	0.2	0.3	9
800 – 960	810	Pulse modulation 18 Hz	2.0	0.3	28

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	870	Pulse modulation 18 Hz	2.0	0.3	28
	930	Pulse modulation 18 Hz	2.0	0.3	28
1700 – 1990	1720	Pulse modulation 217 Hz	2.0	0.3	28
	1845	Pulse modulation 217 Hz	2.0	0.3	28
	1970	Pulse modulation 217 Hz	2.0	0.3	28
2400 – 2570	2450	Pulse modulation 217 Hz	2.0	0.3	28
5100 – 5800	5240	Pulse modulation 217 Hz	0.2	0.3	9
	5500	Pulse modulation 217 Hz	0.2	0.3	9
	5785	Pulse modulation 217 Hz	0.2	0.3	9

Note:

1. For some services, only the uplink frequencies are included.
2. The carrier shall be modulated using a 50% duty cycle square wave signal.
3. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case

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Attachment C: Wireless Communications Specifications

The SmartCardia 7L Platform consists of two wireless links: a Bluetooth link between the 7L Sensor and the SmartCardia smartphone and a cellular link between the SmartCardia smartphone and the internet.

Link	Standard	Frequency	Power output / modulation
BLE link between sensor and phone	IEEE 802.15.4 Bluetooth V 5.0	2.4 Ghz Gaussian	8 dBm Frequency spread spectrum with PSK modulation Gaussian frequency shift
Cellular link between phone and server	Cellular network	746-757 MHz & 776-787 MHz	up to 3 Watts 4G. CDMA-less B2/B3/B4/B5/B7/B12/B13/B20/B66

Operating characteristics:

BLE link

The BLE link is preconfigured by SmartCardia at the time of manufacturing. BLE version 4.0 or greater is implemented. The link is configured such that only SmartCardia sensors will be recognized by the SmartCardia smartphone. No other BL or BLE devices will be recognized. The operating range is within 3 meters. The patient IFU includes a note to keep the 7L Sensor within 10 ft. of the smartphone at all times. Quality of Service and Cybersecurity requirements are managed through the configuration of the sensor and phone by authorized SmartCardia personnel. All data originating in the phone is encrypted at rest and during transport.

Cellular phone link

The cellular phone link is determined by the phone platform, the Samsung Galaxy A12 Smartphone. The phone is configured by SmartCardia authorized personnel and placed in a kiosk mode. The SmartCardia phone hosts no other applications other than the SmartCardia application. The audio telephone operation is disabled. The phone UI includes a cellular signal strength bar. When connectivity is lost the signal strength bar indicated no bars and a notification message is sent to the clinician viewer. When connectivity is restored all data (up to 14 days) stored in the sensor and phone are forwarded to the SmartCardia Server. Quality of Service requirements are managed by SmartCardia when the phone is configured in the kiosk mode. The cellular link is unburdened by all other cellular data allowing only SmartCardia packets to communicate with the SmartCardia server.

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Network Access

Network access is managed only by authorized SmartCardia personnel. All devices are preconfigured during the provisioning process. Users have no access to network administrative functions.

Warnings and Cautions regarding wireless links

Warnings and cautions associated with wireless communications are found in the patient IFU, Clinician IFU and the EMC section of this IFU.

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Attachment D: Cybersecurity Disclosure

SmartCardia is certified to ISO 27001; 2013 Information technology- Security techniques- Information security management systems- Requirements. As continued post-market activities, SmartCardia conducts an annual audit to this standard.

SmartCardia employs a risk-based approach per the ISO 14971 standard to design and develop products with the appropriate cybersecurity protections for the intended use. Hazards are identified early in the project development lifecycle and updated at each phase of development to ensure existing risks are mitigated and any new risk are identified and addressed prior to commercialization. This process ensures the proper maintenance and continuity of device safety and essential performance as well as the continued safety and effectiveness.

The SmartCardia 7L Platform cybersecurity includes:

- **Identification and Protection of Device Assets and Functionality**
    - The SC System is designed to protect assets and functionality to reduce risk of multi-patient harm due to the loss of authenticity, availability, integrity, and confidentiality. Protection mechanisms are established that prevents all unauthorized use (through all interfaces) to ensure code, data, and execution integrity (subversion of system functionality/safety/security features) and protect confidentiality of data (insofar as its release could be leveraged) to effect multi-patient harm.
    - Appropriate protections are in place regarding the SC System that prevents sensitive information from being read by unauthorized parties either in storage or in transmission through the following (Encryption is used)
- **Limit Access to Trusted Users & Devices Only**
    - Access to the SC System is through the authentication of users via:
        - Email and password (for clinicians).
        - Device MAC and patient's date of birth (for patients)
    - Automated time methods will be used to terminate sessions when appropriate.
- **Passwords will be unique for each user and no public access will be given.**
    - During new patient provisioning, a device is assigned to the patient and a monitoring service is configured. The new patient will receive a kit with a device and a phone, with the SmartCardia app already installed. The patient will login using the device MAC and his/her date of birth. This identifies the patient and the specific sensor(s) connected to the mobile App. This authentication is encrypted and stored in an isolated repository with no public access.
    - Administrative access is controlled by a unique Name and Password.

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Cybersecurity Bills of Material (CBOM)

Manufacturer	Manufacturer Reference	Revision	Purpose
Google	Android	10	Mobile Gateway to cloud based server
	com.android.support:support-V4	v4:27.1.1	Support Library
	com.android.support:support-V13	V13:27.1.1	Support Library
	com.android.volley:volley:1.1.0	1.1.0	HTTP request Library
	com.rabbitmq:amqp-client:	4.6.0	AMQP Client for publish/subscribe
	org.greenrobot:eventbus:	3.1	Event bus for inter-module communications
	com.andrognito.flashbar:flashbar:	1.0.3	Customizable alert and notification Library
Google	Chrome Web Browser	93	Web browser Operating system
Ubuntu Server	Linux	18.04 LTS	Server Operating System

Cybersecurity - 7L Sensor:

- The sensor is a sealed unit with no external ports published to an end user.
- There are no software of unknown provenance (SOUP) in the sensor firmware.
- All firmware and software are controlled internally with no access allowed by end users.
- The sensor hardware manufacturer is certified to ISO 13485. The software load is only for a minimum number of functions. Cyclic redundancy checks (CRC) ensure uncorrupted load of data.
- Firmware is loaded after the sensor is completely encapsulated with CRC checks to ensure uncorrupted loading. The sensor is not serviceable.
- Firmware updates are performed over the BLE link using BLE DMU profile. An over-the-air update can only be performed under the control of SmartCardia. Updating sensor software requires acknowledgement of a private key embedded in the sensor firmware. This key is known only to trained authorized SmartCardia personnel.
- The BLE link data is encrypted during transport in normal operation.

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Cybersecurity - Mobile Gateway:

- The Android smartphone mobile gateway is configured and provided by SmartCardia authorized personnel.
- The Android OS is placed in kiosk mode with only necessary functions enabled to support the SmartCardia App. The end user is not allowed to add Apps.
- The USB-C port is disabled of all functionality except battery charging.
- WWAN link is encrypted during transport.
- All data stored by the SmartCardia App is encrypted.
- SW updates are performed only by trained authorized SmartCardia personnel over a secure https link.

Cybersecurity - Backend AWS

- The Amazon Web Service instance is configured and managed by SmartCardia authorized personnel.
- The Amazon Web Service is configured with automatic backup service such that the database can be restored as required by authorized SmartCardia personnel.
- Two factor authentication is required by SmartCardia personnel in order to access administrative functions.
- PHI is separated from physiologic data in the AWS database.
- All data is encrypted at rest and in transport.
- AWS provides routine period scans for the detection of intrusion and malware.

Cybersecurity - Remote Viewing Station

- Access to SmartCardia remote viewing is only through a secured browser.
- All communication between the remote viewing station and backend AWS is encrypted over a https link.

Cybersecurity - Notification to User

In the event of a security breach, users are notified by SmartCardia as soon as the breach becomes noticed. The notification method may be via email or other direct communication.

Forensic Investigation

AWS captures and stores forensic evidence for investigation and resolution.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118
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Attachment E: Reprocessing

Reprovisioning Process

The patient is instructed to return the SmartCardia *7L Sensor*, SmartCardia *Phone*, medical grade charger, and phone cable using the pre-addressed, pre-paid mailing envelope for reprocessing. They should dispose of all unused *7L Patches*.

NOTE: The *7L Sensor* may be returned inside of the used *7L Patch* if there is difficulty removing the *7L Sensor* after use.

The provider organization reprocesses their own patient returned devices or an approved reprocessing center. Both situations follow the same reprocessing steps.

The reprocessing process shall take place at room temperature and humidity on a clean surface that is separated from all other activities.

Individuals performing this process shall be trained and documented in the appropriate training record.

Service life is not adversely impacted by the number of reprocessing cycles.

Receipt of *7L Sensor*, *Phone*, medical grade charger, and phone cable

- Record the date and time they are received for reprocessing.

NOTE: If any unused *7L Patches* are received, discard.

7L Web Browser

- Verify the *7L Sensor* is listed as an available device on the *7L Web Browser* page assigned to the responsible organization. If not, "Unassign" it from the previous patient.

Clean and Disinfect

1. Using protective gloves, inspect the *7L Sensor*, SmartCardia *Phone*, medical grade charger, and phone cable for physical damage including label integrity.

   NOTE: If the used *7L Patch* is returned with the *7L Sensor* still inside, carefully remove the *7L Sensor* and properly dispose of the *7L Patch*.

   NOTE: Do not immerse the *Phone* in water or other liquid.

2. Remove any debris, damaged labels, adhesive, etc. from surfaces with a damp cloth using a mild detergent.
3. Disinfect the *7L Sensor* with PDI Super Sani-Cloth® Germicidal Disposable Wipe for five minutes following the instructions on the package.
4. Wipe Phone with disinfectant wipes per instructions on the disinfectant package.
5. Wipe devices with clean cloth to remove any residual disinfectant.
6. Set devices aside and covered for two minutes with a clean disposable towel to maximize drying time.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ.STATUS@fda.hhs.gov or 301-796-8118

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Testing of Components

1. Check if there is any damage on the *7L Sensor* or labels. If you find any damage, stop using it, and contact SmartCardia Customer Support.
2. Insert *7L Sensor* into a test *7L Patch* to verify it works (LED lights turn on)
3. Turn Phone on and test for wireless link. (Verify BLE link between *Phone* and *7L Sensor* is connected)
4. Using the *7L Mobile Application*, scan for the *7L Sensor*
5. Verify the MAC address of the *7L Sensor* is recognized
6. Record testing of *7L Sensor*, MAC address, and *Phone*
7. Store cleaned and disinfected *7L Sensor*, *Phone*, medical grade charger, and phone cable (keep the *7L Sensor* and SmartCardia *Phone* together as they are paired)

Provision 7L Sensor and Phone for new patient admission

1. "Add Patient" on the *7L Web Browser*
2. Enter patient information
3. Select the *7L Sensor* device and *Phone* that are going to be used by the new patient
4. Insert the selected *7L Sensor* into an unused *7L Patch* (confirm LED lights turn on)
5. Turn on the Phone (confirm that it is fully charged)

NOTE: If "Error occurred while logging you in"

- Select CANCEL at the bottom of the screen
- For password, enter 0111, select "OK".
- Scan
- Select S7L with the MAC address of the *7L Sensor* in use
- Once connection successful, select OK to pair *7L Sensor* and *Phone*

Verification *Sensor* and *Phone* are ready to send patient

1. Verify that the *Phone* screen shows Welcome with the new patient's name asking them to enter their date of birth
2. Turn off *Phone* and remove *7L Sensor* from *7L Patch* used for testing

Preparation of SmartCardia Kit for shipping

Insert the following components into the kit box insert

- *7L Sensor placed in sensor box*
- *Phone*, phone cable, and *Phone* instructions placed in phone box
- Medical grade charger

Place on top of the assembled components listed above

- Small envelope for phone return to put into larger pre-addressed, pre-paid mailing envelope for return following monitoring service

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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- *7L Patch* (two packages)
- Guide card, “let’s get started assembling and positioning patch”
- Patient User Guide

Reference: ISO 17664-1:2021(E) Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

Software License Agreement and Warranty

Contact SmartCardia Customer Support for information about the software license agreement and warranty.

Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118
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UDI	Unique Device Identifier(s) 7L Sensor 7640375610058 7L Patch 7640375610041
	SmartCardia Inc. EPFL Innovation Park, Building C 1015 Lausanne, Switzerland Customer Support: 800-363-8151
REF	PL-08 SmartCardia 7L™ Platform – Patient Guide
	July 15, 2023
Rx ONLY	Prescription Only
	Consult Instructions for Use or User Manual
	Type BF
	See Warnings and Cautions
EC REP	SmartCardia Inc. EPFL Innovation Park, Building C 1015 Lausanne, Switzerland
FCC	This device complies with Part 15 of the FCC Rules. Operation and is subject to the following two conditions. 1. These devices may not cause harmful interference, and 2. These devices must accept any interference received, including interference that may cause undesired operation.
FCC ID:	XPYNINAAB30
	Non-ionizing electromagnetic radiation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118
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· PL-10 SmartCardia 7L Clinician QRG

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We are here to help 800-363-8151

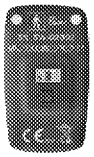
System Description

The SmartCardia 7L™ Platform is a system comprising of a wireless sensor component (the *7L Sensor*), an adhesive patch (the *7L Patch*) that the *7L Sensor* connects to, a mobile component (the SmartCardia *Phone*), and a backend server cloud platform (SmartCardia *7L Web Browser*) used to access the patient data.

SmartCardia *7L Sensor*

A reusable Sensor (NOT Disposable)

- Inserts into *7L Patch*
- Sends patient ECG data to SmartCardia Phone
- Waterproof (IPX7) in *7L Patch*



SmartCardia *7L Patch*

A single-use Patch (Disposable)

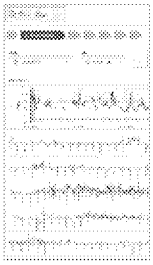
- Includes batteries
- Holds reusable *7L Sensor*
- Medical adhesive to skin on chest

SmartCardia *Phone*

- Mobile gateway for SmartCardia data
- Must always be kept close to SmartCardia *7L Sensor*
- Charge daily (or more often)

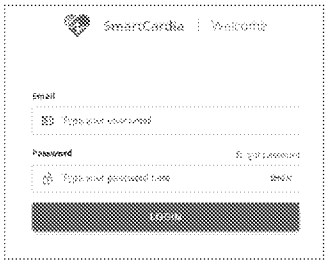
SmartCardia *7L Web Browser*

- Service mode choices (Holter, Extended Holter, Event, Mobile Cardiac Telemetry)
- View patient data, manage alarms, perform Holter analysis, create reports



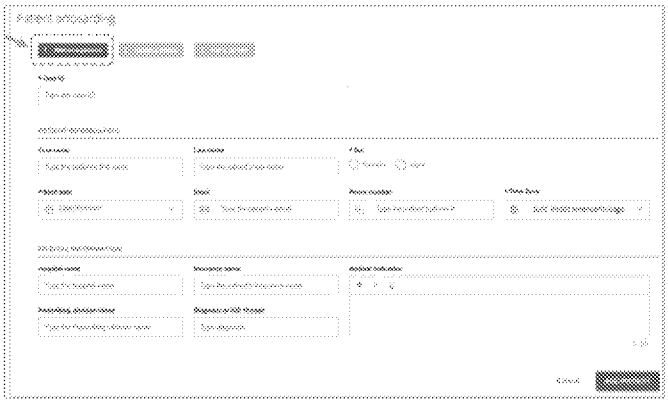
Clinician LOGIN

- Enter your user email and password
- Click LOGIN to show list of patients



Admit a Patient

- On “List of patients” screen in upper right corner select “ADD PATIENT”
- The “Patient onboarding” screen opens with the “Add new patient” screen
- Enter all patient information
- Select “ADD PATIENT” at the bottom right of screen to advance to next step in onboarding process to assign a device



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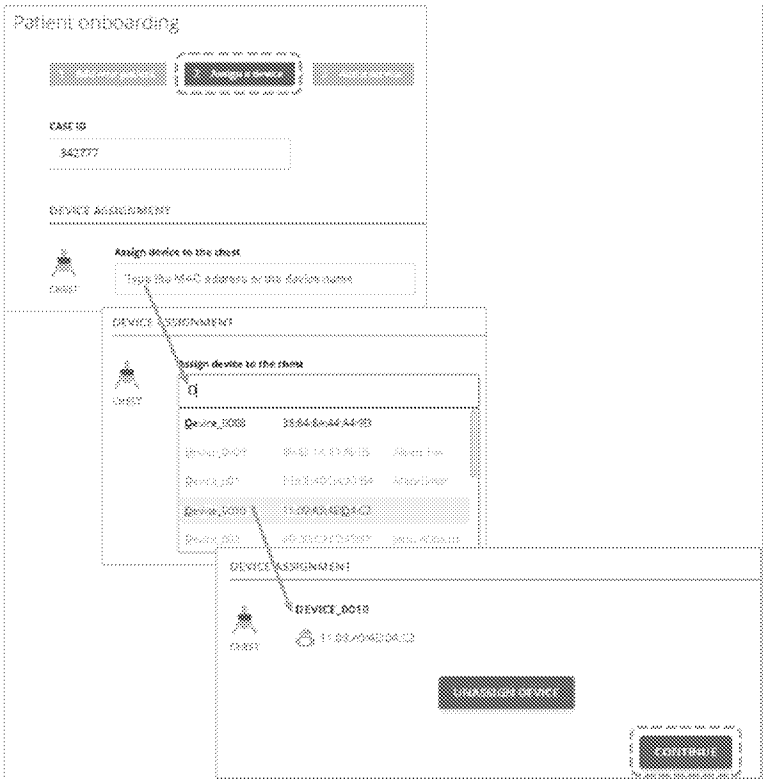
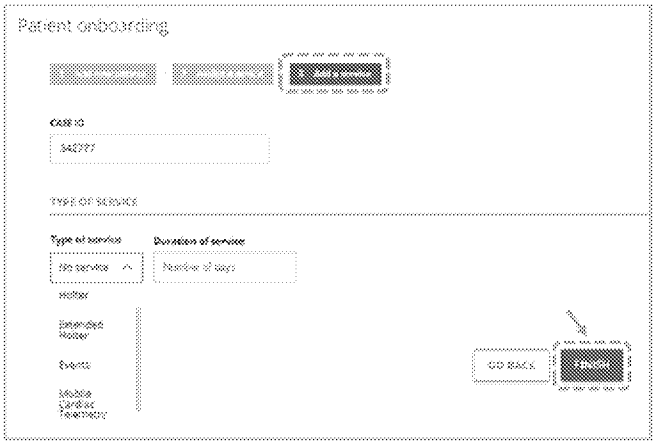
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

- On the next screen "Assign a device"
- Type MAC address or device name. As information is typed, a box below begins to populate with device, then select it from list of options, next select "CONTINUE" to associate *7L Sensor* to the patient (MAC address is found on surface of *7L Sensor* that is inserted into *7L Patch*)
- This advances you to the next step in onboarding process to "ADD A SERVICE"



- From drop-down menu, select type of service
- Enter number of days duration of service
- Select "FINISH"
- This new patient is now added to the patient list and displayed on Multi-Patient View



NOTE: Service begins once *7L Sensor* is on patient's body and connected to *7L Mobile Application*.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display. Consult Technical Manual.

Service type options and features

		Features				
		Measurements	**Event Capture**	**Real Time View**	**Duration**	**Report Editing and Creation**
Service Type	**Holter**	7 leads ECG, Atrial Fibrillation	Yes	Optional	<48 hrs.	Yes
	Extended Holter	7 leads ECG, Atrial Fibrillation	Yes	Optional	>48 hrs.	Yes
	Event	7 leads ECG, Atrial Fibrillation	Yes	Optional	Ordered	Yes
	Mobile Cardiac Telemetry	7 leads ECG, Atrial Fibrillation	Yes	Yes, 24/7 monitor watchers	Ordered	Yes

Type of service for monitoring is listed as ordered by the physician. Status is “Running”, “Not Started”, or “Finished”. Service can be changed or stopped at any time as ordered by the physician.

Select “Stop” to change the type of monitoring service and/or number of days.

Select “Stop” at the completion of monitoring and continue to “Unassign” *7L Sensor* device.

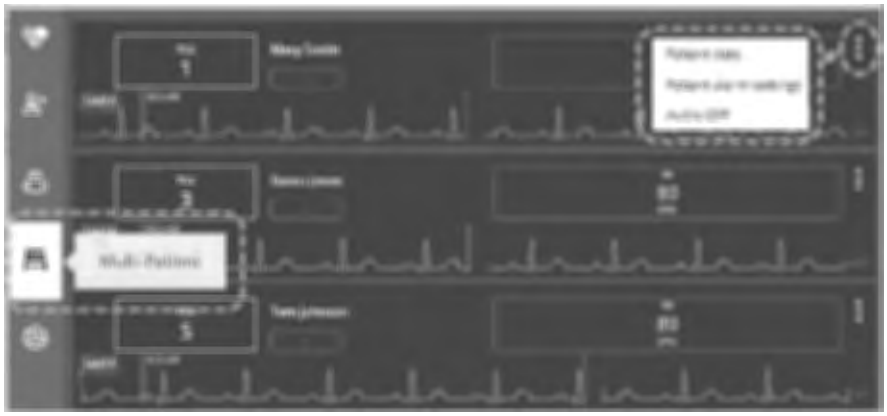
Customizing Heart Rate Alarm and Event Notification Settings for Individual Patients

Alarms and event notifications are pre-set by manufacturer, can be modified to meet practice requirements, customized for patient clinical condition, and provider orders.

- Select patient by clicking on the “Patients” icon on left menu to see list of patients
- Click on patient’s name to adjust their heart rate alarm and arrhythmia event notification settings
- On right navigation menu, select “Alarm Settings” to review and edit heart rate alarm and arrhythmia event notification settings

Access alarm and arrhythmia event notification settings when in “Multi-Patient” view

- Click on ‘Three Dots’ on upper right side of patient tile of your selected patient
- In pop-up window menu, select “Patient alarm settings” to review heart rate alarm and arrhythmia event notification settings and edit settings



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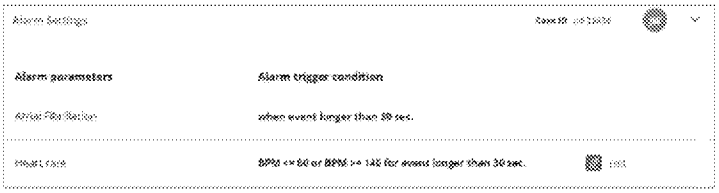
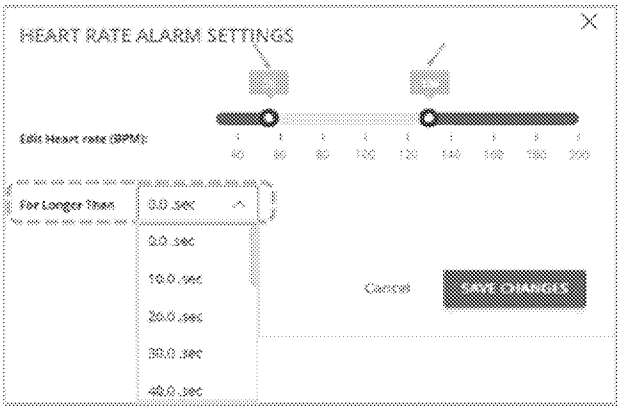
Alarm Settings screen:

Heart Rate Alarm parameters: Customize the alarm trigger condition for heart rate

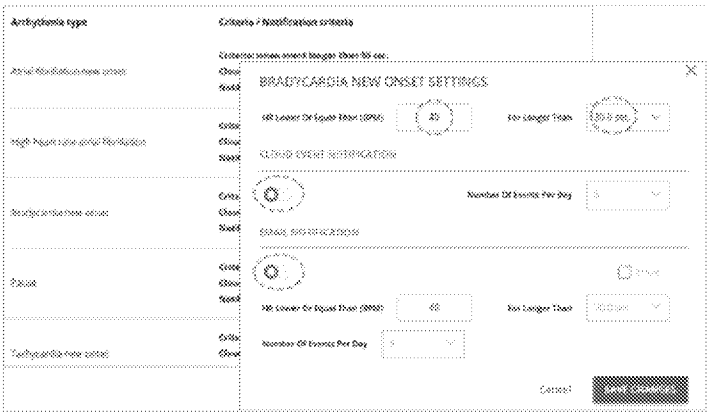
- Select "Edit" to change heart rate alarm setting values
- Slide each circle above scale to the left or right to adjust alarm settings (options in increments of 5 BPM)
- Using drop-down menu you can change length of time (0 – 120 seconds) for this alarm setting (i.e. when heart rate setting is less than 60 or greater than 140 BPM for longer than 30 seconds means an alarm will be triggered when the heart rate is outside of those limits for more than 30 seconds)
- Select "SAVE CHANGES" or "Cancel" if you choose to not make any changes





Arrhythmia Event Notification: Notification criteria and settings can be customized for arrhythmia type

- Select "Edit" to customize arrhythmia event notifications
- Enter numerical value for heart rate limit and select number of seconds duration for length before notification
- Cloud (*7L Web Browser*) Event Notification- use radio button to turn Off/On this arrhythmia event notification to be sent to the *7L Web Browser* and you can set how many of these arrhythmia events per day are sent when this function is enabled
- Email Notification- use radio button to turn Off/On for email to be sent to the patient's clinician listed in their profile and enter numerical value, select number of seconds duration of delay, and number of events per day are emailed when enabled
- Select "SAVE CHANGES" or "Cancel" if you choose to not make any changes



WARNING: Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a skilled clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.

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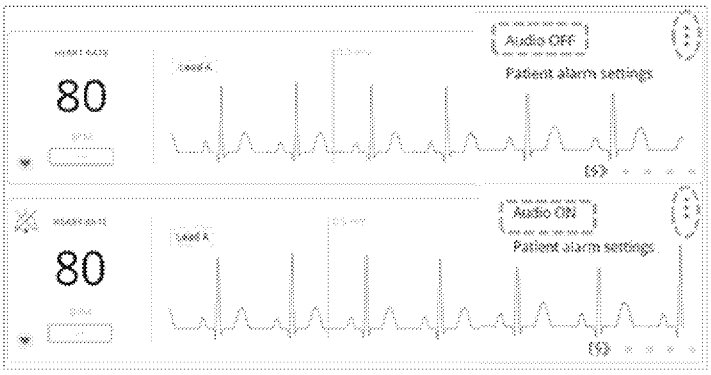
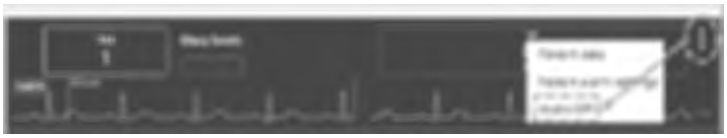
Turning Alarm Audio OFF and Audio ON

- Click on 'Three Dots' on upper right side of patient tile of your selected patient
- When you select "Audio OFF" for the selected patient, all auditory alarm sounds for that patient are turned off for five minutes (indicated by a red "crossed bell" in the upper left corner of patient tile)
- After five minutes of audio OFF, alarm audio turns ON automatically
- When Audio OFF is selected, the next time that menu is opened within the five-minute time period, Audio ON is displayed as option to turn on auditory sound for alarms
- Turning alarm Audio OFF and Audio ON can also be done when using Multi-Patient view in the same way

Individual Patient View



Multi-Patient View



WARNING: Do not try to turn the volume on the personal computer to OFF or Mute. Do not try to adjust the volume to such a low value that auditory alarm signals cannot be heard. The 7L Platform will indicate a warning on the display.

Multi-Patient View

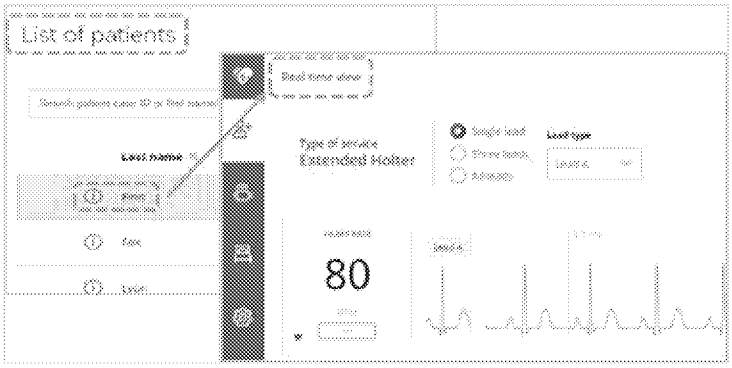
- Select "Multi-Patient" icon on left navigation menu to display all monitored patients
- When a new patient is added they are automatically placed in a patient tile.
- When monitoring more than 12 patients, ensure all patients are viewed at all times by opening another instance of the 7L Web Browser on additional displays.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display.

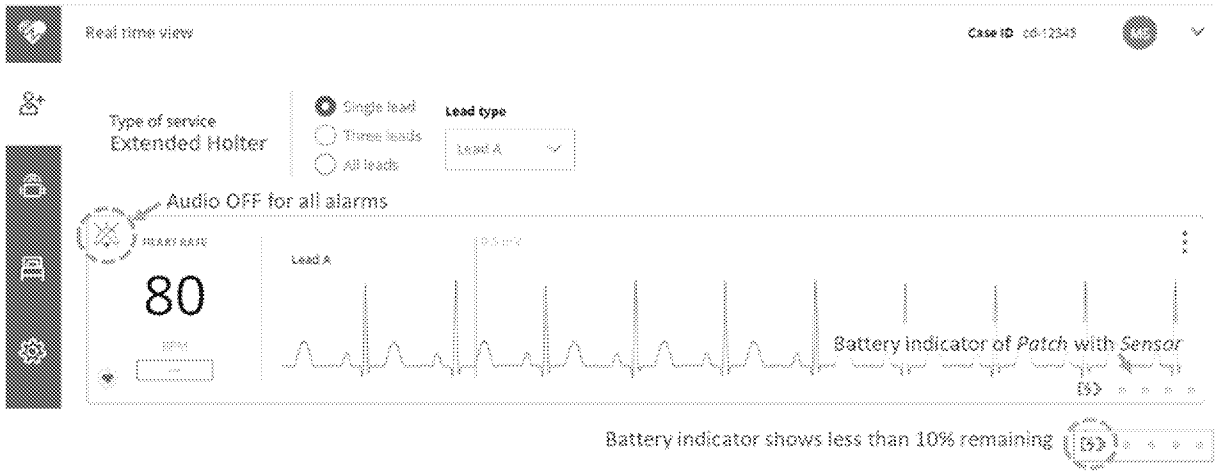
WARNING: When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.

Viewing Patient Data

- Select patient by clicking on "Patients" icon on left navigation menu to see list of patients
- Click on patient's name to view their real time ECG and heart rate.

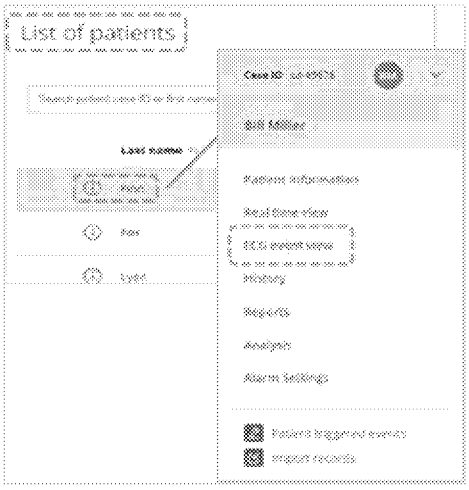


Real Time View screen



Review of Alarm Condition- "ECG event view"

- Select patient by clicking on "Patients" icon on left navigation menu to see list of patients
- Click on patient's name to view their real time streaming ECG and heart rate
- On top right navigation menu select "ECG event view"
- Select date to review



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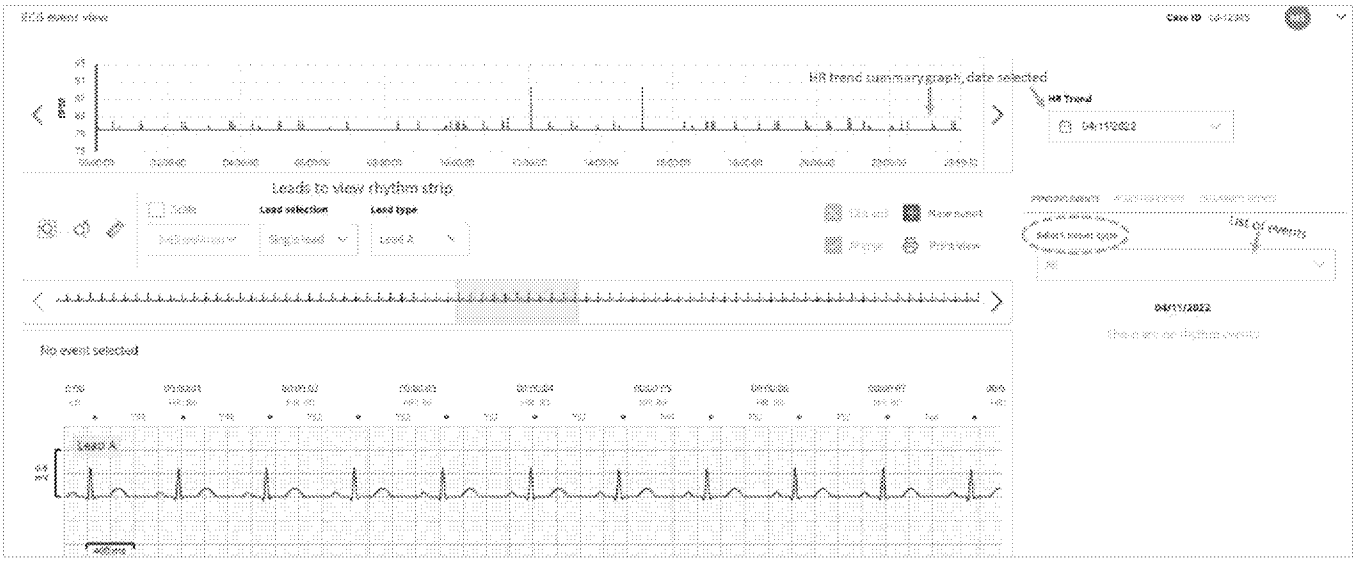
ECG event view



- Use arrows to move through summary graph for data you want to review in detail. Each click shifts ECG by one hour
- ECG shown represents highlighted section on compressed ECG, slide highlighted section left or right to view other ECG segments
- When events are listed, review can be done looking at pending, accepted, and discarded events
- Sorting can be done by event type
- A “New event” can be added, you can Accept, or Discard captured events

WARNING: The 7L Platform™ is not an emergency response system. If the patient has alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

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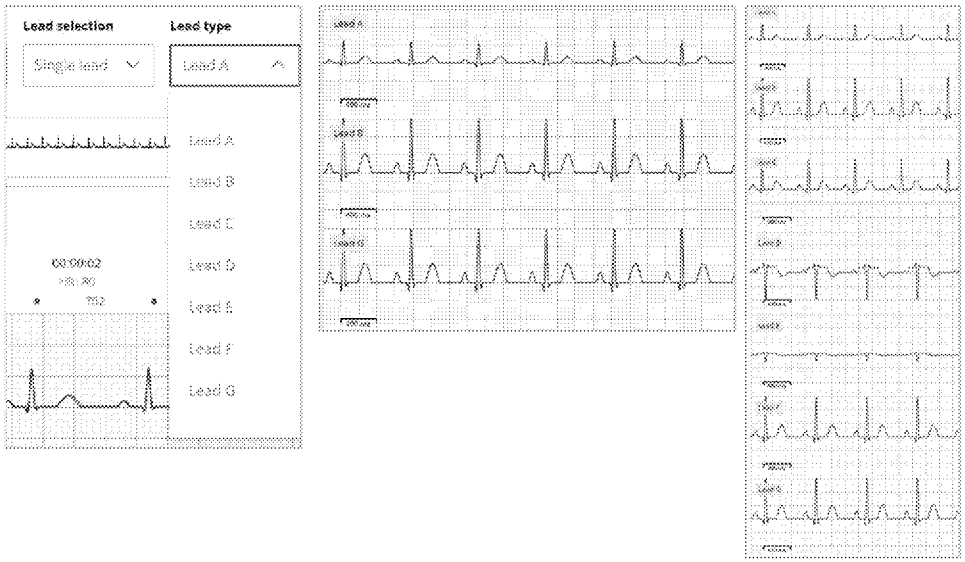
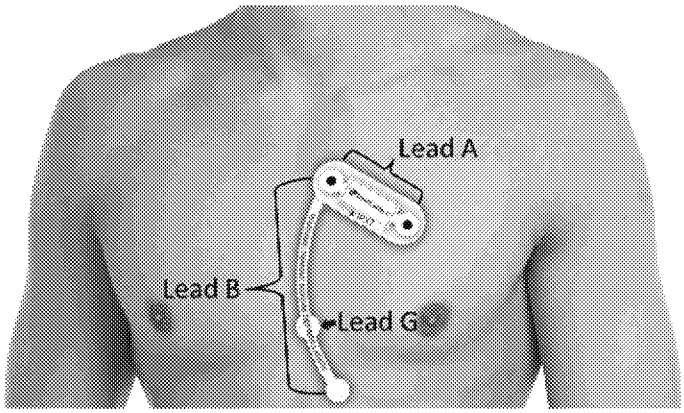
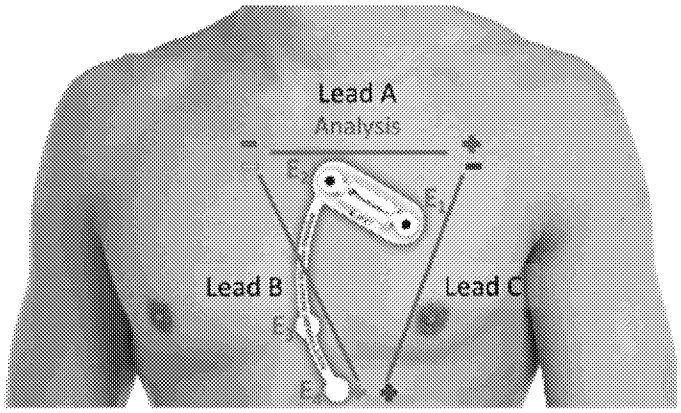
- Rhythm strip can be viewed in one lead, three leads, or seven leads (Leads A, B, C, D, E, F, G)





ECG Channels Transmitted



ECG Electrode Identification (E_x) and Polarity Measurements

NOTE: Analysis is done on Lead A only

WARNING: The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia 7L Patch and 7L Sensor before external defibrillation.

Editing and analyzing patient historical data (Refer to Clinician User Guide for details)

What the patient needs to do (Refer to the Patient User Guide and Kit)

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Specifications

Physical and Environmental	
Size	7L Sensor: 1.97 x 1.18 x .39 inch; (50 x 30 x 10mm) 7L Patch (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14mm)
Weight	7L Sensor: Less than 3.52oz. (100 g) 7L Patch: <1.0 oz. (28.4 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C) Operating: +41 to +104°F (+5 to + 45°C)
Humidity	Storage and transport: relative humidity up to 90%, non-condensing Operating: 10 to 95% at +41 to 95°F (+5 to +35°C) (non-condensing) / 700 – 1060 hPa
Safety	Type BF
Water Ingress	IPX7 (waterproof)
Battery Life	Up to 14 days, depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993-5, ISO 10993-10, ISO 10993-12 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30 - 200	Beats per Minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Manufacturer Default Alarm Settings			
Parameter	Low Limit	High Limit	Alarm Delay
Heart Rate	40	130	9.1 sec. max
Atrial Fibrillation	When event is longer than 30 sec.		NA

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Warnings

- **The 7L Platform™ is not an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.**
- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia 7L Patch and 7L Sensor before external defibrillation.**
- **Alarm conditions must be set to ON for a notification to be presented at the remote viewing station.**
- **When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.**
- **Make sure that parameter limit settings are appropriate for the clinical condition of the patient being monitored - do not set parameter limit settings outside the physiological range for the patient.**
- **Alarm limits are patient or facility specific. The clinician must set and verify alarm limits appropriate for each patient. Failure to set alarm limits properly can lead to false alarms or failure to alarm.**
- **If a patient has severe skin irritation or burning feeling, they should remove 7L Patch right away and contact their doctor.**
- **Do not use this device in an MRI.**
- No computerized interpretation of patient data can correctly detect and classify a medical condition 100% of the time. Use sound clinical judgment when monitoring your patients.
- Audio on the PC used to view the *7L Web Browser* must be ON and sufficiently loud enough.
- When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.
- Do not turn OFF the audible notifications without providing continuous observation of the patient.
- Check notification volume periodically! If the volume is too low, it could result in the inability to hear a notification.
- In certain circumstances the pacemaker pulse may be detected as a heartbeat. Verify heartbeat with an alternative method such as auscultation, radial artery palpation, or viewing ECG.
- Make sure that proper patient preparation and settings are in place to avoid sensitivity to excessive artifact which can result in inaccurate notifications.
- Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.
- The alarms provided on the SmartCardia 7L Platform should be properly assessed by medically trained or relevant qualified and accredited personnel.
- It is the responsibility of the clinician or care provider to respond to alarms consistent with their practice license.
- The SmartCardia 7L Platform should not be used in an aircraft.

Cautions

- The 7L Platform is used for adults over the age of 18 years.
- Install the 7L Platform and use as instructed. Do not attempt to connect it to another piece of equipment.
- Do not try to service the 7L Platform. It is not field repairable and there are no replaceable components.
- The 7L Platform is to be used by adequately trained personnel.
- Do not use with other devices, which have high-level electromagnetic radiation.
- The 7L Platform is not designated for use in the operating room or operating theater.
- Make sure to have a good internet connection and sufficient bandwidth.

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Cautions (continued)

- The 7L Platform is not intended to record the activity of an implanted pacemaker onto the ECG waveform. The 7L Platform is designed to operate in the presence of pacemaker pulses. Caution should be used to not locate the *7L Patch* with the *7L Sensor* on top of a pacemaker.
- The *7L Patch* is single use for a single patient. Do not reuse.
- Follow the instructions to use correctly.
- Make sure the *7L Sensor* is installed correctly and is firmly sealed in the *7L Patch*.
- Care should be taken by the patient if showering. Caution should always be taken when wearing in a wet location.
- Follow the instructions for the correct cleaning solution and process.
- Do not place the *7L Patch* on open wounds.
- The patient must keep the SmartCardia *Phone* within 10 ft of the *7L Sensor* at all times.
- Make sure the SmartCardia *Phone* is fully charged. It is best to charge the phone at night.
- If the Bluetooth on the SmartCardia *Phone* Is OFF, contact SmartCardia customer support.
- Only use the charger provided with the SmartCardia *Phone*.
- It is very important to have a good internet connection.
- For best results, the patient's skin where the *7L Patch* is applied should be cleaned and hair clipped or shaved to reduce artifact and prevent a noisy signal.
- Do not use the *7L Patch* if date of manufacture is more than two years. Refer to the *7L Patch* labeling.
- Keep username and login in a safe place and do not share them with anyone.
- Do not access the cloud platform from a shared computer.
- Make sure to set the correct mode of monitoring operation for the patient (Holter, Extended Holter, Event, or Mobile Cardiac Telemetry).
- Measured vital sign values should be reviewed and verified by alternate means if measurements are suspected to be inaccurate.
- When remote monitoring a patient, remember they may not have a caregiver or helper nearby and they may not be able to respond to communications. Always know how to provide aid for each patient.
- Receipt of alarms is not confirmed.
- Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.
- If the wireless connection from the *7L Sensor* and *7L Patch* to the *Phone* or the *Phone* to the internet/ cloud application is broken, a notification will show on the display. Periodically check to make sure the

Please refer to Clinician User Guide for the complete list of warnings and cautions.

Customer Support
(800) 363-8151

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

SmartCardia 7L™

monitoring the fabric of life™

SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

· PL-17 SmartCardia 7L Platform Technical Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: Vincent Do
CDRH/OPEQ/OHT2/DHT2A

CC: Hong (Laura) Lu, Assistant Director, CDRH | OPEQ | OCEA | DCEA2
Lan Huang, Team Leader, CDRH | OPEQ | OCEA | DCEA2

From: Feiming Chen, Ph.D.
Mathematical Statistician, Biostatistics Team 3 (All Diagnostic Products)
DCEA2: Division of Biostatistics | OCEA: Office of Clinical Evidence and Analysis | OPEQ: Office of Product Evaluation and Quality | CDRH

Due Date: 8/23/2023

Subject: Statistical Review of 510(k) submission K231276-S001 (SmartCardia 7L Platform by SmartCardia SA)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(5)

If you have any questions about this review or the submission in general, please contact me at (301)796-4394 or at Feiming.Chen@fda.hhs.gov.

Feiming Chen -S

Digitally signed by Feiming Chen -S
Date: 2023.08.22 18:25:43 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Redacted per FOIA Request 2023-2112 Released by CDRH on 01-17-2024

electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 2.1 (2022-10-07)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. We tested eSTAR submissions up to 1GB in size. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

Q: If an eSTAR is signed, a message is displayed at the top saying changes were made after signing. Why?

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.1 (2022-10-07): Grey text in FDA standards selection no longer disappears when an SDO is selected. Warning

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	( ) New Application/Submission (•) Additional Information
Please enter the parent application/submission number.	K231276

Records Processed Under FOIA Request 2021-5185 Released Date: Feb 10, 2021

Cover Letter / Letters of Reference

Add Attachment	Attach your Cover Letter	?
Open Attachment	Cover Letter Signed.pdf	Delete Attachment
Add Attachment	Attach any Letters of Reference	?

Applicant Information ?

Contact

Title	Mr.	Last Name	Murali	First Name	Srinivasan
Email	srinivasan.murali@smartcardia.com			Phone Number	+41 7887 50864
Occupation Title	Chief Executive Officer				

Company

Company Name	SmartCardia SA				
Address - Line 1	EPFL Innovation Park Building C				
Address - Line 2					
City	Lausanne	State		Zip	1015
Country/Region	Switzerland				

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title		Last Name	Steurer	First Name	Robert
Email	steurerbob@gmail.com			Phone Number	425-358-1072
Occupation Title	Consultant				

Company

Company Name	Steurer Consulting Group LLC				
Address - Line 1	800 Blue Quail Rd				
Address - Line 2					
City	Keller	State	TX	Zip	76248
Country/Region	United States				

Add Correspondent/Consultant | Delete Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Are there prior related submissions or regulator interaction for the subject device(s)? Yes

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

(b)(4) Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment 002_Prior Coorespondence and Regulator Interaction QSUB Delete Attachment

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A	19-46	Delete Standard

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment K231276_S001_60601-1 Extent of Standard Conformance Checklist Delete Attachment

Add Standard

IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36	Delete Standard

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collater

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment K231276_S001_60601-2 EMC Extent of Standard Conformance Checklist Delete Attachment

Add Standard

IEC	60601-1-11 Edition 2.0 2015-01	19-14	Delete Standard

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collate

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment K231276_S001_60601-1-11 Home Healthcare_Redline.pdf Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request released by CDRH on 10-02-2024

Add Standard

IEC	60601-2-47 Edition 2.0 2012-02	3-155	Delete Standard

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | K231276_60601-2-47 Ambulatory ECG Extend to Standard Conformance | Delete Attachment

Add Standard

IEC	60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131	Delete Standard

Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance ¿ Collate

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | K231276_S001_ISO 60601-1-8 Alarm Standard Checklist Redline.pdf | Delete Attachment

Add Standard

ISO	10993-5 Third edition 2009-06-01	2-245	Delete Standard

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO	10993-10 Third Edition 2010-08-01	2-174	Delete Standard

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO	10993-23 First edition 2021-01	2-291	Delete Standard

Biological evaluation of medical devices - Part 23: Tests for irritation

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request released by CDRH on 10-02-2024

Add Standard

ANSI AAMI	EC12:2000/(R)2015	3-52	Delete Standard
Disposable ECG electrodes			

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	K231276_S001_EC12 Disposable ECG Electrodes Checklist RedLine.pdf	Delete Attachment

Add Standard

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Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

SmartCardia 7L Platform	Model Number/Name	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	No
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	Yes
• Please check the attributes that are applicable to your device.	☒ Cloud Communication ☒ Network connection (active or not) ☒ Wireless communication in any form ☐ USB/serial ports/removable media ☒ Software upgrades (this includes patches) ☐ None of the above
Is the device or a component packaged as sterile?	No
The device/system uses or is... (choose all that apply)	☒ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use device(s) ☒ a reusable multi-patient use device(s)
The environment of use of the device/system includes... (choose all that apply)	☒ Professional Healthcare Facility ☒ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the device a combination product?	No
Is the device electrical (battery or wall powered)?	Yes, it is battery and mains powered
• Does the device/system include wireless technology?	Yes
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

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If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S)

(b)(4)

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	007_Comprehensive Device Description and Principles of	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	008_Device Description Sensor mechanical dwgs.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	010_Description of Device Packaging.pdf	Delete Attachment

Accessories

Redacted per Exemption 4 of FOIA 5 U.S.C. 552(b)(4) and (b)(6); Released by CDRH on 10-02-2024

Is the device intended to be marketed with accessories? Yes

Add Accessory | List all the accessories to be marketed with the submission.

7L Patch | Delete Accessory

Please include a description of each accessory (see help text for the information we request be included). Please also provide the submission number if the accessory was previously marketed (or a statement that it was not).

The SmartCardia 7L Patch is a single use component that is disposable. If extended use of the SmartCardia 7L Platform is required, the 7L Patch is replaced. The SmartCardia 7L Patch has not been previously marketed.

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request? No

Add Attachment | Please attach Accessory Pictures, Illustrations, Schematics, and/or Diagrams

Open Attachment | 009_SmartCardia 7L Patch Accessory Photo.pdf | Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

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(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231276

Device Name

SmartCardia 7L Platform

Indications for Use *(Describe)*

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:
1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening
conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450).

Medical Specialty	
Regulation	
Product Code	DSI

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-arrhythmia-detector-and-alarm-guidance-industry-and-fda

Associated Product Code(s)	DRG

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K192757
Predicate Device Trade Name	VitalPatch
Predicate Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DRG

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K160064
Predicate/Reference Device Trade Name	MoMe Kardia Wireless Ambulatory ECG Monitoring And Dete
Predicate/Reference Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DSI

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Predicates and Substantial Equivalence Summary
Primary Predicate
VitalConnect VitalPatch K192757
Product Code: DRG
Intended Use:
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.
The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

Predicate/Reference Device
InfoBionics MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System K160064
Product Code: DSI
Intended Use:
MoMe® Kardia is intended to be used for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.
MoMe® Kardia is contraindicated for:
1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life

Contains Nonbinding Recommendations

threatening arrhythmias.

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Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Substantial Equivalence Comparison Statement
The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

Substantial Equivalence Comparison Technological Characteristics Statement
The SmartCardia 7L Platform has the same technological characteristics as the predicate device and the predicate/reference device.
1) They are body worn sensors that communicate wirelessly to a gateway device that transmits the data to a cloud bases server for storage and further analysis.
2) The material used in the predicate device and the SmartCardia 7L body worn device is the same.
a. The ECG electrodes are a hydrogel component
b. The adhesive body is a hydrocolloid material.
c. The predicate/reference device uses individual ECG electrodes connected to the transmitter device via wire leads.
d. The devices use integrated batteries to power the body worn sensor.
i. The predicate device uses zinc air and the SmartCardia 7L body worn device uses manganese oxide-lithium.
ii. Both are disposable and do not require charging.
e. The predicate device and SmartCardia 7L body worn device both use Bluetooth BLE communication to a gateway.
i. The predicate device communicates to a tablet,
ii. The SmartCardia 7L body worn device communicates to a smartphone.
iii. The predicate/reference device incorporates a cellular transmitter directly into the sensor and transmits via cellular technology to the cloud server.
iv. These gateways then transmit the data to a cloud server.
3) The VitalConnect predicate device measures more physiological parameters than the SmartCardia 7L Platform.
4) The InfoBionics predicate/reference device measures just ECG and heart rate which is the same as the SmartCardia 7L Platform.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	011_Substantial Equivalence Comparison Table Attachment.pdf	Delete Attachment

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Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	PL-09 Clinician User Guide IFU, Icon and Symbol Table, pages 40, 41, 42, and 43 of 235 (IFU pages 15, 16, 17, 18); PL-17 Technical Manual, pages 186 and 187 of 235
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	MR Unsafe

Package Labeling

Add Attachment	Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.	
Open Attachment	012 Package Labeling.pdf	Delete Attachment

Package Insert / Instructions for Use

Add Attachment	Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.	
Open Attachment	Redline IFU (b)(4) Proposed Labeling SmartCardia Update (b)(4) pdf	Delete Attachment
Open Attachment	Redline Tech Manual (b)(4) Proposed Labeling SmartCardia	Delete Attachment
Open Attachment	013_Instructions for Use from eSTAR redlined after AINN.pdf	Delete Attachment
Open Attachment	013_Instructions for Use K231276_S001.pdf	Delete Attachment

Other Labeling

Add Attachment	Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	013_Instructions for Use K231276; PL-08 Patient Guide, page 23 of
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	File 013_Instructions for Use K231276, PL-08 Patient Guide, page
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	File 013_Instructions for Use K231276, PL-08 Patient Guide, page 23 of 235, and 24 of 235;

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, reprocessing information, but no sterility information, is needed.

Reprocessing

Are cleaning or disinfection or sterilization instructions included in the labeling?	Yes
How many different sets of reprocessing instructions are included (maximum of 4):	(b)(4)

Reprocessing Instructions 1

Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

SmartCardia 7L Sensor, SmartCardia Phone, Charger and charger cable

Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.	013_Instructions for Use, Page 161 of

Cleaning Instructions

Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?	No
Is a Point-of-Use care instruction included (e.g., to prevent drying)?	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable. (Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161
If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.	N/A
Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235

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Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., "no visual contamination"), and 3) steps the user should repeat if the endpoint is not met.	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161
If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.	7L Patch is single use, stated in 013_Instructions for

Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

Which types of microbicidal process instructions are present in these instructions?	None (cleaning alone)

Technically Feasible, Understandable, and Comprehensive

Be sure the reprocessing instructions can be understood and reasonably implemented by the end user in the intended reprocessing location. If a device is intended to be reprocessed in the home, then reprocessing steps should include products that are available for use in the home (not sterilizers or high-level disinfectants) and are appropriate for the reprocessing procedure (e.g., baby bottle sanitizers are not recommended for reprocessing most medical devices).

If the device is initially supplied non-sterile to the user and specifies to sterilize the device before use, the device should be prominently labeled "Non-sterile" directly on the individual device label (e.g., as opposed to only on the shipper carton).

When warranted, the labeling should include special warnings or precautions about potential damage to the device from improper reprocessing procedures. These may be related to user safety or emphasize

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conditions that could significantly alter the safety or effectiveness of reprocessing or performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. Not all devices may need this type of warning in the labeling. If you are unsure, check if similar devices have labeling with this type of warning.

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A, no special controls for reprocessing or sterility.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf-life?	2	Years

Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

Device is not a sterile device. Device tested per IEC 60601-1-11 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.	?

Other

Open Attachment	014_Reprocessing_Sterility_Shelf-Life_Documents.pdf	Delete Attachment

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Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? *(See Help Text if multiple materials share the same justification for no testing.)*	(b)(4)

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrogel electrode component

Please state the exact name and any identifiable information for the particular material used.

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility

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tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

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Conclusion

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Methods

(b)(4)

Comments

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(b)(4)

documentation error did not impact assessment of the study endpoints.

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Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 2

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrocolloid adhesive component

Please state the exact name and any identifiable information for the particular material used.

Hydrocolloid, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

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Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No Hydrogel, No Hydrocolloid)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Records processed under FOIA Request # 2024-6000 by CDRH on 10-02-2024

Tissue Contacting Material 3

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, adhesive component

Please state the exact name and any identifiable information for the particular material used.

Adhesive, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, No hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 4

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, (b)(4)

Please state the exact name and any identifiable information for the particular material used.

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A." ?

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No ?
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution) ?
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.
Open Attachment	015_ISO 10993 Biocompatibility Test Reports.pdf Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, software, cybersecurity, and interoperability information is needed.

Software

Software Level of Concern (LOC) Determination ?

Does the Software qualify as Blood Establishment Computer Software?	(b)(4)
Is the Software intended to be used in combination with a drug or biologic?	
Is the Software an accessory to a medical device that has a Major LOC?	
Prior to mitigation of hazards, could a failure of the Software result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a) Does the Software control a life supporting or life sustaining function? b) Does the Software control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c) Does the Software control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d) Does the Software provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e) Does the Software provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	
Is the Software an accessory to a medical device that has a Moderate LOC?	(b)(4)
Prior to mitigation of hazards, could a failure of the Software result in Minor Injury, either to a patient or to a user of the device?	
Could malfunction of, or a latent design flaw in, the software lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	

Based on the questions answered above, your LOC is determined to be: (b)(4)

The software documentation below is recommended for the level of concern specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Software Description ?

Add Attachment — Please attach a description of the software / firmware that includes: a textual description of the software / firmware, the version number of the software / firmware, the input parameters (user inputs), and the output parameters (device actions).

Open Attachment — 016_Software Description.pdf — Delete Attachment

Records processed under FOIA Request 2024-4118 released by CDRH on 10-02-2024

Software Documentation

Add Attachment	Device Hazard Analysis	?
Open Attachment	016_K231276_S0(b)(4)	Delete Attachment
Add Attachment	Software Requirements Specifications (SRS)	?
Open Attachment	SW Requirements Specification (b)(4) Design Inputs.pdf	Delete Attachment
Add Attachment	Architecture Design Chart	?
Open Attachment	(b)(4) SmartCardia 7L Platform Software Architecture.pdf	Delete Attachment
Add Attachment	Software Design Specifications (SDS)	?
Open Attachment	Software Design Specification (SDS).pdf	Delete Attachment
Add Attachment	Traceability Analysis/Matrix	?
Open Attachment	Tracability Analysis-Matrix (b)(4) Design Inputs Trace Matrix.pdf	Delete Attachment
Add Attachment	Software Development Environment/Life Cycle Process Description	?
Open Attachment	SW Development EnvironmentLifeCycle ProcessDescription.pdf	Delete Attachment
Add Attachment	Verification & Validation Testing	?
Open Attachment	016_K231276_S0(b)(4)	Delete Attachment
Add Attachment	Revision Level History	?
Open Attachment	Software Information SmartCardia Revision History.pdf	Delete Attachment
Add Attachment	Unresolved Anomalies	?
Open Attachment	Unresolved Anomalies.pdf	Delete Attachment

Cybersecurity

Add Attachment	Risk Management	?
Open Attachment	017_Cybersecurity Risk Management.pdf	Delete Attachment
Add Attachment	Cybersecurity Management Plan / Plan for Continuing Support	?
Open Attachment	017_Cybersecurity Plan and Design.pdf	Delete Attachment

Please specifically cite the attachment(s) and page number(s) where the cybersecurity labeling is located. (Note: If there is separate cybersecurity labeling for the device, please attach this in the Labeling section above.)	013_Instructions for Use K231276, PL-09 Clinician User Guide ?

Interoperability

How many Electronic Interfaces are there?	3 ?

Electronic Interface 1

Name the Electronic Interface	7L Sensor to SmartCardia Phone, Bluetooth BLE

Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 2	
Name the Electronic Interface	SmartCardia Phone to SmartCardia back end, cellular
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 3	
Name the Electronic Interface	SmartCardia back end to SmartCardia 7L Web Browser, wifi
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes

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EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Based on the answers provided in the Device Description section, EMC and wireless technology information is needed.

Electromagnetic Compatibility (EMC)

How many devices/accessories/components were subjected to EMC testing (maximum of 4)? (b)(4)

EMC Test 1

Device Specific EMC Considerations

Please select the highest possible risk associated with this device(s) resulting from potential malfunction, disruption, or degradation due to electromagnetic interference (EMI) that could cause harm to the patient, user, or operator.

Deaths or Serious Injuries: Medical device-related deaths or **serious injuries** include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to a death or injury or illness that is life-threatening, results in permanent impairment or damage to the body, or requires medical or surgical intervention to prevent permanent harm to the body.

Non-Serious Adverse Events: Medical device-related non-serious adverse events include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to minor, temporary or medically reversible injuries that do not meet the criteria for classification as a medical device-related serious injury.

No Reported Or Potential Harm: Medical device-related events without reported or potential harm include medical device nonconformities that have no related harm, medical device malfunctions that have no related harm, and procedure-related complications with no related harm.

(b)(4)

Was testing performed according to a recognized edition of IEC 60601-1-2 and, if so, was an ASCA test summary report provided? Please attach any summaries/reports in the "EMC, Wireless & EMT Documentation" section below.	(b)(4)
Please list the Essential Performance that is specific to the device, or provide a rationale why the device has no Essential Performance, in the space below.	

1. The SmartCardia 7L Platform shall provide correct data output for the vital sign parameters that it measures.

Please provide the page number(s) in the summary/report that include pass/fail criteria specific to the device that are based on the device functions, intended use, and Essential Performance. It is recommended that all device functions that are associated with basic safety or Essential performance be tested and include device-specific pass/fail criteria.	021_Pages 10 and 11 of 305 (Pages 8, 9 of test report)

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If the device under test is not the final finished version, please provide a justification for why the differences don't affect EMC. If the device under test is the final finished version, please state this.	
The device tested is a pre-production unit that represents the final finished version of the product. There were no changes to hardware from the pre-production device tested to the production unit.	
Please provide the page number(s) in the summary/report that include a description of the device/system configuration that adequately addresses and monitors the specific functions of the device that were tested.	021_Pages 8 and 9 of 305 (pages 6 and 7 of test report)
If the wireless technology is used in the medical device to achieve its intended use, was it "On" and communicating with other medical device subsystems or ancillary equipment during EMC testing?	Yes

EMC Emissions and Immunity Test Information

Please provide the page number(s) in the summary/report where the CISPR 11 emission limits are located.	021_Pages 16, 17 of 305; Pages, 23 and
If the device includes any smart batteries that can be removed from the device for recharging, were the batteries tested as a standalone component during ESD testing?	Inapplicable
Please provide the page number(s) in the summary/report where the IEC 61000-4-2 electrostatic discharge (ESD) immunity test levels and test results (or observations) are located.	021_Page 30 of 305 (test report page 28)
Please provide the page number(s) in the summary/report where the IEC 61000-4-3 radiated RF electromagnetic field immunity test levels and test results (or observations) are located.	021_Pages 33 and 35 of 305 (test report pages 31,33)
Please provide the page number(s) in the summary/report where the proximity field immunity test levels and test results (or observations) from IEC 60601-1-2 Sec 8.10 and Table 9 are located.	021_Pages 33, 35, and 37 of 305 (test report pages 31, 33,
Please provide the page number(s) in the summary/report where the IEC 61000-4-8 power frequency magnetic field immunity test levels and test results (or observations) are located.	021_Page 45 of 305 (test report page 43)
Please provide the page number(s) in the summary/report where the IEC 61000-4-6 conducted disturbances induced by RF fields immunity test levels and test results (or observations) are located.	021_Page 43 of 305 (test report page 41)
Please provide the page number(s) in the summary/report where the IEC 61000-4-4 electrical fast transient/burst immunity test levels and test results (or observations) are located.	021_Page 39 of 305 (test report page 37)
Please provide the page number(s) in the summary/report where the IEC 61000-4-5 surge immunity test levels and test results (or observations) are located.	021_Page 41 of 305 (test report page 39)
Please provide the page number(s) in the summary/report where the IEC 61000-4-11 voltage dips, short interruptions, and voltage variations immunity test levels and test results (or observations) are located.	021_Page 47 of 305 (test report page 45)

Questions? Contact CDRH/OCE/DPH at CARTLEOISTATUS@fda.hhs.gov or 301-796-8118

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Please provide the page number(s) in the summary/report where test data for the specifications in Section 20 (RF immunity, category R) of RTCA DO-160 are located. Alternatively, please specifically cite the attachment and page number where the labeling mitigation that cautions against the use of the device in an aircraft is located.	013_Instructions for Use K231276, PL-09, page 126 (page 151 of 235); PL-17 Technical

If there were any degradations or observations noted during the testing, describe how the device(s) continued to meet the essential performance during these degradations or observations.

Add Attachment	Please add an attachment (e.g., Summary Report) that demonstrates that the device passed testing according to IEC 60601-4-2. If a Declaration of Conformity was used, choose TR 60601-4-2 in the Standards section above, and indicate you are declaring conformity to it (i.e., it is not for general use). Then attach a statement here indicating this standard is included in the eSTAR generated Declaration of Conformity in the Administrative Documentation section below.
Open Attachment	018_EMC Summary Report for TR 60601-4-2.pdf Delete Attachment

Emitters, Allowances, Deviations & Modifications

If any of the referenced standard's allowances were used during the testing (e.g., lowered ESD immunity), please provide these below.

If there were any deviations from the referenced standard, please describe these below.

Add Attachment	Please add an attachment that includes descriptions of all modifications, as well as a statement indicating that all changes or modifications will be incorporated in the device intended for marketing. Not providing an attachment indicates no modifications were made in order to pass any of the EMC tests. In addition, be sure you include an adequate assessment of whether these modifications might impact other aspects of the device (e.g., performance, biocompatibility). It is recommended that the attachment contain information to demonstrate that the modifications would have no impact on the other aspects or that the modified device was used for the other performance tests.

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Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to common EM emitters including but not limited to: radio-frequency identification (RFID) readers, security systems (e.g., metal detectors or electronic article surveillance (EAS)), wireless power transfer (WPT), and 5G cellular signals. Security systems may be excluded if the device is only intended for use in a Professional Healthcare Facility environment.	018_Page 1 and 2 "Results Summary"
Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to unique medical emitters, such as electrocautery, MRI, electrosurgical units, and diathermy devices. Alternatively, if the intent is to caution against exposure to these or other specific potential electromagnetic disturbance sources, please specifically cite the attachment(s) and page number(s) where the instructions describe avoiding the source or other mitigations.	013_Instructions for Use K231276; Warnings and Cautions are included in PL-09 IFU against exposure to other specific potential

Device Labeling

Please specifically cite the attachment(s) and page number(s) where the recommended separation distances and appropriate environment(s) of use are located in the labeling. This information is analogous to the Guidance Tables 1 through 8 from the 3rd edition of IEC 60601-1-2.	013_Instructions for Use K231276; PL-09, Instructions for Use, pages 148 to 155 of 235
Please specifically cite the attachment(s) and page number(s) where the performance of the device that was determined to be Essential Performance and a description of what the operator can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances are located in the labeling.	013_Instructions for Use K231276; Page 148 of 235 (IFU page 123); Page 210 of 235 (TM page 31)
Please specifically cite the attachment(s) and page number(s) where the compliance for each emissions and immunity standard or test specified by the collateral standard (e.g., emissions class and group and immunity test level) are located in the labeling.	013_Instructions for Use K231276; PL-09, Instructions for Use, pages 148 to 155 of 235
Please specifically cite the attachment(s) and page number(s) where any deviations from the collateral standard and allowances used are described in the labeling. Type "N/A" if not applicable.	N/A

Wireless Technology

How many separate wireless functions are there (maximum of 5)?	2

Wireless Function 1

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

Wireless Bluetooth link from 7L Sensor to SmartCardia Phone to transmit patient data.
Delay in treatment is the primary risk category for failure of the wireless link.
Mitigation is implemented to store all data internal to the 7L Sensor so when a link is broken, the data are

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re-transmitted when the link is restored.

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Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The BLE link shall pass all digitized data from the sensor to the SmartCardia phone which is in the RF chamber.

Please select all the technologies that apply to this wireless function:

☒ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☐ Cellular ☐ Other

Bluetooth

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? **Yes**

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? **No**

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 019_Wireless Coexistence and RFID Testing_BlueTooth.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

The Functional Wireless Performance (FWP) of the SmartCardia 7L Platform was monitored using the Key Performance Indicators listed in the attached test report, pages 019_Page 16 of 36 and 019_Page 17 of 36.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	(b)(4)
Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use K231276, pages
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use K231276, pages 013_148 of 235 through
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Wireless Function 2

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

Wireless Cellular link from the SmartCardia Phone to the SmartCardia back end cloud server.
Delay in treatment is the primary risk category for failure of the wireless link.
Mitigation is implemented to store all data internal to the 7L Sensor so when a wireless link is broken, the data are re-transmitted when the link is restored.

Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The Cellular link is expected to disconnect while in the RF Chamber Data corrupted or lost packets due to RF interference shall be retransmitted when the interference is removed. Pass criteria is a continuous ECG waveform file reviewed in the SmartCardia backend at the conclusion of the test.

Please select all the technologies that apply to this wireless function:

☐ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☒ Cellular ☐ Other

Cellular

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 020_Wireless Coexistence and RFID Testing_Cellular.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

The Functional Wireless Performance (FWP) of the SmartCardia 7L Platform was monitored using the Key Performance Indicators listed in the attached test report, pages 020_Page 16 of 36 and 020_Page 17 of 36.

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	

(b)(4)

Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	(b)(4)
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use K231276, pages
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use K231276, pages 013_148 of 235 through
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The SmartCardia 7L Platform was tested for compliance with the following standards to verify the electrical, mechanical, and thermal safety considerations:

- IEC 60601-1 General Requirements for Basic Safety and Essential Performance
  - o Essential Performance – Defibrillation Performance (b)(4)
- IEC 60601-1-2 Collateral Standard, Electromagnetic Disturbances – Requirements and Tests
  - o Wireless Coexistence (ANSI C63.27) and Exposure to RFID (AIM 7351731)
- IEC 60601-1-11 Collateral Standard, Medical Equipment used in the Home Healthcare Environment
- IEC 60601-2-47 Requirements for Ambulatory ECG Systems
- IEC 60601-1-8 General requirements, tests and guidance for Alarm Systems in Medical Equipment
- EC12 Requirements for Disposable ECG Electrodes
- ISO 10993-5 Biological Evaluation for Cytotoxicity
- ISO 10993-10 Biological Evaluation for Sensitivity

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• ISO 10993-23 Biological Evaluation for Intracutaneous Irritation

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(b)(4)

The SmartCardia 7L Platform was tested for energy reduction to verify defibrillation safety required by IEC 60601-1 ed3, second amendment clause 8.5.5.2.
The energy reduction test was performed as directed in the standard and the results of the test are provided in IEC 60601-1 report from (b)(4) This is included in the file 022_Performance Testing – Bench.

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.	
Open Attachment	021_EMC, Wireless, & EMT Test Reports.pdf	Delete Attachment

Records processed under FDA Premarket 510(k) Pilot Program by CDRH on 10-02-2024

Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.	K192757

Records processed under FOIA Request 2023-6118, Released by CDRH on 10-02-2024

Add Attachment	Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.	?

Other Non-Clinical Evidence

Open Attachment	022_Performance Testing - Bench K231276_S001.pdf	Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118, Released by CDRH on 10-02-2024

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request # 2024-3918 Released by CDRH on 10-02-2024

References

Is literature referenced in the submission? Yes

Add Attachment | Please add legible reprints or a summary of each article in English.

Open Attachment | 023_Reference Literature.pdf | Delete Attachment

Please include a discussion of how each article is applicable to support the submission.

Summary of Literature Supporting the SmartCardia 7L Platform
Published scientific papers or documents are referenced to support the SmartCardia 7L Platform.

1. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part IV: The ST Segment, T and U Waves, and the QT Interval. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society

Pentti M. Rautaharju, MD, PhD; Borys Surawicz, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC

(b)(4)

2. Cleveland Clinic: Center for Continuing Education, Atrial Fibrillation; Cantillon, Daniel J, Amuthan, Ram. August 2018 www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/atrial-fibrillation/

(b)(4)

3. Hannun, A.Y., Rajpurkar, P., Haghpanahi, M. et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nature Medicine 25, 65–69 (2019).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

4. Steven Walfish, November 30, 2016, FOI Services Teleconference TC161130 Presentation, Slide 'Sample Size for Proportions'. https://www.foiservices.com/tc-docs/tc161130/TC161130A.pdf

(b)(4)

Administrative Documentation

Add Attachment	General Summary of Submission/Executive Summary	?
Open Attachment	023_General Summary of Submission-Executive Summary.pdf	Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.	Yes
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	No

Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.	?
Open Attachment	User Fee Cover Sheet.pdf	Delete Attachment

Please enter in the User Fee Payment Identification Number.	(b)(4)	?

Show User Fee Introduction

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of SmartCardia SA, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Srinivasan Murali

Digitally signed by Srinivasan Murali
Date: 2023.07.28 21:59:08 +05'30'

Date Signed: 2023-07-28

510(k)#: K231276 For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Declaration of Conformity

Application # K231276

Company Name	SmartCardia SA
Company Address	EPFL Innovation Park Building C Lausanne 1015 Switzerland
Device Trade Name	SmartCardia 7L Platform

The object of the declaration described above is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:201	19-46
IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
IEC	60601-1-11 Edition 2.0 2015-01	19-14
IEC	60601-2-47 Edition 2.0 2012-02	3-155
ISO	10993-5 Third edition 2009-06-01	2-245
ISO	10993-10 Third Edition 2010-08-01	2-174
ISO	10993-23 First edition 2021-01	2-291
ANSI AAMI	EC12:2000/(R)2015	3-52

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of:	Lausanne	2023.07.28
Full Name and Function:	Srinivasan Murali, CEO	
Signature	Srinivasan Murali Digitally signed by Srinivasan Murali Date: 2023.07.28 22:00:41 +05'30'	

510(k) Summary

Prepared on: 2023-07-28

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Additional Information Response

Is this a response to an Additional Information request?	Yes

Additional Information

Changes that are necessary to resolve deficiencies should be made in the respective section. For example, if additional Sterilization information will be provided to resolve a deficiency, this documentation should be added to the Sterilization documentation that is already present. If attachments need to be updated, remove the old attachments and replace them with the new attachments (be sure to give new attachments a different name in comparison to the old attachments to ensure they are distinguished). Data that are typed in can also be modified. If you need to respond to subsequent Additional Information requests, you should replace the deficiencies below with those from the latest Additional Information request when responding. Although previously submitted data and attachments will remain in the FDA database, old data superseded by new data will not be considered the final data in our final review.

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2023-6118 released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See response to 3a, and 3b below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See Responses to 4a, 4b, 4b i, 4b ii below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2018-8118, Released by CDRH on 10-02-2018

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See Response to 4b i and 4b ii below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2018-8118, Released by CDRH on 10-02-2021

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See Response to 5a, 5b, 5c, 5d, 5e below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

Electronically processed under FOIA Request 2023-8113, Released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Records processed under FOIA Request 2023-4138; Released by CDRH on 10-02-2024

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2018-8118, released by CDRH on 10-02-2018

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Records processed under FOIA Request 2024-6418 released by CDRH on 10-02-2024

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation
Additional Information Response

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review to the Center for Devices and Radiological Health (CDRH) using

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

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7L Revision History

The following revisions are for the 7L Platform

Sensor

(b)(4)

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SmartCardia 7L Platform List of Unresolved Anomalies

- SmartCardia is not aware of any unresolved anomalies that have an impact on safety or effectiveness for the 7L Platform

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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021_EMC Wireless, and EMT Test Reports

- IEC 60601-2 EMC (b)(4)
  Report No. (b)(4)

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(b)(4)

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TEST REPORT

Report Number: (b)(4)
Project Number: (b)(4)

Equipment designation
SmartCardia 7L Platform

to
IEC 60601-1-2 Edition 4.1: 2020
Class B for Emissions,
Immunity for Professional Healthcare Facility Environment
and
Immunity for Home Healthcare Environment

For
SmartCardia SA

(b)(4)

Client:
SmartCardia
EPFL Innovation Park, Building C, 1015
Lausanne Switzerland

(b)(4)

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Verifiacation and Validation Testing

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(b)(4) Verification and Validation Plan

NOTES:

1. Validation and Human Factors testing and product validation is included in this section following verification reports.
2. The test report documents contain the design input specification, associated hazard, test protocol, test acceptance criteria, and pass/fail information as well as observations/comments.

Questions? Contact FDA/CDRH/OCE/DIDTC/CDRHFOIASTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Verification Test Results - Physical Requirements, Hardware

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(b)(4) Verification Test Results - ECG Hardware

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(b)(4) Verification Test Results - Sensor CPU/Memory Hardware

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(b)(4) Verification Test Results - BLE Sensor Hardware (BH)

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(b)(4) Verification Test Results - Backend Hardware

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(b)(4) Verification Test Results – Labeling

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(b)(4) Kit Shipping Verification Test Report

Questions? Contact FDA/CDRH/OCE/DID 7C CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Verification Test Results - ECG SEM Software

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(b)(4) Verification Test Results - ECG Cloud/Server Software

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(b)(4) Verification Test Results - Notifications (Alerts/Alarms) Software

- (b)(4) Alarm Visibility Protocol
- (b)(4) Alarm Visibility Test Results

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(b)(4) Verification Test Results - Sensor to Mobile Link Software

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(b)(4) Verification Test Results - Battery Indicator Software

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(b)(4) Verification Test Results - Mobile SW Application Software

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(b)(4) Verification Test Results - Frontend Web Software

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(b)(4) Verification Test Results - Backend Software

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(b)(4) Verification Test Results - Web Browser Review

(b)(4) Software

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(b)(4) Verification Test Results - Cybersecurity Requirements

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Human Factors Testing and Product Validation

- (b)(4) Use Related Risk Analysis – Patient
- (b)(4) User Related Risk Analysis – Clinician
- (b)(4) Formative Test Plan – Patient
  - (b)(4) Formative Test Report – Patient
- (b)(4) Formative Test Plan – Clinician
  - (b)(4) Formative Test Report – Clinician
- (b)(4) Human Factors Validation (Summative) Test Protocol
  - (b)(4) Human Factors Validation Test Report
    - (b)(4) Validation Report (Research Collective)
- (b)(4) Product Validation Protocol
  - (b)(4) Product Validation Report

(b)(4)

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(b)(4) User Related Risk Analysis – Clinician

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(b)(4) Formative Test Plan – Patient

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(b)(4) Human Factors Validation (Summative) Test Protocol

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(b)(4) Human Factors Validation Test Report

(b)(4) Validation Report (Research Collective

(b)(4)

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Human Factors Engineering & Usability Engineering Report for the SmartCardia 7L Platform

Prepared for
SmartCardia, Inc.

(b)(4)

(b)(4)

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Extent of Standard Conformance: **IEC 60601-1 Summary Report Table**

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Extent of Standard Conformance: **IEC 60601-1-2 Summary Report Table**.

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Extent of Standard Conformance: **IEC 60601-1-11 Summary Report Table**

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Extent of Standard Conformance: IEC 60601-2-47 Summary Report Table

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Extent of Standard Conformance: **EC12 Summary Report Table**

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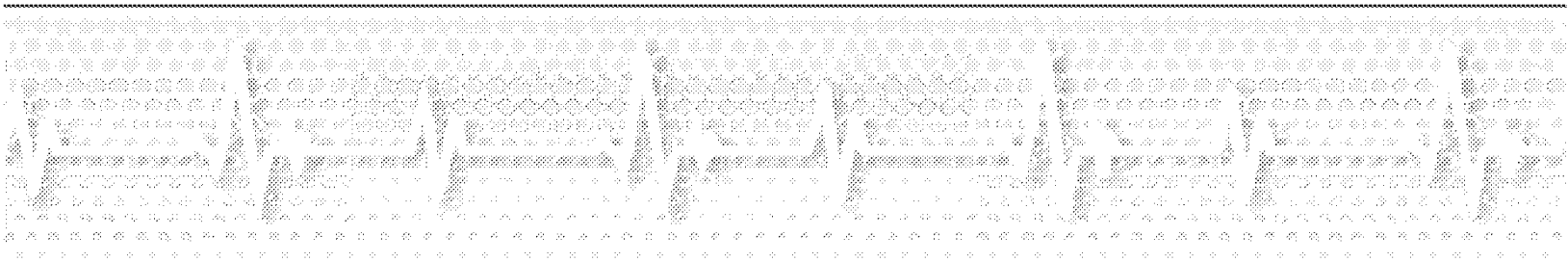

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013_Instructions for Use - Redlined Updates after AINN

- PL-08 SmartCardia 7L Patient Guide
- PL-09 SmartCardia 7L Clinician User Guide
- PL-10 SmartCardia 7L Clinician QRG
- PL-17 SmartCardia 7L Platform Technical Manual

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013_Instructions for Use K231276 (b)(4)

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- PL-09 SmartCardia 7L Clinician User Guide
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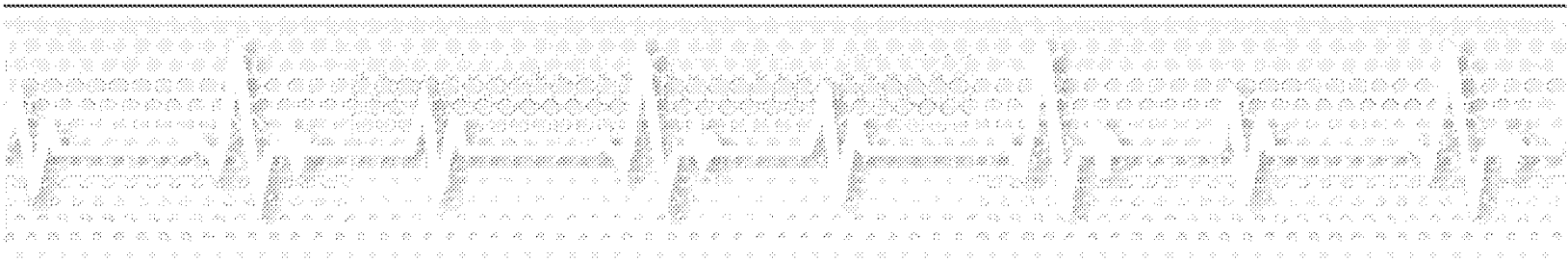

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Welcome!

Your doctor has prescribed this device so they can remotely view your vital signs.

We are here to help you.

So feel free to give us a call anytime at 800-363-8151.

SmartCardia 7L
monitoring the fabric of life®

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About This Manual

This Patient Guide describes how to use the SmartCardia 7L™ Platform.
For more information about SmartCardia 7L, visit www.SmartCardia.com.

Safety Precautions

This manual contains safety precautions as shown below.

	WARNING
	Indicates a hazard or unsafe use that could cause death or serious injury.

	CAUTION
	Indicates a hazard or unsafe use that could cause minor injury or product damage.

Note	A note shows more information about using the product.

Note: *The information contained in this document is subject to change without notice.*

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Warnings and Cautions

WARNING

- **The SmartCardia 7L system is not an emergency response service. If you experience symptoms that are cause for concern, immediately seek medical help.**
- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**
- **If you have severe skin irritation or burning feeling, remove 7L Patch right away and contact your doctor.**
- **Do not use this device in an MRI**

CAUTION

- Do not try to service the SmartCardia 7L system. The SmartCardia 7L system is not field reparable and there are no replaceable components.
- Do not use in a hospital operating room.
- To avoid the risk of fire, do not use the SmartCardia 7L system around anything flammable. Do not try to take apart the *7L Patch* or *7L Sensor*.
- Do not try to change the battery in the *7L Patch*.
- Stay away from heavy electrical equipment or other sources of interference.
- The SmartCardia 7L system is used for adults over the age of 18 years.
- Take care if showering. Caution should always be taken when wearing in a wet location.
- Install and use the SmartCardia 7L system as instructed. Do not attempt to connect it to another piece of equipment.
- Only use the charger provided with the Phone.
- Place the *7L Sensor* and *7L Patch* on the body as instructed.
- Keep the SmartCardia *Phone* closer than 10 feet at all times.

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	• The SmartCardia 7L Platform should not be used in an aircraft.

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Intended Use/Indications for Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

Measurements include: electrocardiogram (ECG signal), R-R interval, and Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

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Getting Started

Product Description

The SmartCardia 7L Platform is used to monitor your heart using the SmartCardia *7L Sensor* and *7L Patch*. This is worn on the body and monitors and saves your vital signals and sends this data to your doctor using the SmartCardia *Phone*.

SmartCardia 7L Components

SmartCardia 7L Sensor (the *7L Sensor*)

A reusable Sensor **(do not throw away)**

- Inserts into the *7L Patch*
- Monitors ECG
- Sends your data to the SmartCardia *Phone*
- Is waterproof when used with the 7L Patch

SmartCardia 7L Patch (the *7L Patch*)

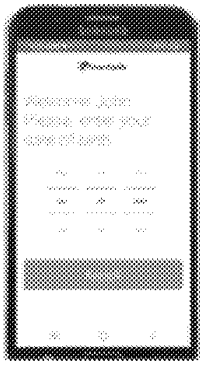
A single-use patch **(you can throw away)**

- Includes batteries
- Holds the reusable *7L Sensor*
- Sticks to your skin
- Expected shelf life up to 14 days

	WARNING
	The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.

SmartCardia Phone (the *Phone*)

Sends your data to the doctor



- Always keep it close to the SmartCardia *7L Sensor* (within 10 ft.)
- Charge daily (or more often)

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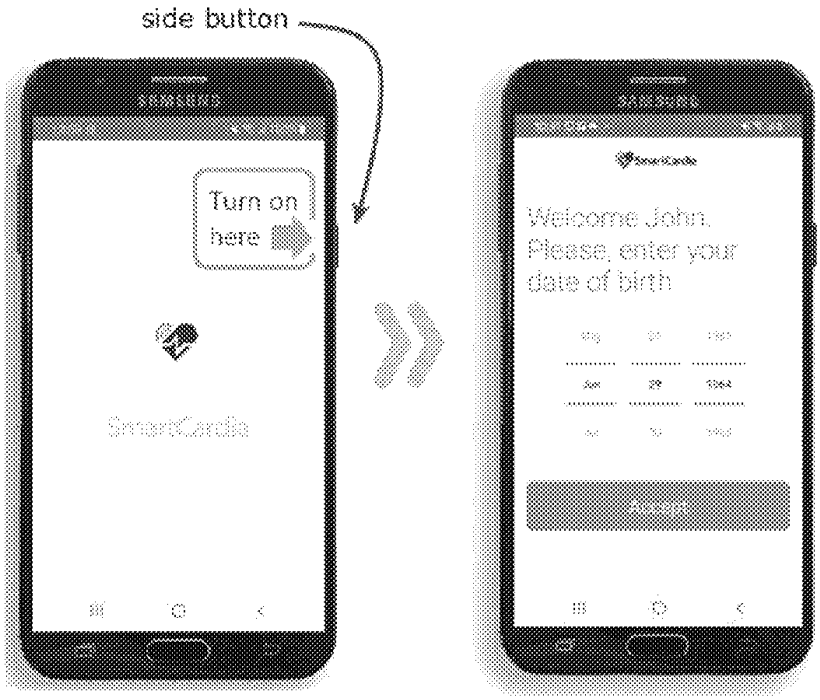
Start the Phone

Step 1
Push the side button on the *Phone* to turn on. (This may take several minutes) Swipe up to unlock *Phone*

Step 2
Enter your date of birth on the screen display.



Note: *You cannot make personal phone calls on this phone. This phone will not make calls or send emails. It is for SmartCardia use only.*

Note: *After you attach the 7L Patch, your heart rhythm will appear on the screen. See page 12 for more details.*

⚠	**CAUTION**
	Keep the SmartCardia *Phone* closer than 10 feet at all times.

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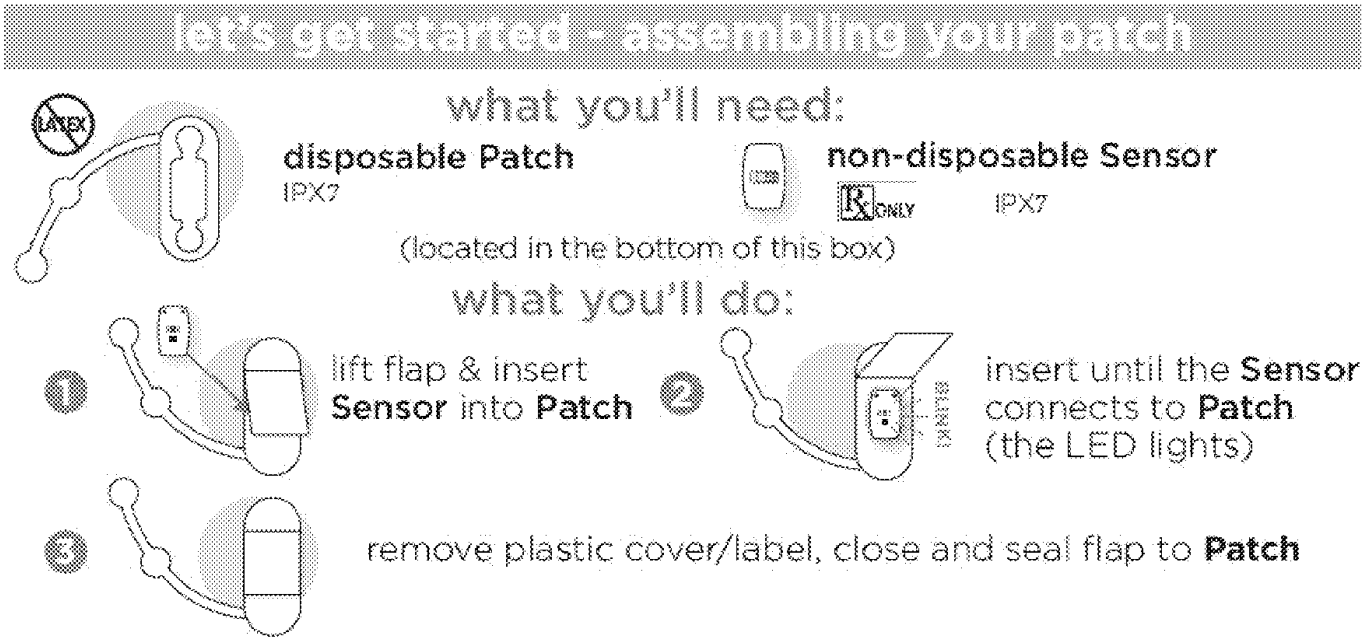
Attach Patch with Sensor

The *7L Patch* is placed on your skin to monitor your heart (shown in the diagrams below).

Step 1

The *7L Sensor* (**not disposable**) is inserted into the disposable *7L Patch*.

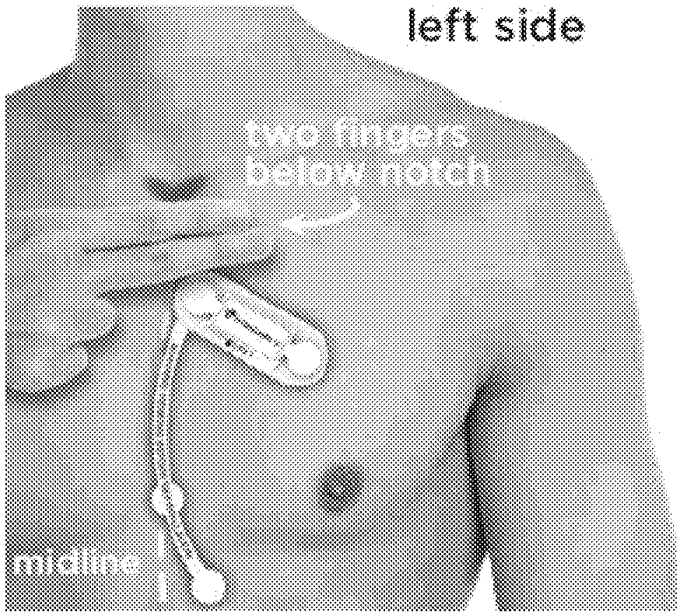
Note: *The 7L Sensor will fit into the 7L Patch in only one direction. Make sure to align the 'marks' on the 7L Sensor to those on the 7L Patch.*



Step 2

Clean and dry your skin before the *7L Patch* is placed on your body.

For men, chest hair should be shaved or clipped where the *7L Patch* will be placed.



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	WARNING **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**

	CAUTION The 7L Patch should be applied immediately after the pouch is opened. Dispose of the patch and do not use if the pouch has been opened before.

Note: *The 7L Patch should never be placed on injured areas of skin or on open wounds.*

Note: *Failure to prepare the skin area can make removal of the 7L Patch difficult.*

	WARNING **If you have severe skin irritation or burning feeling, remove *7L Patch* right away and contact your doctor.**

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Monitoring

Once finished you are free to go about your normal daily activities, unless told otherwise.

Note: *Once you start, do not remove the 7L Patch and 7L Sensor. It must be worn all the time, even when you sleep.*

- Your doctor will tell you how long you should wear the *7L Patch* and *7L Sensor*. You must change the patch if you have to wear the patch for longer than 14 days. Refer to page 15.
- When you are finished, you will return the *7L Sensor*, the *Phone*, and phone charger in the enclosed prepaid package.
- Your doctor will review your data.

IMPORTANT

- Always keep the SmartCardia *Phone* closer than 10 feet from you.
- You may shower.

Note: *The body worn system is waterproof, but the Phone is not.*

CAUTION

Do not get the SmartCardia *Phone* wet or in water.

CAUTION

If water seeps into the *7L Patch* or the *7L Patch* falls off, replace the *7L Patch*.

Note: *If the Patch peels or lifts at the edges, try to press, and hold along the edges to re-apply.*

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	CAUTION
	Continue to wear the *7L Patch* for the length of time prescribed by your doctor.

SmartCardia Phone

The *Phone* is used to:

- Send your data from the *7L Sensor*
- Mark events when you press the EVENT button
- Show your heart rate

Note: *The Phone is for use only with the SmartCardia 7L Platform. It will not work as a cell phone.*

Note: *Do not drop the Phone and always keep it in a dry and safe place.*

Note: *Do not worry if you are in an area where the Phone has no cell service. The 7L Sensor and 7L Patch saves the data. When cell service comes back, the saved data is sent to your doctor.*

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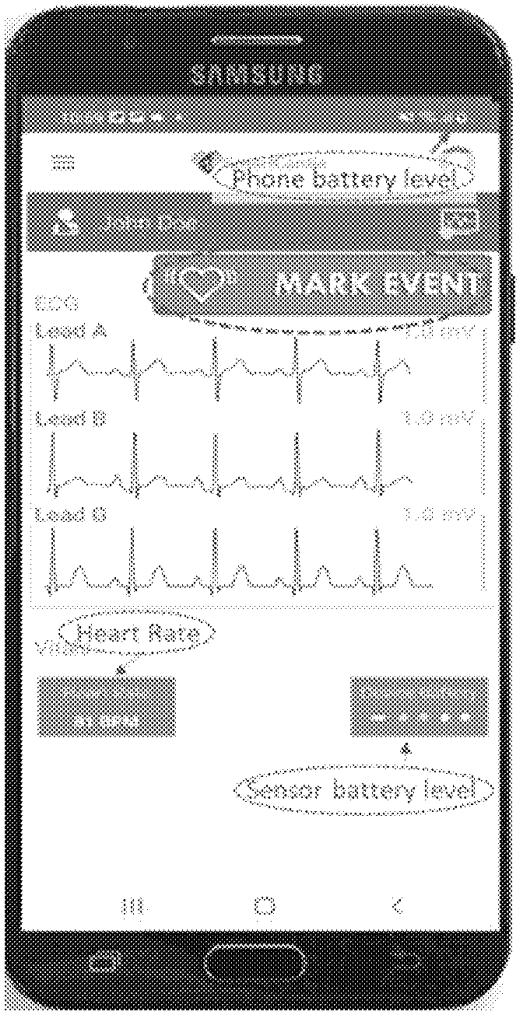
Phone Screen Display

The *Phone* allows you to see your data. When the *Phone* is turned on it shows:

- Your name
- Phone battery level (always keep charged)
- MARK EVENT button to press when you do not feel well
- Your ECG waveform
- Your heart rate
- The *7L Sensor* battery level (device battery)
  - The battery level of the *7L Sensor* is shown when it is connected to the *Phone*
  - The battery level is shown by four dots. When the dots are green that is the battery life remaining
  - A low battery level alert will be shown in red



Using the MARK EVENT Button on SmartCardia Phone

If you feel dizzy, short of breath, or have chest pain, press the MARK EVENT button, and select event duration then select what you are feeling.

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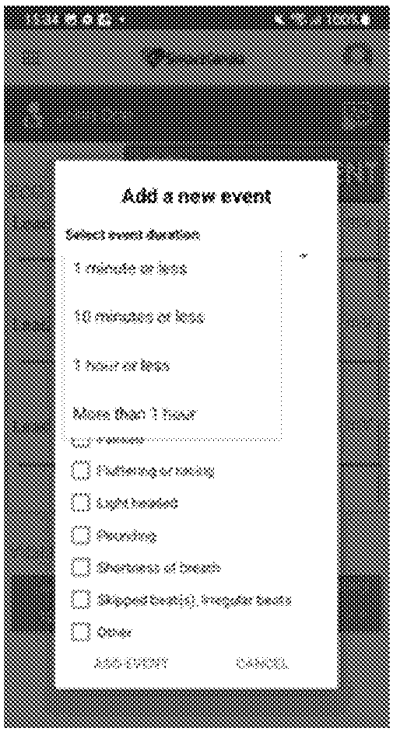

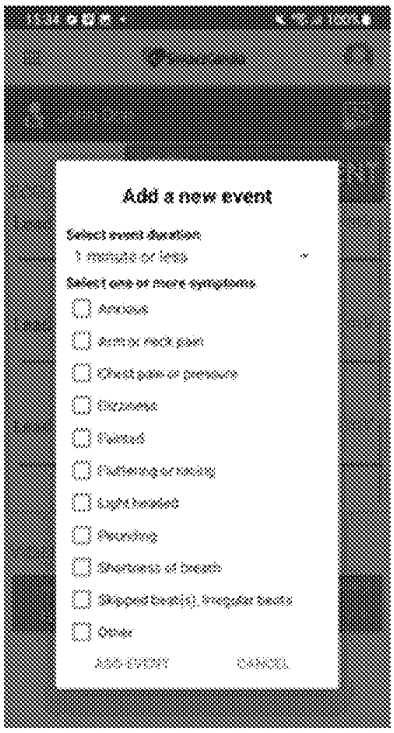

	WARNING
⚠	**The SmartCardia 7L Platform is not an emergency response system. If you experience a symptom that you feel is a medical emergency, call 911 immediately for emergency medical attention.**

Charging the *Phone*

The *Phone* must be charged all the time. It is best to do this every day when you are resting or sleeping.

When to Change the *7L Patch*

Do not remove the *7L Sensor* and *7L Patch* unless:

- The *7L Sensor* and *7L Patch* become damaged.
- Your skin under the *7L Sensor* and *7L Patch* has a rash.
- The *7L Sensor* and *7L Patch* begins to come off.
- You are told to do so by your doctor or caregiver.

How to Change the *7L Patch*

Step 1

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Carefully remove the *7L Sensor* and *7L Patch*. Use of baby oil to loosen the adhesive may make it easier to remove.

Step 2

Gently take out the *7L Sensor* from the *7L Patch.*

Get the new *7L Patch* and repeat the Set-Up Process (refer to pages 9/10).

Cleaning and Disinfecting the *7L Sensor*

Step 1

Clean the *7L Sensor* with warm water and dish soap using a cloth or sponge to remove surface dirt.

Step 2

Disinfect the *7L Sensor* with PDI Super Sani-Cloth® Germicidal Disposable Wipe for five minutes following the instructions on the package.

When You Are Finished

- Remove the *7L Sensor* and the *7L Patch* from your body.
- Take out the *7L Sensor* from inside the *7L Patch* and place it into the SmartCardia large pre-addressed shipping envelope for return.
- Place the *Phone* in the small envelope and put into larger pre-addressed shipping envelope along with the 7L Sensor, phone charger and cable for return.
- Discard the used *7L Patch*.

Note: *If you have difficulty removing the 7L Sensor from the 7L Patch, return both.*

Return to SmartCardia

- Seal pre-addressed shipping envelope tightly.
- Drop the shipping package off at the specified carrier shipping location.
- Document the tracking number from the carrier for your records.

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Troubleshooting

What to do if you get skin irritation

The *7L Patch* uses a medical adhesive that can be worn for a long time.

- Mild itching, irritation or rash on the skin may occur. This is normal and usually temporary.
- If you have severe itching or redness, contact your doctor.

WARNING

If you have severe skin irritation or burning feeling, remove *7L Patch* right away and contact your doctor.

Problem	What is the Cause	What to Do
7L Sensor will not go into *7L Patch*	*7L Sensor* is put in backward	• Check the instructions on the *7L Patch* for correct alignment • Make sure the connector (green side) on the *7L Sensor* is facing the *7L Patch* • Align the marks on the *7L Sensor* with the marks on the *7L Patch*
Phone will not turn ON	The *Phone* is out of battery	Plug in phone charger and check to see if phone is charging
ECG is not shown on *Phone*	• *7L Sensor* and *7L Patch* are not sending ECG to *Phone* • *Phone* is out of battery • *7L Sensor* and *7L Patch* are out of battery	• Make sure the *Phone* is closer than 10 feet from you at all times • Plug in the phone charger and check to see if it is charging • Check the battery level on the *Phone* and if it does not indicate“Device Battery” remaining, replace the *7L Patch* as instructed

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Warranty and Services

For help at any time, call 1-800-363-8151.

The *7L Sensor* requires no calibration.

In the event the *7L Sensor* is not working properly, use the troubleshooting steps outlined above. If the *7L Sensor* is still not working properly, contact SmartCardia SA for technical and service support by calling 1-800-363-8151 or email info@smartcardia.com.

SmartCardia SA warrants the *7L Sensor* hardware against defects in materials and workmanship when used normally per the *7L Sensor* instructions for a period of Two (2) Years from the date of original retail purchase by the end- user purchaser (“Warranty Period”).

SmartCardia does not warrant that the operation of the *7L Sensor* will be uninterrupted or error-free.

SmartCardia SA is not responsible for the damage arising from the failure to follow instructions relating to the *7L Sensor* device.

The *7L Patch* has a shelf life of Two (2) Years when handled properly and stored within its stated environmental conditions (see *Specifications*).

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Symbols Used

Symbol	Title of Symbol	Symbol Description
	Manufacturer	Shows who manufactured the product
	European Conformity	The product meets the standards for Medical Device in the European Union
	Batch code	Indicates the manufacturer's Lot code
	Catalog number	Indicates the manufacturer's catalogue number
	Serial number	Indicates the serial number of the medical device
	Non-sterile	The product is not sterile
	Do not use if package is damaged	Do not use if package has been damaged or opened
	Fragile, handle with care	Indicates you should handle the product with care
	Not made with natural rubber latex	There is no natural rubber latex in the product or its package
	Do not use in MRI	Do not use the product in a magnetic resonance imaging instrument
	Keep dry	The product needs to be kept dry
	Temperature limits	Indicates the high and low temperatures for storage and use
	Humidity limits	Indicates the high and low humidity for storage and operation
	Do not re-use	Product is for single use only and not to use on another patient
	Consult instructions for use	For more information, read the operation manual or instructions for use
	Caution or Warning	Consult the instructions for use of important warnings and cautions that are printed on the product
	Use-by-date	The date after which the product or accessories should not be used
	Crossed-off wheeled bin	The product contains electrical parts and must be disposed of properly, not into any bin, but must be placed in an electrical equipment bin
	Non-ionizing radiation	The product does radiate RF, but it is non-ionizing
	BF applied part	To identify a type BF applied part complying with IEC 60601-1

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Specifications

Physical and Environmental	
Size (approximate)	*7L Sensor*: 1.97 x 1.18 x .39 inch; (50 x 30 x 10 mm) *7L Patch* (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14 mm)
Weight (approximate)	*7L Sensor and 7L Patch*: Less than 3.52 oz. (100 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C) Operating: +41 to +104°F (+5 to + 45°C)
Humidity	0 to 90% at +41 to 95°F (+5 to +35°C) (non-condensing) / 70 – 106 kPa
Safety	Type BF
Water Ingress	IPX7 (Waterproof)
Battery Life	Up to 14 days depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993-5, ISO 10993-10, ISO 10993-12 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30-200	Beats per minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

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Unique Device Identifier(s)

7L Sensor 7640375610058
7L Patch 7640375610041

SmartCardia SA
EPFL Innovation Park, Building C 1015Lausanne, Switzerland
Customer Support: 800-363-8151

PL-08 SmartCardia 7L™ Platform – Patient Guide

Prescription Only

Consult Instructions for Use or User Manual

Type BF

See Warnings and Cautions

SmartCardia SA
EPFL Innovation Park,
Building C
1015 Lausanne, Switzerland

FCC

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:

1. These devices may not cause harmful interference, and
2. These devices must accept any interference received, including interference that may cause undesired operation.

FCC ID: XPYNINAAB30

Non-ionizing electromagnetic radiation

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monitoring the fabric of life™

SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

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· PL-09 SmartCardia 7L Clinician User Guide

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SmartCardia 7L Platform™
Clinician User Guide

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About SmartCardia

SmartCardia, SA is a Swiss medical device company that focuses on clinical quality data and validation. The company works with key opinion leaders across a variety of clinical fields; from cardiology, vascular medicine, sleep, and COPD to validate the unique insights our systems provide.

SmartCardia is an ISO 13485 certified medical device manufacturer that meets the strict quality control standards for our solutions. The company is also ISO 27001 certified for data security and privacy.

Through rigorous clinical testing and validation, the 7L Patch, cloud and software are CE-marked as a Class IIa medical device.

CE 2803 ISO 13485:2016 HTCert Health Technology Certification

This *Clinician User Guide* describes the features of this product, main structure, function, specifications, correct method for transportation, installation, usage, operation, repair, maintenance, and storage, as well as safety procedures to protect both the user and the equipment.

EPFL Innovation Park, Building C

1015 Lausanne, Switzerland

Email: contact@smartcardia.com

Customer Support (800) 363-8151

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About this User Guide

User Guide Use and Audience

This user guide is a key part of the SmartCardia 7L Platform™ and describes the use of the system.

This user guide is for use by clinical professionals. They should have the appropriate training to observe and interpret patients' heart condition and check for abnormalities of heart rate and arrhythmias. It is important for the clinician to recognize and respond appropriately to changes in patient's heart rate and any abnormal conditions in patients' heart rhythm. In addition, analysis and creation of reports is necessary to provide a complete and accurate record of time that patients are monitored. Using the SmartCardia 7L Platform should not replace using sound clinical judgment when monitoring patients.

User Guide Style

The following styles and naming are used in the user guide to emphasize text or indicate an action.

Bold	Important information
Italic	References the components of the SmartCardia 7L Platform
Bold italic	Used for emphasis
Bold red text	Most important information, used to bring attention to a warning or caution
Select	The word select means to choose and confirm
“ ”	Quotation marks indicates this is an option to select on the 7L Web Browser screen
NOTE	Provides additional helpful information

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SmartCardia 7L Platform Naming Convention

Component Name	Name	Part Number	Brief Description
SmartCardia 7L Sensor	*7L Sensor*	DS-36	Electronic unit collects ECG data
SmartCardia 7L Patch	*7L Patch*	DS-33	Connects to skin and holds and powers the *7L Sensor*
SmartCardia Phone	*Phone*	DS-39	Android phone configured in kiosk mode, uses cellular service to transmit ECG using the *7L Mobile Application* to Cloud, viewed on *7L Web Browser*
SmartCardia 7L Web Browser	*7L Web Browser*	DS-41	Chrome web browser for clinicians to manage ECG data

Illustrations and Names

This user guide uses illustrations to show examples. They may not include all possible configurations available in the SmartCardia 7L Platform.

Reference Materials

- PL-10 Clinician Quick Reference Guide (QRG)
- PL-13 Clinician training video
- PL-08 Patient User Guide
- SmartCardia Customer Support (800) 363-8151

Safety

Warnings and Cautions

To ensure safe use of the equipment, please read the following statements. This user guide contains safety precautions that are explained below.

	WARNING
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

	CAUTION
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

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SmartCardia 7L Platform

WARNING: The 7L Platform™ is not an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

CAUTIONS:

- The 7L Platform is used for adults over the age of 18 years.
- Install the 7L Platform and use as instructed. Do **not** attempt to connect it to another piece of equipment.
- Do **not** try to service the 7L Platform. It is **not** field repairable and there are no replaceable components.
- The 7L Platform is to be used by adequately trained personnel.
- Do not use with other devices, which have high-level electromagnetic radiation.
- The 7L Platform is not designated for use in the operating room or operating theater.
- Make sure to have a good internet connection and sufficient bandwidth.
- The SmartCardia 7L Platform should not be used in an aircraft.

7L Sensor, 7L Patch, and SmartCardia Phone

WARNINGS:

- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**
- **If a patient has severe skin irritation or burning feeling, they should remove the 7L Patch right away and contact their doctor.**
- **Do not use this device in an MRI.**

CAUTIONS:

- The 7L Platform is designed to operate in the presence of pacemaker pulses. Caution should be used to not locate the *7L Patch* with the *7L Sensor* on top of a pacemaker.
- The SmartCardia *Phone* should not be placed over a pacemaker.
- Do not try to take apart the *7L Patch* or *7L Sensor*.
- Do not try to change the battery in the *7L Patch*.
- Do not use the device if the *7L Sensor* or *7L Patch* is damaged.
- The *7L Patch* is single use for a single patient. Do not reuse.
- Follow the instructions to use correctly.
- Make sure the *7L Sensor* is installed correctly and is firmly sealed in the *7L Patch*.
- The *7L Sensor* and *7L Patch* should be placed on the patient's body as instructed.
- Care should be taken by the patient if showering. Caution should always be taken when wearing in a wet location.
- The SmartCardia *Phone* cannot get wet.
- Avoid extreme high or low temperature and humidity.
- Follow the instructions for the correct cleaning solution and process.

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- Do not use the device if the battery is depleted**.** Refer to the SmartCardia documentation for the battery life expectancy.
- Do not place the *7L Patch* on open wounds.
- The patient must keep the SmartCardia *Phone* within 10 ft of the *7L Sensor* at all times.
- Make sure the SmartCardia *Phone* is fully charged. It is best to charge the phone each night.
- If the Bluetooth on the SmartCardia *Phone* Is OFF, contact SmartCardia Customer Support.
- Only use the charger provided with the SmartCardia *Phone*.
- It is very important to have a good internet connection.
- For best results, the patient's skin where the *7L Patch* is applied should be cleaned and hair clipped or shaved to reduce artifact and prevent a noisy signal.
- Do not use the *7L Patch* if date of manufacture is more than two years. Refer to the *7L Patch* labeling.
- The patient must stay away from heavy electrical equipment or other sources of interference. For additional information regarding Electromagnetic Compatibility (EMC), see Attachment B.

SmartCardia 7L Web Browser

CAUTIONS:

- Keep username and login in a safe place and do not share them with anyone.
- Do not leave your session open if you leave the device unattended. Always log out.
- Do not access the cloud platform from a shared computer.
- Make sure to set the correct mode of monitoring operation for the patient (Holter, Extended Holter, Event, or Mobile Cardiac Telemetry).
- Measured vital sign values should be reviewed and verified by alternate means if measurements are suspected to be inaccurate.

Alarms

WARNINGS:

- **Alarm conditions must be set to ON for a notification to be presented at the remote viewing station.**
- **Make sure that parameter limit settings are appropriate for the clinical condition of the patient being monitored - do not set parameter limit settings outside the physiological range for the patient.**
- **When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.**
- **Alarm limits are patient or facility specific. The clinician must set and verify alarm limits appropriate for each patient. Failure to set alarm limits properly can lead to false alarms or failure to alarm.**

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- **No computerized interpretation of patient data can correctly detect and classify a medical condition 100% of the time. Use sound clinical judgment when monitoring your patients.**
- **Audio on the PC used to view the *7L Web Browser* must be ON and sufficiently loud enough.**
- **When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**
- **Do not turn OFF the audible notifications without providing continuous observation of the patient.**
- **Check notification volume periodically! If the volume is too low, it could result in the inability to hear a notification.**
- **In certain circumstances the pacemaker pulse may be detected as a heartbeat. Verify heartbeat with an alternative method such as auscultation, radial artery palpation, or viewing ECG.**
- **Make sure that proper patient preparation and settings are in place to avoid sensitivity to excessive artifact which can result in inaccurate notifications.**
- **Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a clinician views these events, they should follow their practice guidelines and manually document the event in the patient record.**
- **The alarms provided on the SmartCardia 7L Platform should be properly assessed by medically trained or relevant qualified and accredited personnel.**
- **It is the responsibility of the clinician or care provider to respond to alarms consistent with their practice license.**

CAUTIONS:

- When remote monitoring a patient, remember they may not have a caregiver or helper nearby and they may not be able to respond to communications. Always know how to provide aid for each patient.
- Receipt of alarm signals is not confirmed.
- Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.
- If the wireless connection from the *7L Sensor* and *7L Patch* to the SmartCardia *Phone* or the *Phone* to the internet/cloud application is disconnected, a notification will show on the display. Periodically check to make sure the connection is intact.

Questions? Contact FDA/CDRH/OHT5/DHT5P at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

Measurements include: electrocardiogram (ECG signal), R-R interval, and Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Questions? Contact FDA/CDRH/OCE/DHS at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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SmartCardia 7L Platform™ Introduction

System Description

The SmartCardia, Inc. 7L Platform™ is a system comprising a wireless sensor component (the *7L Sensor*), an adhesive patch (the *7L Patch*) which the *7L Sensor* connects to, a mobile component (the SmartCardia *Phone*), and a backend server component (*SmartCardia 7L Web Browser*) to access the patient database. The SmartCardia *Phone* is an Android OS mobile phone that is configured by SmartCardia in a kiosk mode so it can only be used by the SmartCardia *7L Mobile Application* (it does not function as a usable phone, only as a mobile gateway for the SmartCardia data). The data are viewed on the SmartCardia *Phone* and via a SmartCardia *7L Web Browser* application.

The *7L Sensor* and *7L Patch* make up a body worn applied device consisting of the ***reusable*** electronic *7L Sensor* and a ***disposable*** adhesive *7L Patch* into which the *7L Sensor* is inserted and connection is made. The accessory *7L Patch* has four electrodes. The sensor and patch assembly adheres to the chest and contains the batteries to power the connected reusable *7L Sensor* to wirelessly monitor electrocardiogram (ECG) and heart rate of the patient.

The SmartCardia 7L Platform provides near real time monitoring for Holter applications and supports three monitoring service modes:

- Holter Monitoring (up to 48 hours) and Extended Holter Monitoring (greater than 48 hours)
- Event Monitoring
- Mobile Cardiac Outpatient Telemetry, or Mobile Cardiac Telemetry (MCT)

The SmartCardia 7L Platform has the following characteristics:

- It provides a near-real time, continuous monitoring for any operation mode,
- It is non-invasive and has no significant safety issues, and
- It uses electrode and ECG technology that is in use today.

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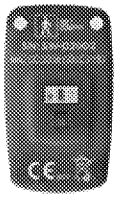
SmartCardia 7L Platform Components

SmartCardia 7L Sensor (the *7L Sensor*)
A reusable Sensor (do **not** throw away)

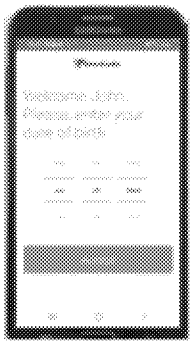


- Inserts into the *7L Patch*
- Monitors ECG
- Sends patient data to the SmartCardia *Phone*
- Is waterproof when used with the *7L Patch*

SmartCardia 7L Patch (the *7L Patch*)
A single-use patch (disposable)

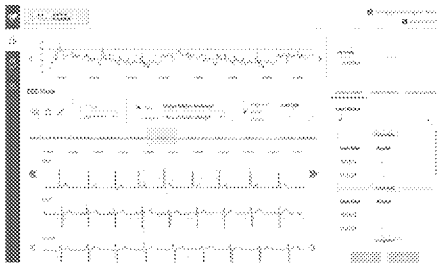
- Includes batteries
- Holds the reusable *7L Sensor*
- Includes ECG Electrodes
- Medical adhesive used to apply to the skin

SmartCardia Phone (the *Phone*)



- Is a gateway to send patient data to the provider viewed on the *7L Web Browser*
- Always kept close within 10 feet of the SmartCardia *7L Sensor*
- Charged daily (or more often as needed)
- Uses the *7L Mobile Application*
- Provided and configured by SmartCardia

SmartCardia 7L Web Browser (the *7L Web Browser*)



- Application is validated on Google Chrome browser only
- Service mode choices (Holter, Extended Holter, Event Recording, and Mobile Cardiac Telemetry
- View patient data, manage alarms, analyze ECG, and create reports

Responsibilities

Clinician responsibility

- Patient registration in the system
- Provide remote support for the patient

Responsibility of SmartCardia

- Remote clinical support
- Remote technical support

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Abbreviations

ECG: Electrocardiogram
HR: Heart Rate
BPM: Beats per minute

Icon & Symbol Table

Symbols on the Product and Packaging

Symbol	Title of Symbol	Symbol Description
	SmartCardia	Represents the SmartCardia logo
	European Conformity	The product meets the standards for Medical Device in the European Union and Subscript text next to the symbol indicates the code of the notified body
	Manufacturer	Indicates the medical device manufacturer
	Authorized Representative in the European Community	Indicates the Authorized representative in the European Community
	Date of manufacture	Indicates the date when the medical device was manufactured
	Use-by-date	The date after which the product or the accessories should not be used
	FCC Compliance Mark	Meets FCC requirements per 21 CFR Part 15
	Serial number	Indicates the serial number of the medical device
	Catalog number	Indicates the manufacturer's catalogue number so the medical device can be identified
	Batch code	Indicates the manufacturer's Lot code
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	Temperature limits	Indicates the high and low temperatures for storage and use
	Humidity limits	Indicates the high and low humidity for storage and operation

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Symbol	Title of Symbol	Symbol Description
	Do not re-use	Product is for single use only and not to use on another patient
	Keep dry	The product needs to be kept dry
	Non-ionizing electromagnetic radiation	This product does radiate RF, but it is non-ionizing
	Restriction of hazardous substances	Product is in accordance with the requirements restricting the use of specific hazardous materials
	BF applied part	To identify a type BF applied part complying with IEC 60601-1
	Do not use in MRI	Do not use the product in a magnetic resonance imaging instrument
	Not made with natural rubber latex	There is no natural rubber latex in the product or its package
	Non-sterile	The product is not sterile
	Crossed-off wheeled bin	The product contains electrical parts and must be disposed of properly, not into any bin, but must be placed in an electrical equipment bin
	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Consult instructions for use	For more information, read the operation manual or instructions for use
	Do not use if package is damaged	Do not use if the package has been damaged or opened
IPX7	Ingress protection (IP) rating	Indicates the assembled 7L Sensor and 7L Patch can withstand ingress of water in harmful quantity when immersed in water under defined conditions of pressure and time (up to 1 meter (3 ft 3 in) of submersion)
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Warning	Consult the instructions for use for important warning information that cannot be presented on the medical device itself
	Caution	Consult the instructions for use for important cautionary information that cannot be presented on the medical device itself

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Symbols on the User Interface

Symbol	Title of Symbol	Symbol Description
	Mail	Refers to email
	Phone	Refers to phone number
	Password	Refers to password
	Clinician	Refers to clinician
	Patient	Refers to patient
	Multi-Patient	Refers to the display of 12 or more patient tiles
	Device	Refers to the SmartCardia *7L Sensor*
	Chest device location	Represents the *7L Patch* with *7L Sensor* on the patient's chest
	Bell cancel	To identify the control where an audio alarm sound may be switched off or to indicate the operating status of the alarm audio.
	Edit	Represents that data can be edited
	Delete	Represents that data can be deleted
	Calendar	Refers to a calendar where date can be selected
	Clock	Refers to the time
	Time zone	Refers to the time zone
	Add	Refers to adding or seeing more information
	Heart	Represents the patient's heartbeat

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Symbol	Title of Symbol	Symbol Description
	Import Records / Upload File	Refers to the action of importing a record (upload a SmartCardia file)
	Clipboard	Represents information
	Return	Represents the action of coming back to the initial state
	Zoom	Represents the zoom action
	Undo	Represents that the action can be undone
	Search	Represents the action of searching
	Sort	Represents the action of sorting
	Logout	Refers to logout action
	Stop	Refers to stopping an action
	Measure	Represents ECG chart measurement
	Close	The tab can be closed
	Arrow	Clinicians use the arrows to scroll through the graph
	File	The report created by the clinician can be downloaded
	Link	Refers to the association between one patient and a device
	Unlink	There is no patient-device association
	Battery	Refers to the battery of the *7L Patch*
	Battery critically low	Battery of the *7L Patch,* less than 10% remains

Questions? Contact FDAAccessCDRH@fda.hhs.gov or 301-796-8118

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7L Web Browser Navigation

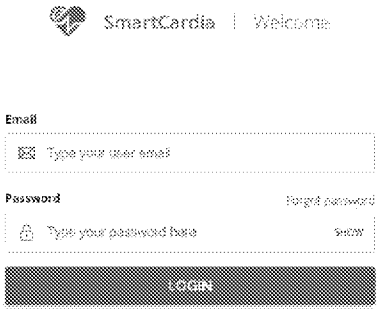
Clinician Login

General Recommendations

- The cloud platform known as the *7L Web Browser* should always be accessed using Google Chrome from an authorized and secured device with at least 4 GB of RAM.
- The *7L Web Browser* must only be used by clinical personnel who have been properly trained on the safe and efficacious use of the product.

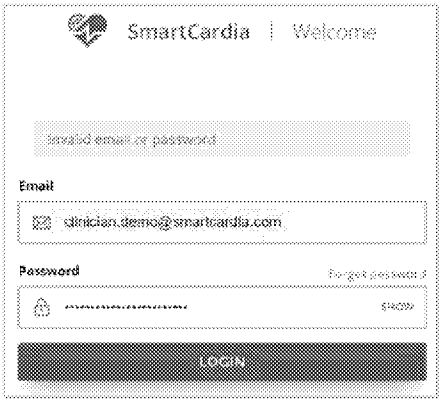
The first view accessed by the clinician when opening the application is the Login window. The user must enter his/her email address (email@example.com), which has been previously registered in the SmartCardia 7L Platform and their corresponding password.

- Enter your user Email and Password
- Click "LOGIN" to show a list of patients



NOTE: If there is a problem when entering your password without displaying it, you can press the "SHOW" button to the right side in the Password box to display it.

- If the email or password is entered incorrectly, an error message box is displayed.
- Re-enter the Email, Password, and LOGIN.



Questions? Contact FDAACDRHDOCSTAR at CDRH-FOISTAT@fda.hhs.gov or 301-796-8118

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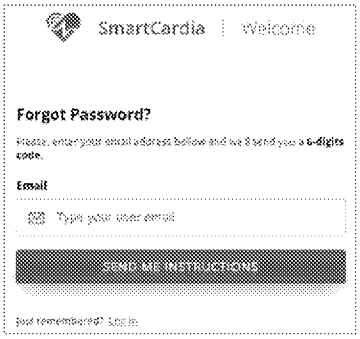
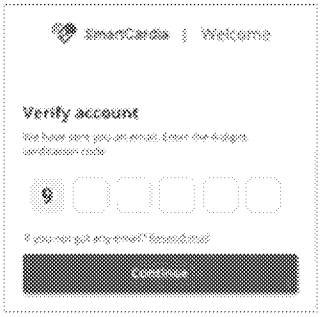
Forgot your password?



- Select the “Forgot password?” button located to the right of the Password box just above it. This new window opens to retrieve your password
- In the new window, in case the password is remembered, at the lower left corner of the box, the “Log in” hyperlink can be selected to return to the log in page
- In the event you do not remember your password, enter your email, and press the “Send me instructions” button



- You will then receive a message with a six-digit code to enter in the new window to verify your account
- In case you do not receive any message, you can request a new code again by pressing the “Resend mail” button.
- After entering the six-digit verification code, press the “Continue” button and if the verification code is correct, a new window will appear.

- In the reset password new window, you enter a new password according to the following rules:
  - Minimum length of 10 characters
  - At least 1 uppercase
  - At least 1 lowercase
  - At least 1 digit
- After pressing the “Update password” button, you will be redirected to the Login page

NOTE: In case of error, the user has three more attempts before being locked out. Contact SmartCardia Customer Support.

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Main Menu: Navigation Bar

The *7L Web Browser* has a main navigation menu that allows the user to move through the application. The main navigation bar can be used showing symbols and item names or showing only the symbols. The main navigation, which always appears on the left side of the web application and consists of the following symbols that appear from top to bottom:

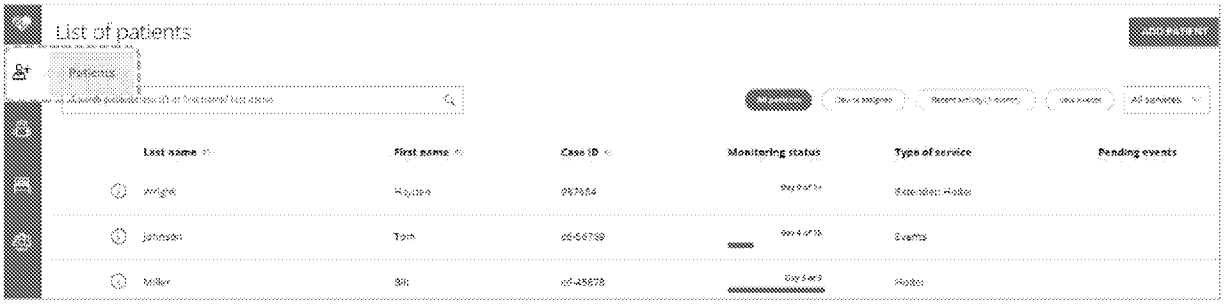
	SmartCardia logo
	Patients- press the button to access the list of patients
	Devices- press to access the list of devices
	Multi-Patient- press to access the view of multiple patient tiles
	Settings- access for clinician administrative information and settings
	Clinician- allows you to log out of the application

Patient Management

Main Page: List of Patients

Navigation Menu

The main page of the application is the “List of patients”, as shown below.

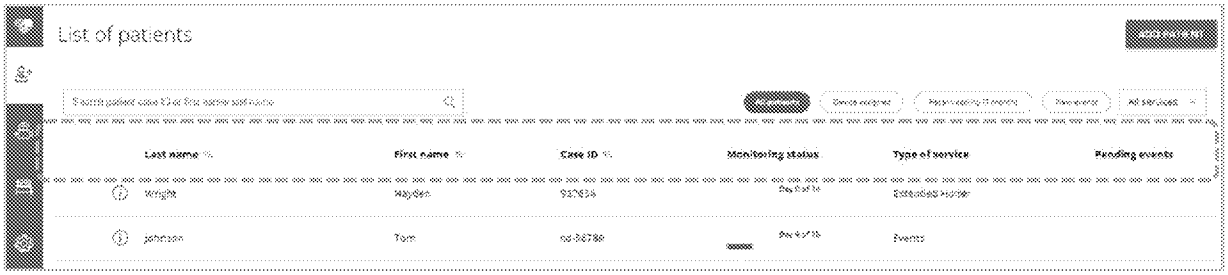


Questions? Contact FDAACDRHDOCSTAR at CDRH-FOISTAR@fda.hhs.gov or 301-796-8118

Functions to select across the top include:

- The search bar box can be used to search for a patient using the patient case ID, first name, or last name
- "All patients" provides the list of all patients ever added to the system
- "Device assigned" shows the list of patients that currently have a device assigned (the *7L Sensor*) presented in alphabetical and numerical order
- "Recent activity (1 month)" lists activity for the past one month
- "New events" displays the list of patients with pending events (all new events triggered based on the alarm and notification settings)
- "All services" provides a drop-down menu list of service types to sort list of patients (All services, Holter, Extended Holter, Events, or Mobile Cardiac Telemetry)

The column headers below provide navigation and information about the list of patients.



- Patients can be sorted by last name, first name, or case ID by clicking on the "Sort" icon on the right side of the column headers
- Monitoring status shows the current number of days that have been monitored and the number of days remaining
- Type of service displays the type of service currently in use for each patient
- Pending events lists pending events, the number of events is listed inside the red circle

Questions? Contact FDA/CDRH/OSEL/DIDSR at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118

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List of Patients

One of the important functionalities for the clinician on the main page is to view additional information about a patient.

Clinicians can see detailed information for each patient by selecting the information sign to the left of the patient's name.

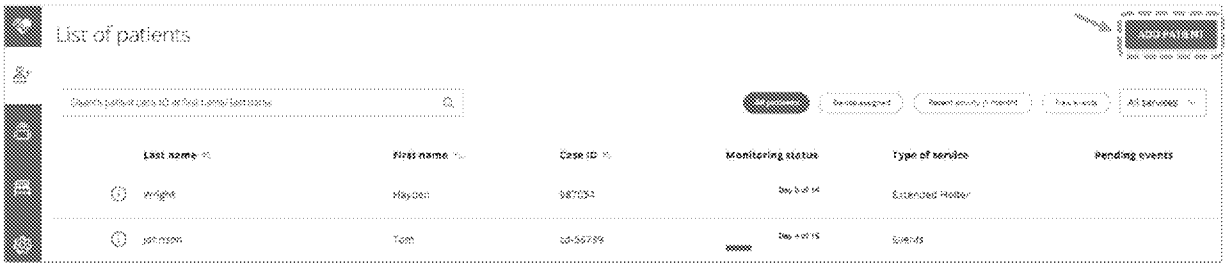
The detailed information includes:

- Last name, first name
- Age: patient's age
- Sex: patient's sex
- Multi-Patient Tile #: viewing location of patient tile assigned to the patient

  Note: The patient is automatically assigned to a Multi-Patient Tile when admitted
- Chest device: the device is attached to the chest and a green solid circle with the device name is listed

Add a Patient

The other important functionality for the clinician that appears on the main page is the addition of a new patient, this happens when the user selects the "ADD PATIENT" button located in the upper right corner.



The patient onboarding screen opens, and you are on the add new patient screen.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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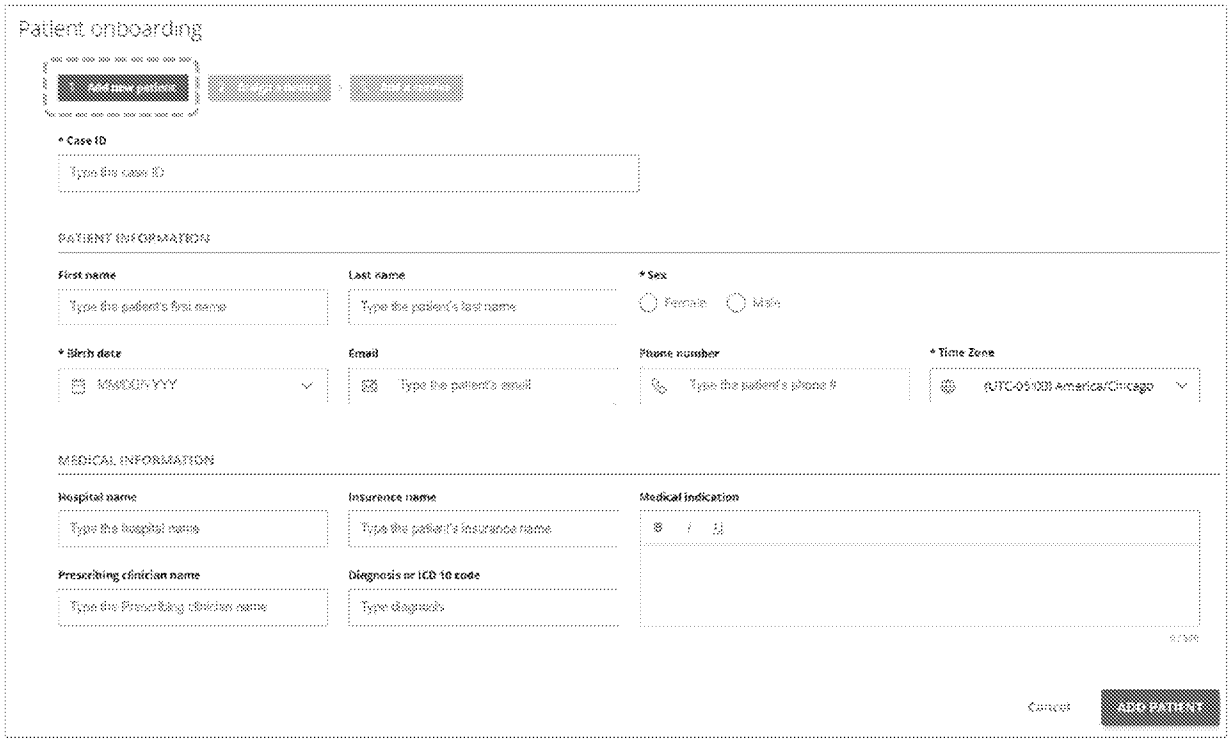
Patient Onboarding- Step 1: Add a new patient

Enter the patient and medical information on the form.



To exit the form without filling it out, press the “Cancel” button.

In the form, complete the following fields (* indicates required field):

- Case ID*- identifier associated with each patient (must be a unique number)
- Name- patient's first and last name
- Sex*- select the sex of the patient (female or male)
- Birth date*- use the calendar to enter the birth date of the patient (to enter the year, select the year displayed then scroll to the one desired and select it. To enter the month, select the month displayed, then scroll to the appropriate one and select it.)
- Time zone*- if not filled with the correct time zone, using the drop-down list select the time zone of the patient’s location

When finished filling out the form without errors, at the lower area of the patient onboarding screen, select the “ADD PATIENT” button. The screen then wraps to the next step in the process.

NOTE: If an error occurs when inserting the new patient information, the fields where errors are detected will be highlighted in red, indicating that there has been a problem and the new patient cannot be added until those errors are corrected.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-EDISTATUS@fda.hhs.gov or 301-796-8118

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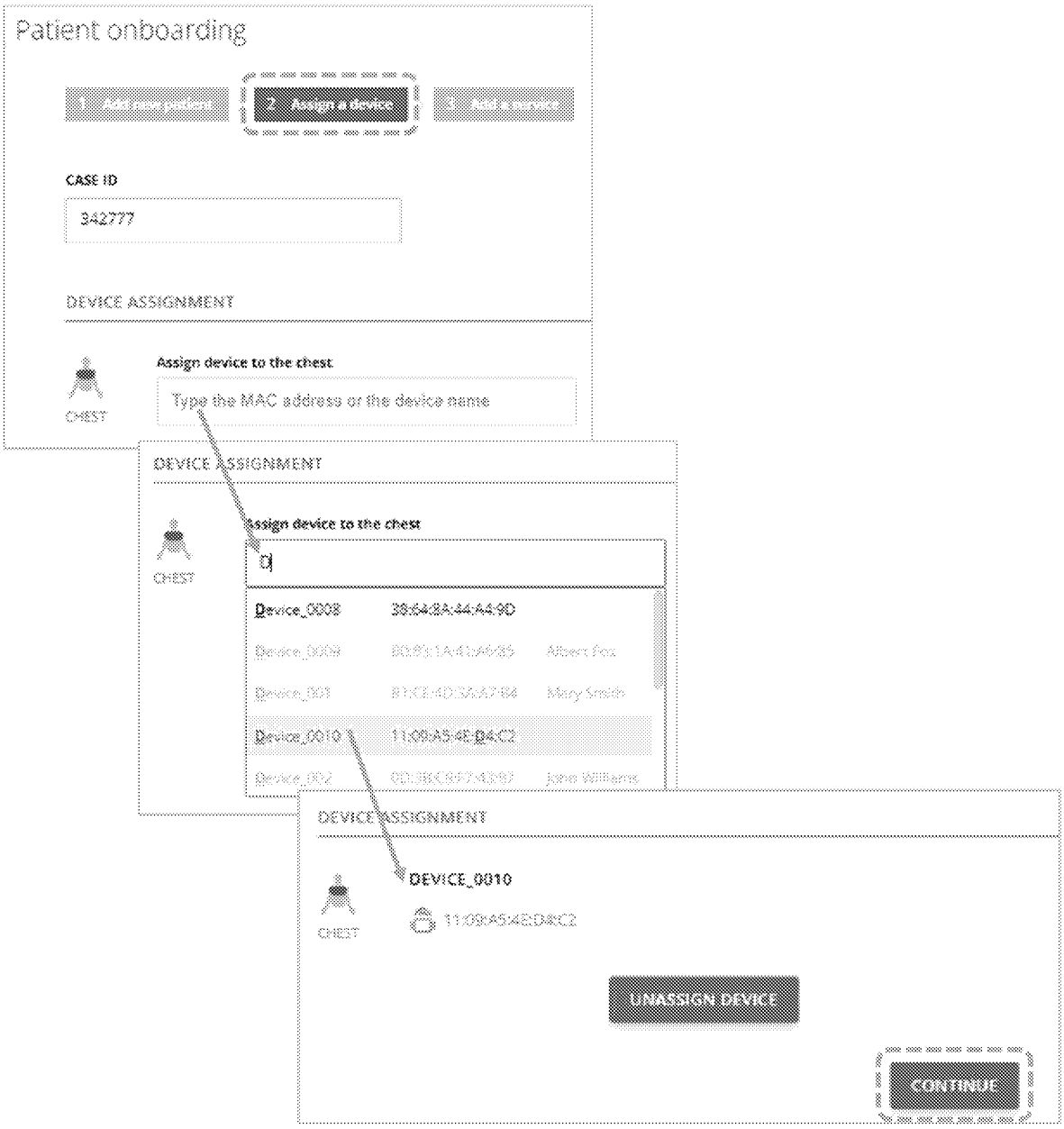
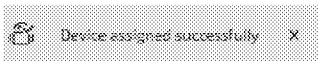
Patient Onboarding Step 2: Assign a device for the patient

- On the screen "ASSIGN A DEVICE"
- Type the MAC address or device name. As the information is typed, a box below begins to populate with the device, then select it from the list of options, next select "CONTINUE" to associate the *7L Sensor* to the patient.

NOTE: The MAC address is found on the surface of the *7L Sensor* that is inserted into the *7L Patch.*



After selection of "CONTINUE" a confirmation message 

is displayed and you advance to the next step in the onboarding process.

Questions? Contact FDAACDRHDOCSPDS at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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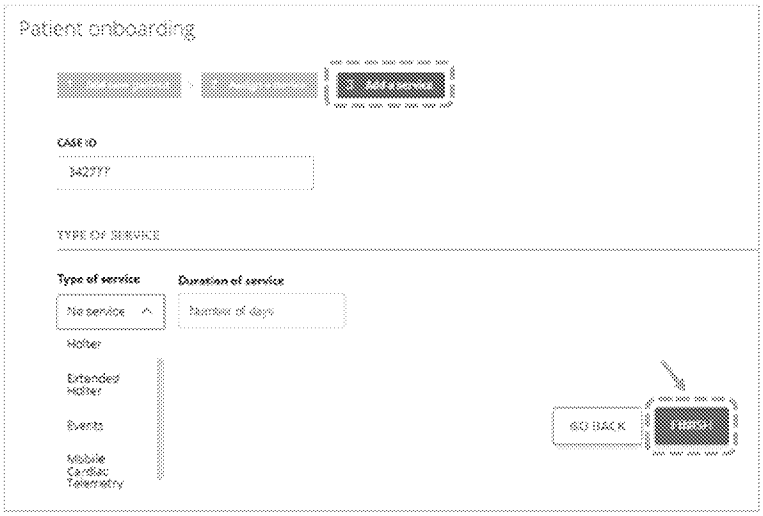
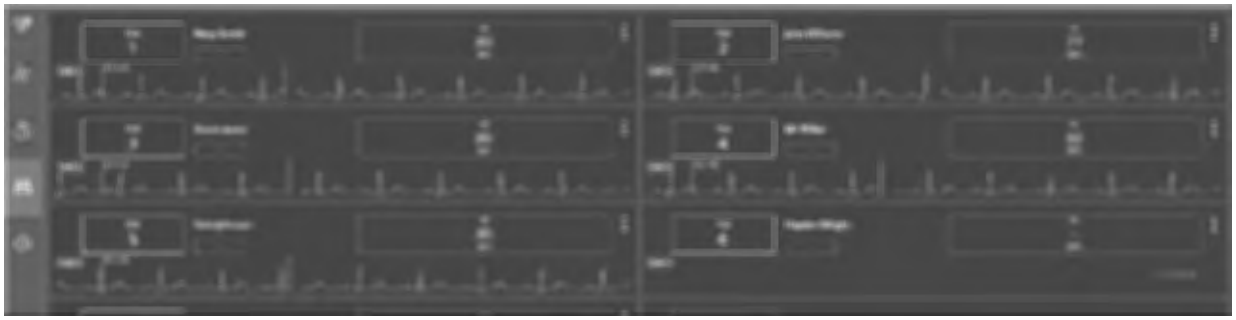
Patient Onboarding Step 3: Choose the monitoring service type for the patient

- From the drop-down menu, select the service type (No service, Holter, Extended Holter, Events, or Mobile Cardiac Telemetry)
- Enter the number of days for the duration of service
- Select "FINISH" this new patient is now added to the patient list
- Once "FINISH" is selected you are taken to the Alarm Settings screen to review and customize alarms for the patient just added (see *Alarms and Alarm Management* section on *page 35* for detailed information)



NOTE: Once admission is finished the new patient is added to the Multi-Patient view screen as shown below. No signal is displayed until service begins once the *7L Sensor* is on the patient's body and connected to the *7L Mobile Application*.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display. Consult the *PL-17 SmartCardia 7L PlatformTechnical Manual.*



Service type options and features:

		Features				
		Measurements	**Event Capture**	**Real Time View**	**Duration**	**Report Editing and Creation**
Service Type	**Holter**	7 leads ECG, Atrial Fibrillation	Yes	Optional	<48 hrs.	Yes
	Extended Holter	7 leads ECG, Atrial Fibrillation	Yes	Optional	>48 hrs.	Yes
	Event	7 leads ECG, Atrial Fibrillation	Yes	Optional	Ordered	Yes
	Mobile Cardiac Telemetry	7 leads ECG, Atrial Fibrillation	Yes	Yes, 24/7 monitor watchers	Ordered	Yes

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PolStat19@fda.hhs.gov or 301-796-8118

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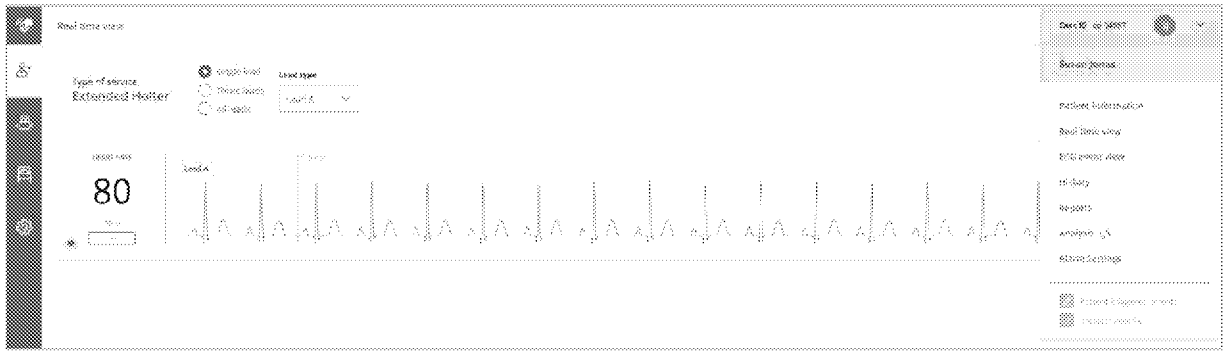
Individual Patient Page

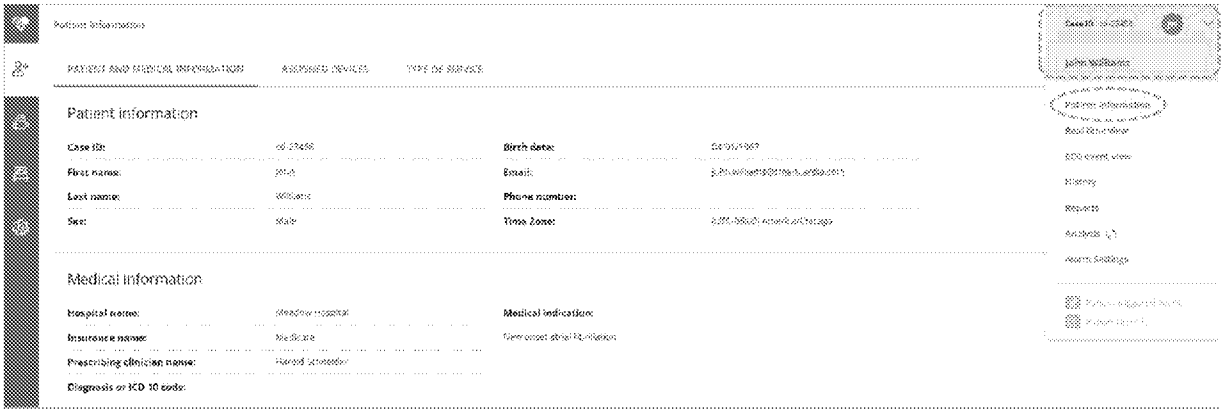
Select “PATIENTS” on the left navigation menu, which displays the list of patients. Once the desired patient name is selected, the “real time” view for the patient is displayed. In the upper right corner, select the arrow on the right of the patient’s Case ID and blue circle with patient initials.

This dropdown menu displays the patient’s name and the options to view and manage this patient.



Patient Information/Medical Information

The following patient information is displayed for the selected patient. This data was entered manually when the patient was added to the system.



The information displayed is the patient's personal information (Case ID, first name, last name, sex, birth date, email, phone number, and time zone).

In addition, the medical information is displayed (hospital name, insurance name, prescribing clinician name, diagnosis or ICD 10 code, and medical indication).

This information can be edited by selecting the “Edit” button on the right side of the screen.

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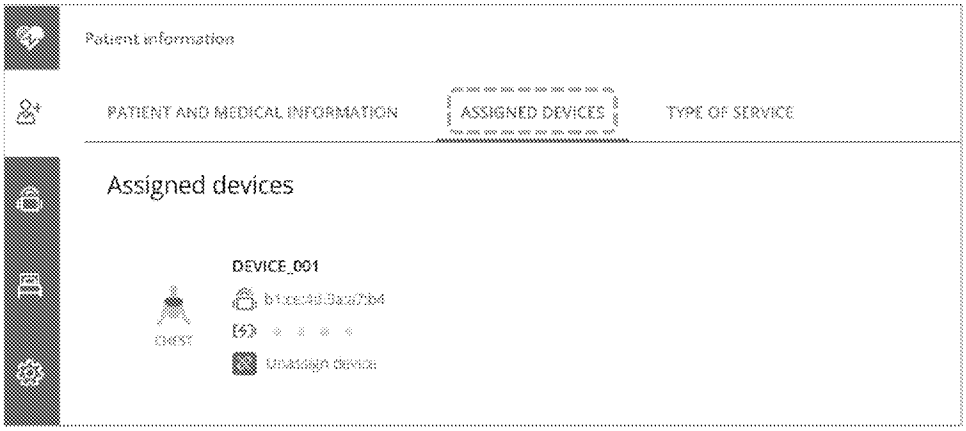
Assigned Devices

The "ASSIGNED DEVICES" tab displays the information related to the device (*7L Sensor*) for the selected patient. If the patient has an assigned device, it is shown next to the picture of the chest which is the location of the *7L Patch with 7L Sensor*. The designated device name, its MAC address, and the battery level are displayed.

In addition, the "Unassign device" button used to dissociate the patient to the device is shown.



The *7L Sensor* battery level displays as a percentage of fully charged.

Device battery is fully charged (100%)	
Device battery has 75% remaining	
Device battery has 50% remaining	
Device battery has 25% remaining	
Device battery level is critically low with less than 10% strength remaining	

Questions? Contact FDAACDRHOCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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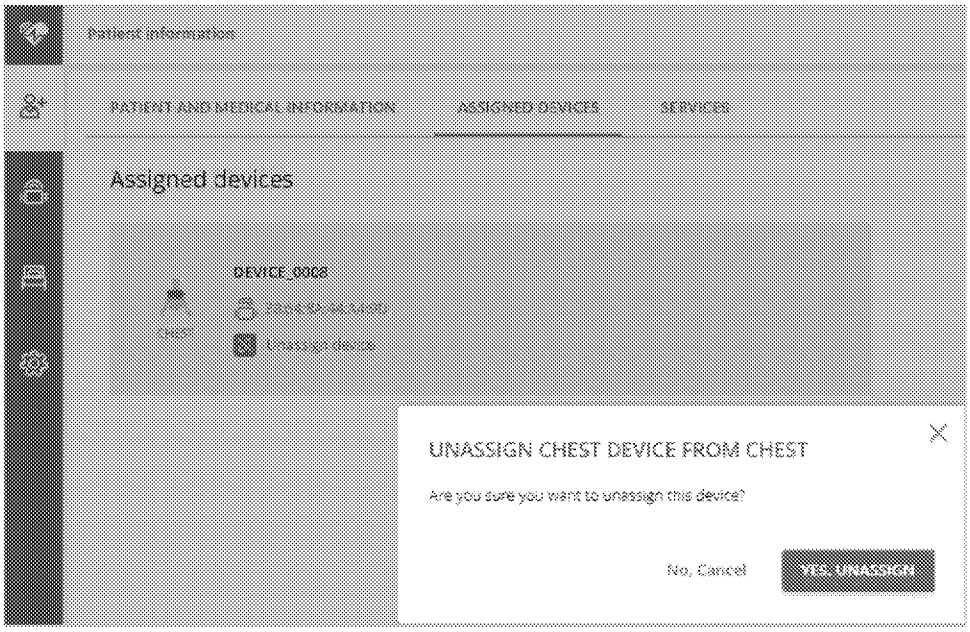
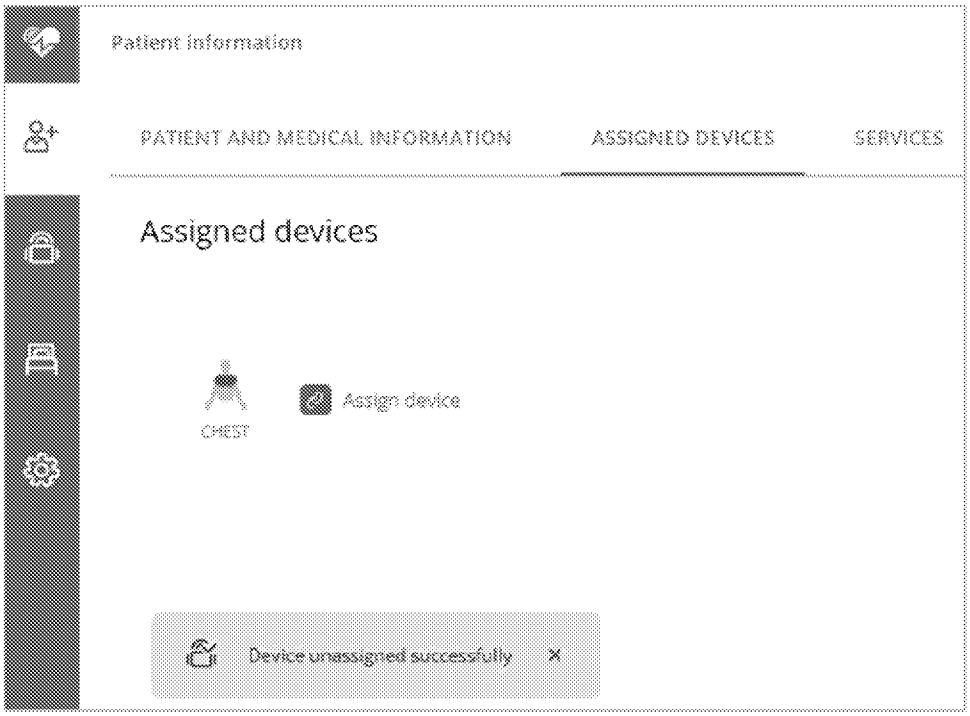
When you select the “Unassign device” button (in red text), a box is displayed with the options: “No, Cancel” or “YES, UNASSIGN”.



When “YES, UNASSIGN” is accepted, the confirmation message “Device unassigned successfully” in a green text box appears.



NOTE: You can only assign a device to a patient if the desired device has already been added to the device list.

Questions? Contact FDA/CDRH/OHT5/DHT5 at CDRH-PMISTAFF@fda.hhs.gov or 301-796-8118

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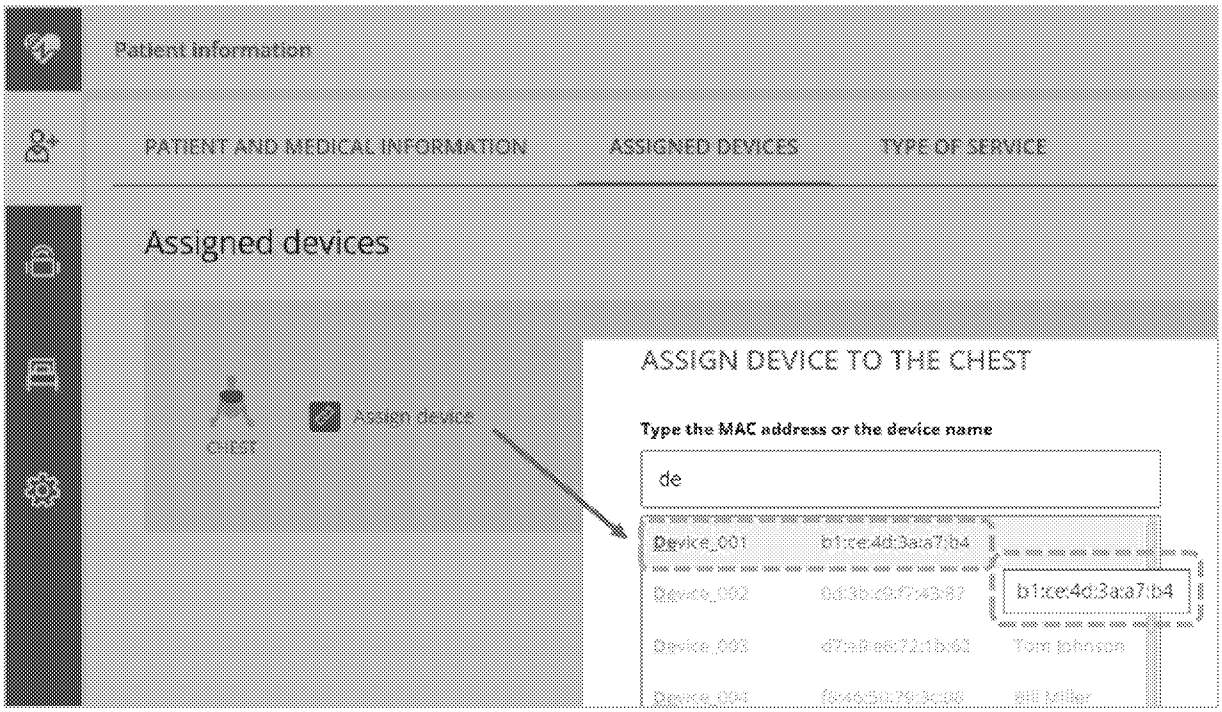
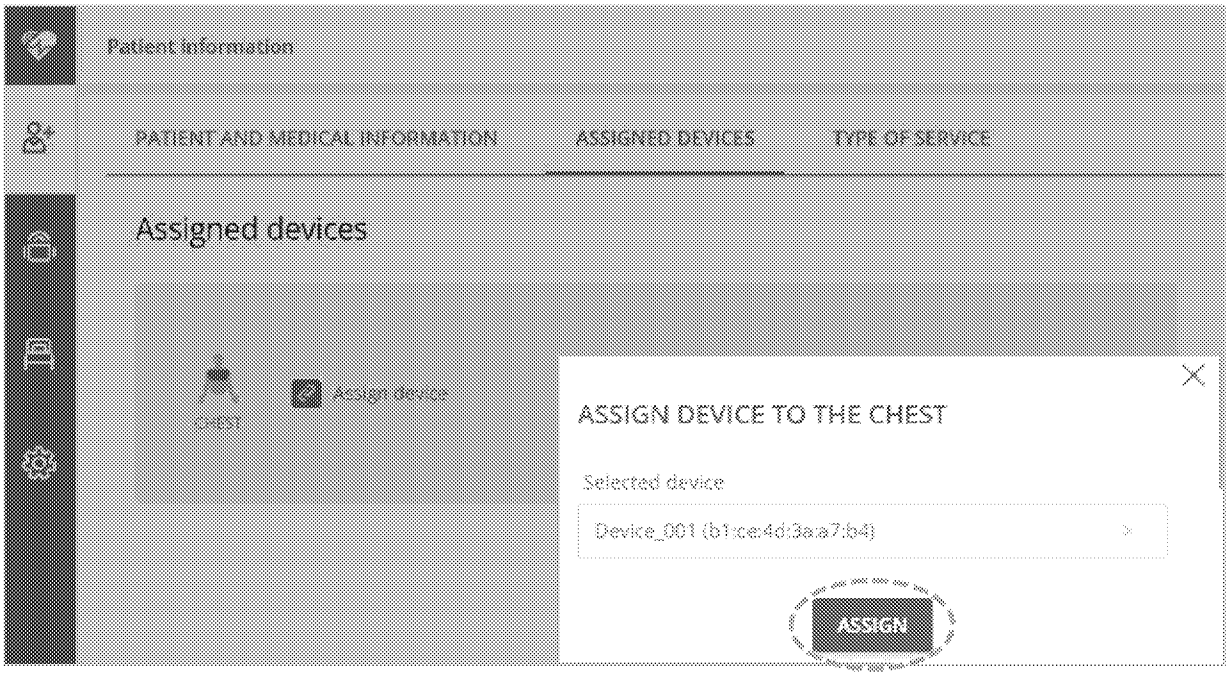
To help you interact with the application, when you start typing the name of the device or its MAC address, suggestions will appear in a text box. Listed devices in gray text indicate they are not available because they are assigned to a different patient. Available devices are those listed in black text that changes to blue text when hovering over it and it is selectable.



Once the desired device has been entered, select the “ASSIGN” button.



Questions? Contact FDAACCESS@fda.hhs.gov or 301-796-8118
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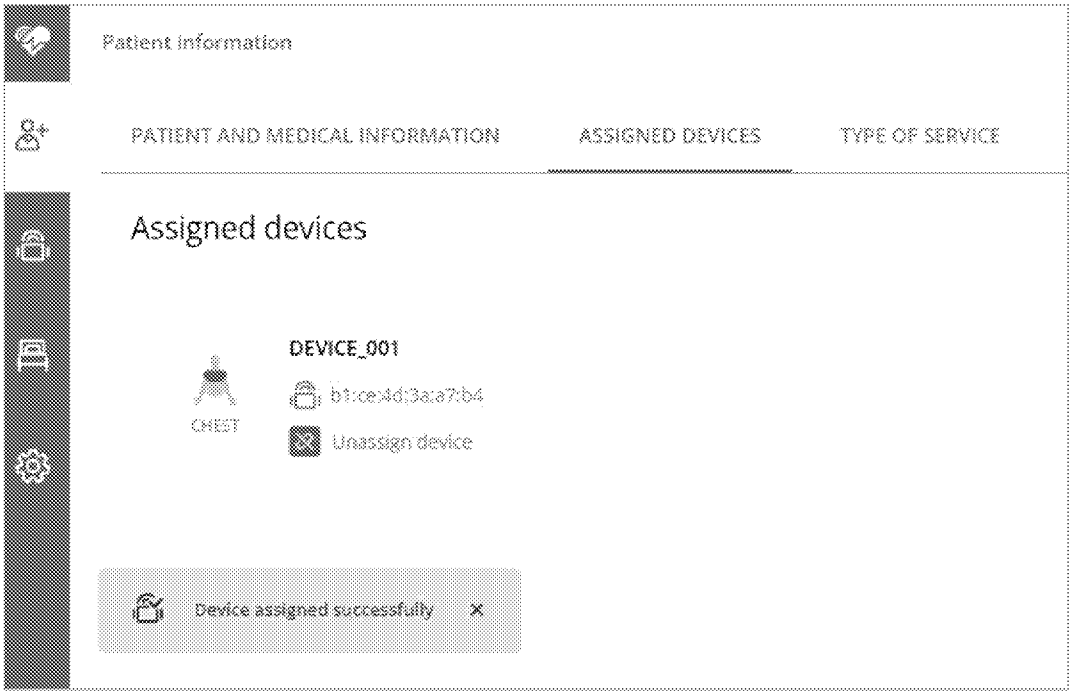
The confirmation message “Device assigned successfully” in the green text box is displayed. In case of an error, a red error message is displayed, explaining the error produced.

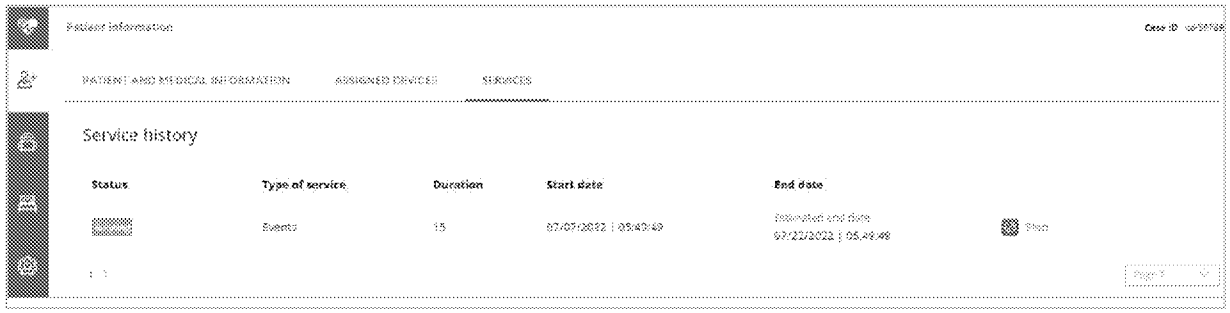


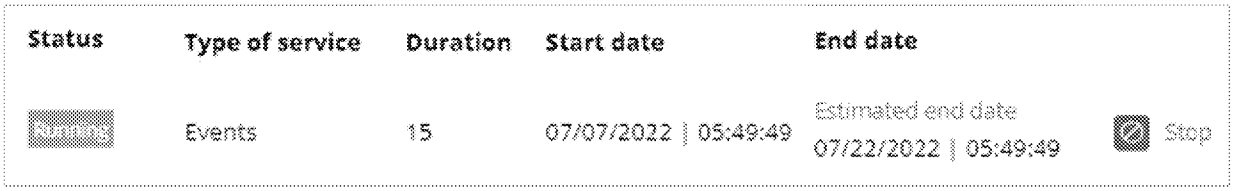
Type of Service

The type of service for monitoring is listed as ordered by the physician. Status is “Running” or “Not Started”. Service can be changed at any time as ordered by the physician.

NOTE: Service begins once the *7L Sensor* is on the patient’s body and connected to the *7L Mobile Application*.

Select “Stop” to change the type of monitoring service and/or the number of days.





Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATE@fda.hhs.gov or 301-796-8118
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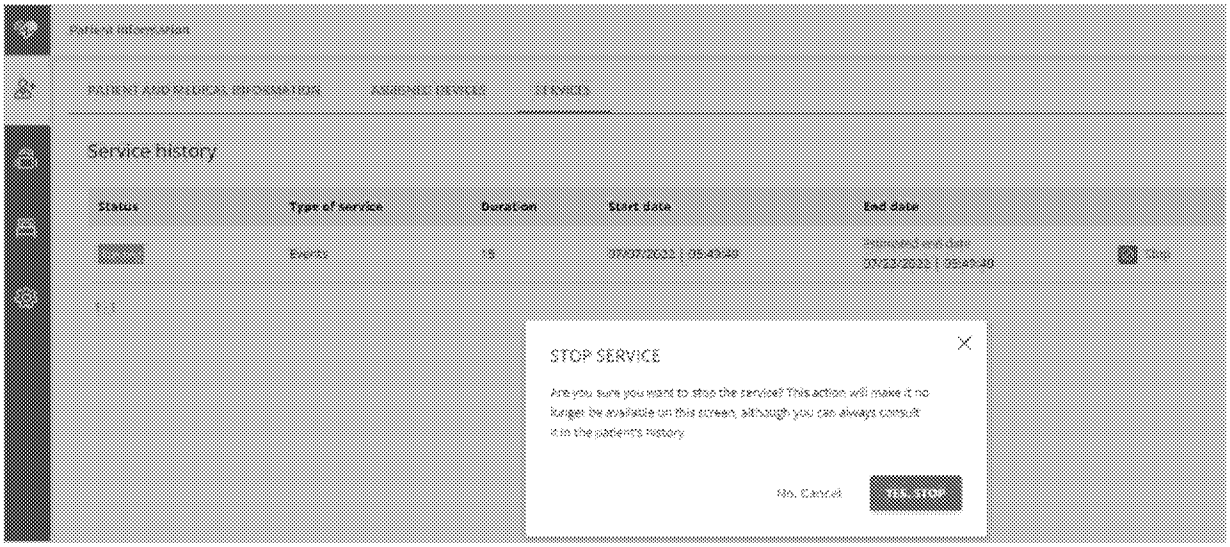
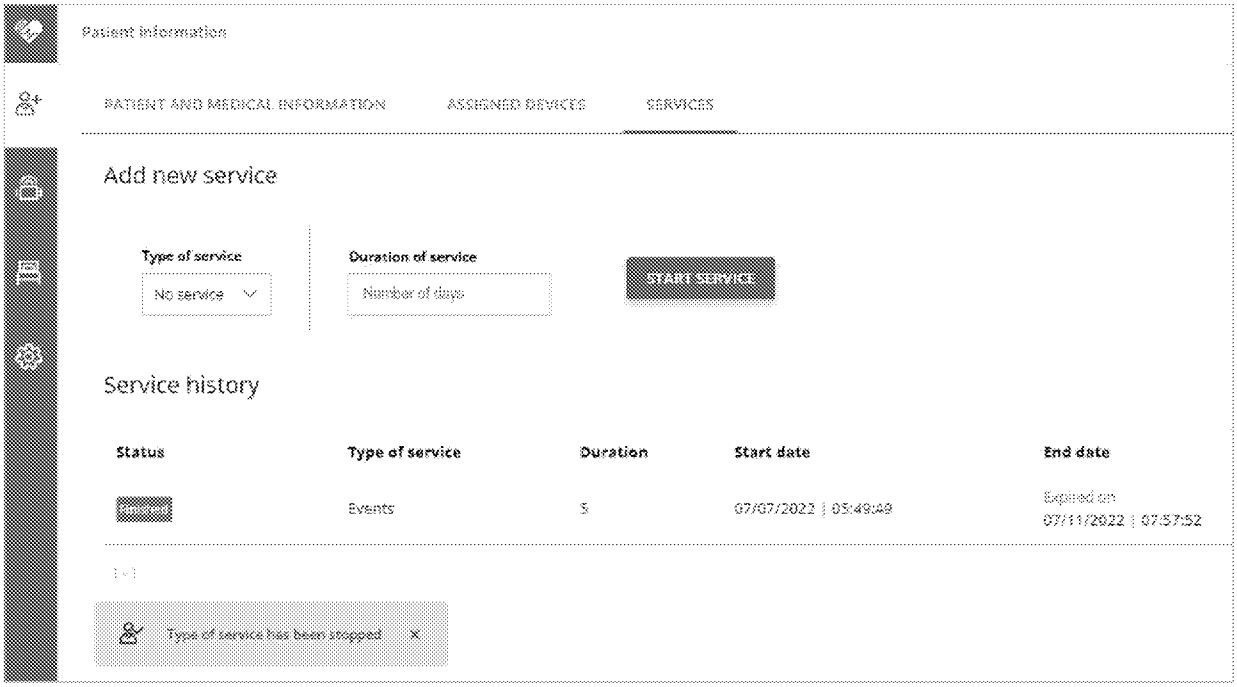
If monitoring is in progress, to discontinue current monitoring service type select “Stop”. The following text box is displayed with the option “No, Cancel” or “YES, STOP”.



Once service is stopped, the confirmation message “Type of service has been stopped” is shown in the green text box.



Questions? Contact FDAACDRHDOCSUB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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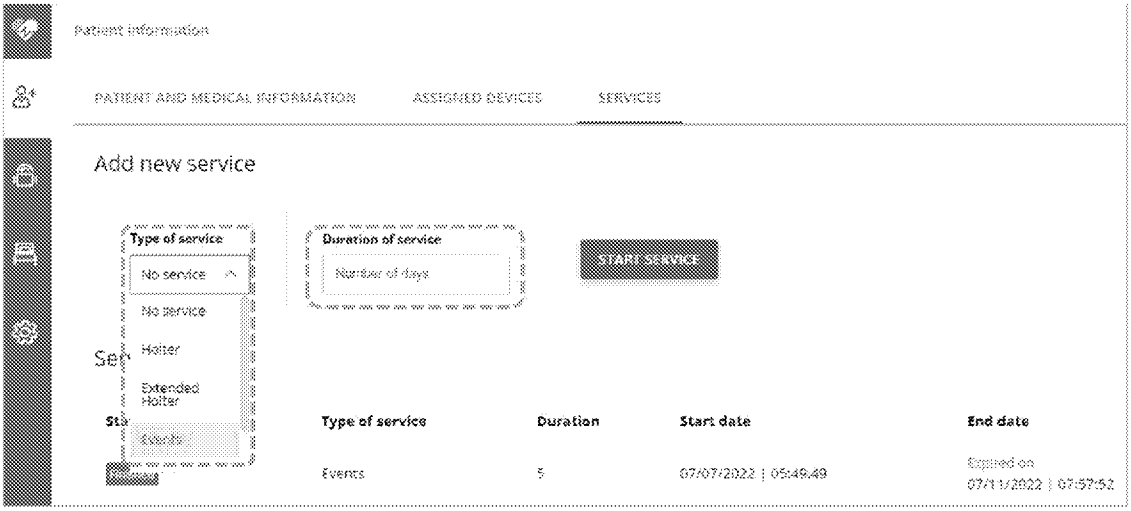
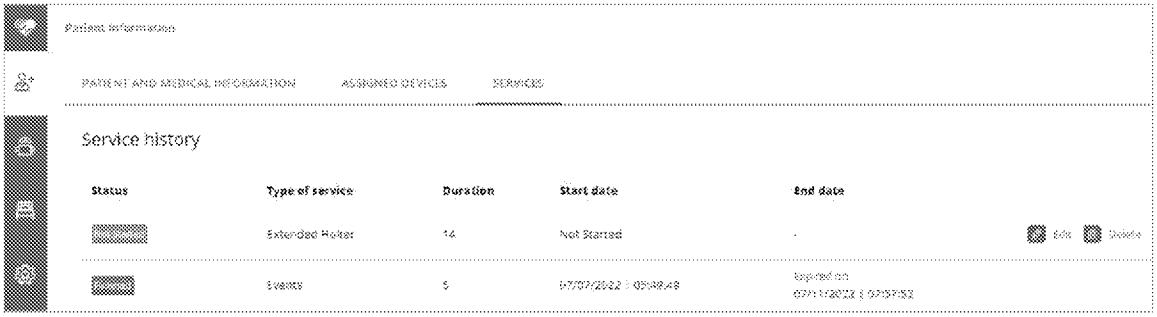
You can now make the new selection of type and duration of service

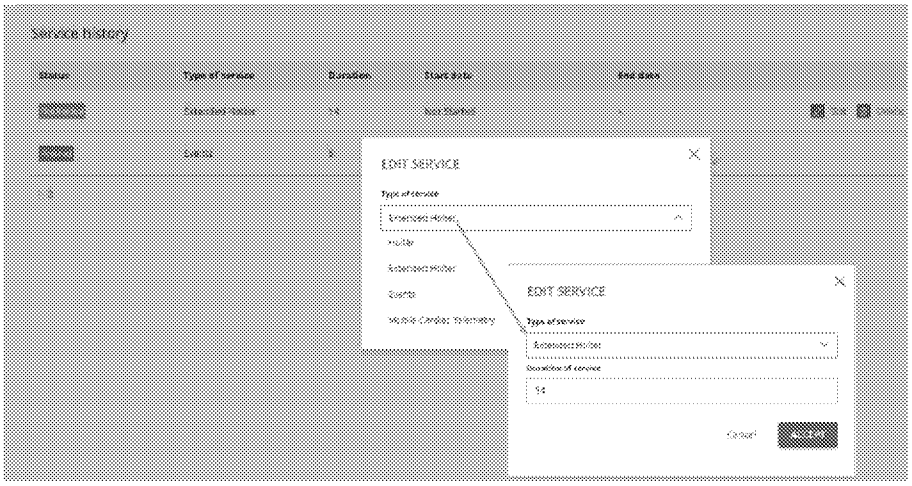


Once “START SERVICE” is selected, a message is displayed.

Service history is listed as shown below. Most recent service information is shown at the top with the option to edit or delete.



When “Edit” is selected, the box below allows you to make any changes then select “Cancel” or “ACCEPT”.



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118

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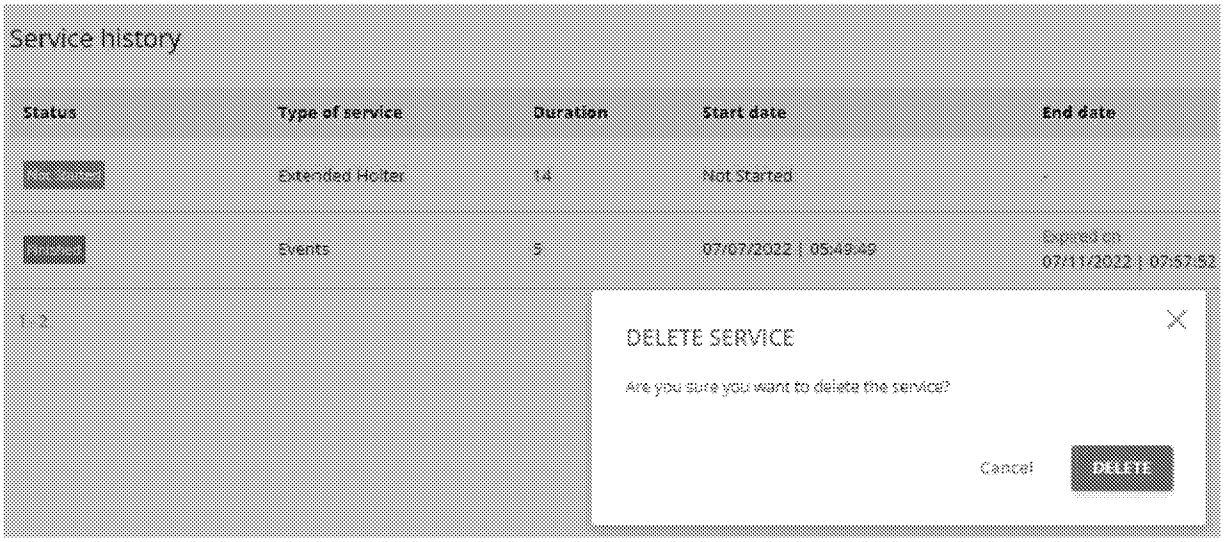
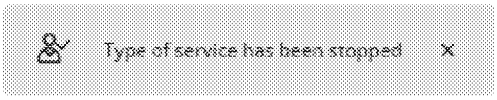
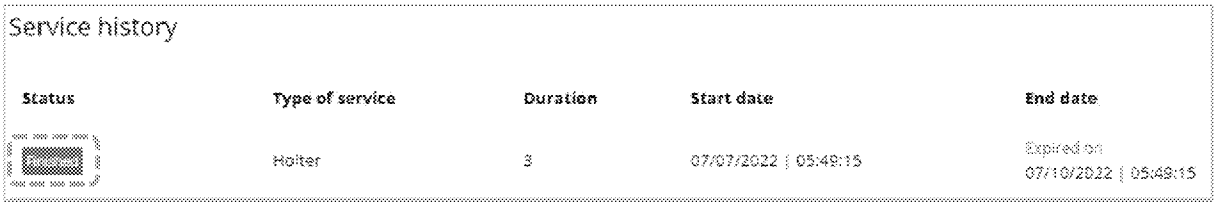
Selecting “Delete” provides option to “Cancel” or “DELETE”



Once service is deleted, it is no longer listed in Service history and a message is posted.



At the completion of the prescribed service period, select “Stop” to discontinue monitoring. The service history will display status as finished. The next step to discontinue monitoring is to Unassign device”. See page 105



Questions? Contact FDAACCDRH@OCS.HHS.gov or CDRH-POLSTATHELP@fda.hhs.gov or 301-796-8118
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Alarms and Alarm Management

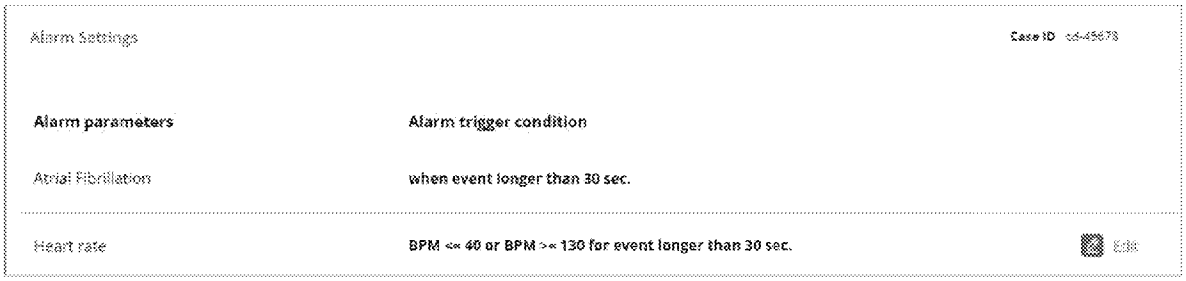
Alarm signals are created when a measured parameter value exceeds the threshold alarm limit settings or when algorithmic analysis (such as atrial fibrillation) detects an alarm condition. For additional information about the SmartCardia 7L Platform alarm system, see Attachment A.

Alarm Signals

Alarm signals are created and presented on the SmartCardia Web Browser when the heart rate exceeds pre-set limit thresholds or when specific arrhythmia events occur. Visual messages are shown when the heart rate and the ECG waveforms are displayed along with an auditory sound. It is the responsibility of the clinician to review and respond to alarm signals.

Alarm conditions that display an alarm signal include:

- Atrial fibrillation
- High or low heart rate



Alarm Signals and Indications

Parameter	Display Parameter	Alarm Trigger Condition	Visual and audio when alarm conditions are met	Alarm Priority
Electrocardiogram (ECG)	High heart rate (HR)	HR ≥ High HR threshold	HR parameter value display turns RED and background flashes Audio alarm provided every 10 seconds	High
	Low heart rate (HR)	HR ≤ Low HR threshold		
	Atrial fibrillation (AF)	Atrial Fibrillation Present	AF in yellow text posted on live ECG screen and flashes Audio alarm provided every 10 seconds	Medium

The following are the manufacturers preset limits for heart rate.

Vital Sign	Upper Threshold	Lower Threshold
HR	130 beats/min	40 beats/min

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATHS@fda.hhs.gov or 301-796-8118

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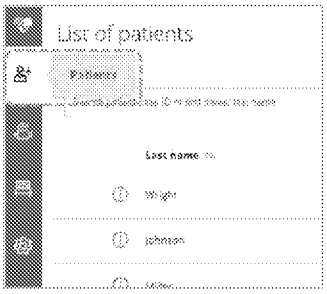
Customizing Alarm Settings for Individual Patients

Alarms are pre-set by the manufacturer, can be modified to meet the practice requirements, and can be customized for the clinical condition of the patient and any provider orders.

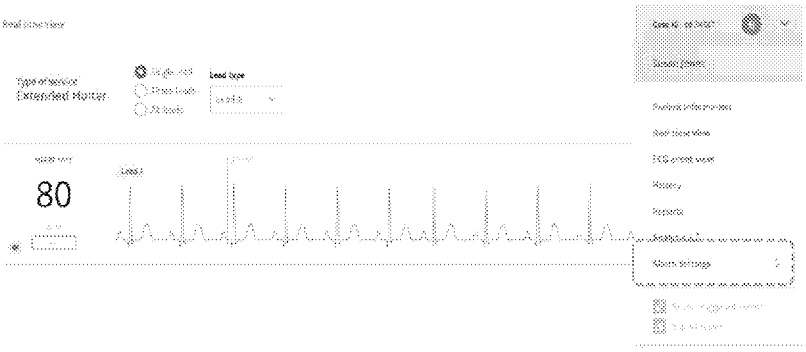
There are three ways to access the “Patient alarm settings” where you can adjust the patient alarm limit settings.

- Option 1: After adding a new patient, you are taken directly to the “Patient alarm settings” to review the current settings and customize to meet the clinical needs of the patient.
- Option 2: Select the patient from the list of patients, go to “Alarm Settings”.

  - On the left navigation menu, select “Patients” to bring up the list of patients



  - Next select the desired patient from the patient list and select “Alarm Settings” from the drop-down menu in the upper right corner



- Option 3: In the Multi-Patient view, on the desired patient tile, select the three dots in the upper right side, go to “Patient alarm settings”.

  - Select the three dots in the upper right corner
  - In the pop-up menu, select “Patient alarm settings”

Questions? Contact FDAACDRHOCE@fda.hhs.gov or 301-796-8118
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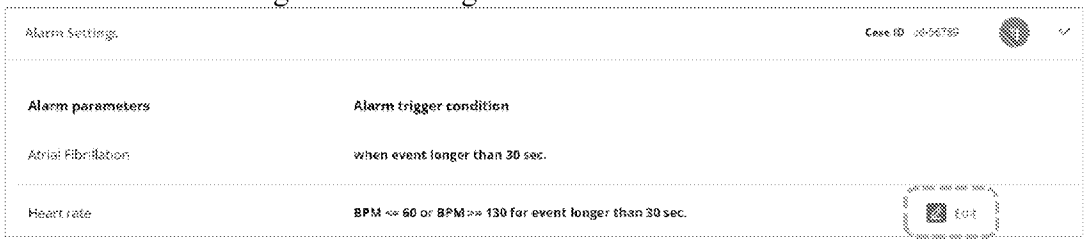
Heart Rate Alarm Parameter Settings

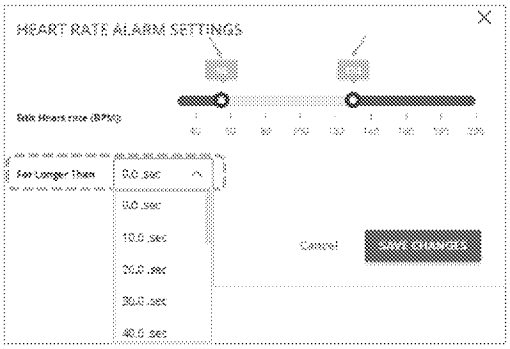
On the patient alarm settings screen, you can review the atrial fibrillation, heart rate alarms, and edit the heart rate alarm limits. (Lowest heart rate setting is 30 and highest heart rate setting is 200)

Customize the alarm trigger conditions

- Select “Edit” to change alarm setting values.



- In this Heart Rate Alarm Setting example, slide each circle above the scale to the left or right to adjust the alarm settings (options in increments of 5 BPM)
- Select length of time for the event, “For Longer Than”
  NOTE: Adding an alarm delay can help reduce clinical non-actionable alarms that result from momentary heart rates that exceed the limit settings
- Select “SAVE CHANGES” or “Cancel” if you choose to not make any changes



Responding to alarms

- Verify the alarm notification is clinically actionable (i.e., requires a patient intervention).
- Take appropriate action or notify the appropriate provider
- If the alarm is not clinically actionable, secure approvals from the provider to modify alarm settings
- Continue to monitor the patient. Call 911 (Emergency Services) if the patient's condition is an emergency

	WARNING: The SmartCardia 7L Platform is NOT an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATHS@fda.hhs.gov or 301-796-8118
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Arrhythmia Event Notifications

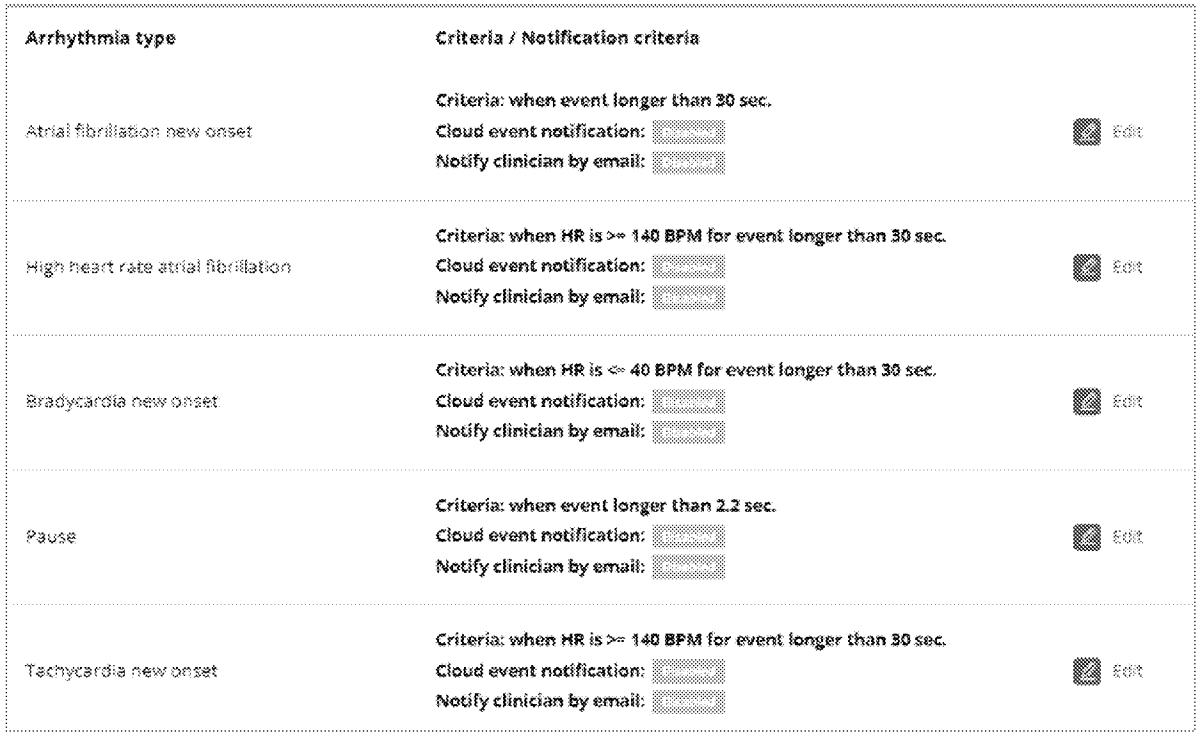
Arrhythmia Events

Arrhythmia events are triggered when specific arrhythmia criteria are met. Arrhythmia events are not alarms and do not provide automated alarm signal notifications. The user can view, accept, or discard an arrhythmia event. User settings can be enabled to notify a clinician of the event at their registered email address.

These events do not generate a real time visual or audible alarm signal.

Arrhythmia events include:

- Atrial fibrillation new onset
- Bradycardia new onset
- Pause
- Tachycardia new onset



When “Cloud event notification” is enabled, events will be identified and marked as pending in the patient list.

When “Notify clinician by email” is enabled, an email that describes the event will be sent to the clinician email that is registered in the system.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118
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Arrhythmia Event Notifications

The arrhythmia events or notifications are triggered as follows. The events are visible to the user and can be accepted or discarded. The accepted events go into subsequent reports generated by the clinician for the patient. The events that have not been accepted or discarded are visible to the user as "Pending Events".

Arrhythmia Condition	Cloud event Notification	Notification by email	Preset Thresholds for event notifications*
Atrial fibrillation new onset	User selectable for maximum number of event notifications per day	User selectable for maximum number of event notifications per day	Atrial fibrillation detection every 10 seconds using the last 30 seconds of ECG, maximum number of events per day set to 5
Bradycardia new onset	HR ≤ low HR threshold for N seconds	HR ≤ low HR threshold for N seconds	Low HR threshold = 40 beats/min for notification on cloud platform and notification by email. N is set to 40 seconds for cloud platform and notification by email
Pause	Pause ≥ Length, User selectable for maximum number of event notifications per day	Pause ≥ Length, User selectable for maximum number of event notifications per day	Length set to 2.2 seconds for cloud platform, 3 seconds notification by email
Tachycardia new onset	HR ≥ high HR threshold for N seconds	HR ≥ high HR threshold for N seconds	Notification when heart rate is 140 beats/min for greater than 30 seconds for cloud platform and notification by email

WARNING: Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a skilled clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118

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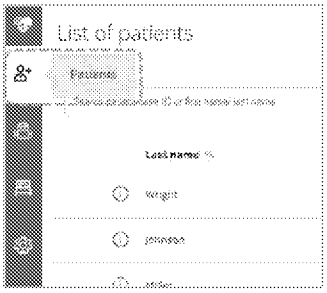
Customizing Notification Settings for Individual Patients

Alarms and notifications are pre-set by the manufacturer, can be modified to meet the practice requirements, and can be customized for the clinical condition of the patient and any provider orders.

There are three ways to access the "Patient alarm settings" where you can adjust the patient alarm limit settings, arrhythmia criteria and notifications.

- Option 1: After adding a new patient, you are taken directly to the "Patient alarm settings" to review the current settings and customize to meet the clinical needs of the patient.
- Option 2: Select the patient from the list of patients, go to "Alarm Settings".

  - On the left navigation menu, select "Patients" to bring up the list of patients



  - Next select the desired patient from the patient list and select "Alarm Settings" from the drop-down menu in the upper right corner

3. Option 3: In the Multi-Patient view, on the desired patient tile, select the three dots in the upper right side, go to "Patient alarm settings".

  - Select the three dots in the upper right corner
  - In the pop-up menu, select "Patient alarm settings"

Questions? Contact FDA/CDRH/OCE/DHT8 at CDRH-PMOSTATHS@fda.hhs.gov or 301-796-8118

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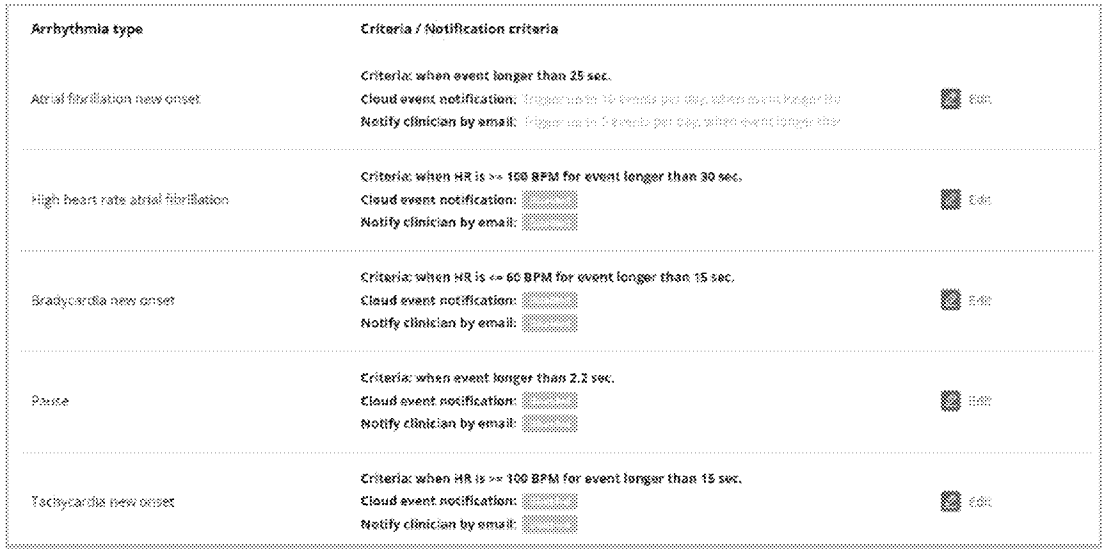
On the patient alarm settings screen, you can review the arrhythmia event notification, turn them on or off, and edit the settings value.



Arrhythmia Type Criteria and Notification Settings

Select “Edit” to change criteria and notification settings. You can also change and identify the events to be included in the patient’s report.

Questions? Contact FDAACDRHOCE@fda.hhs.gov or 301-796-8118
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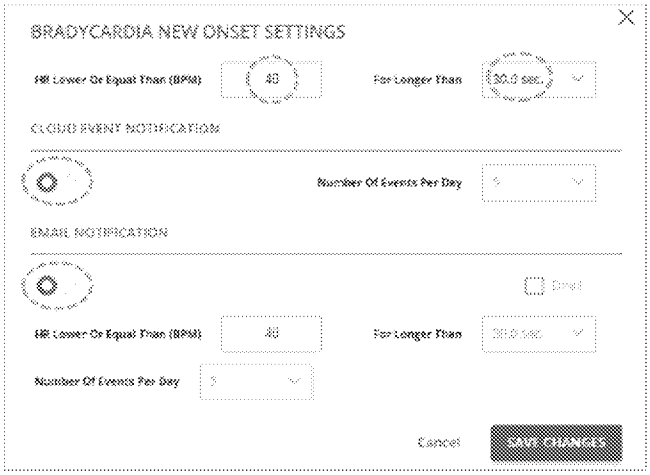
Customize the criteria and notification settings for each arrhythmia type

- Enter numerical value and select the number of seconds duration
- Cloud event notification- use radio button to turn Off/On and set number of events per day for notifications when enabled
- Email notification to clinician email listed in patient and medical information- use radio button to turn Off/On and enter the numerical value, select number of seconds duration, and number of events per day
- Select “SAVE CHANGES” or “Cancel” if you choose to not make any changes



⚠	**CAUTION: Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.**

Patient Preparation for Monitoring

There are two ways for the patient to begin monitoring with the SmartCardia 7L Platform.

- Patient goes to the physician office and the clinical staff applies the device
- The SmartCardia Kit is sent to the patient’s home for them to apply themselves

Refer to the Patient User Guide PN PL-08 that is included in the SmartCardia Patient Kit.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHS@fda.hhs.gov or 301-796-8118

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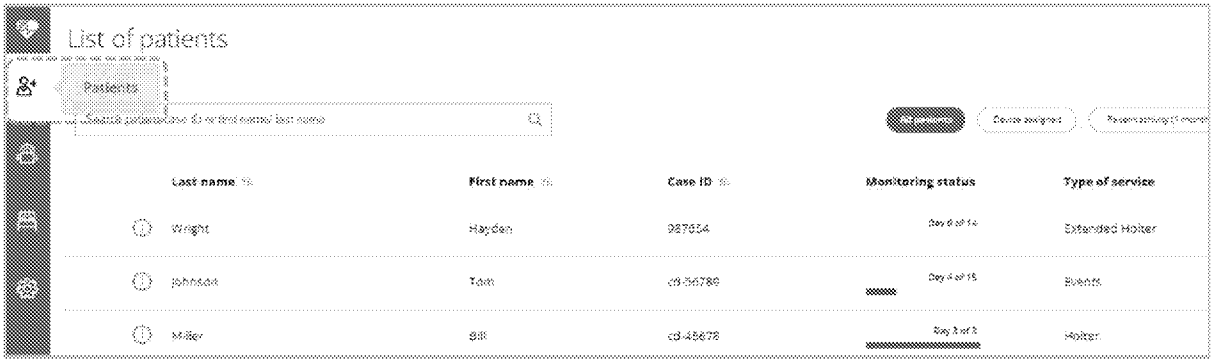
Viewing Patient Data

There are two ways to view a patient's ECG. You can view a patient one at a time or many patients on the Multi-Patient view.

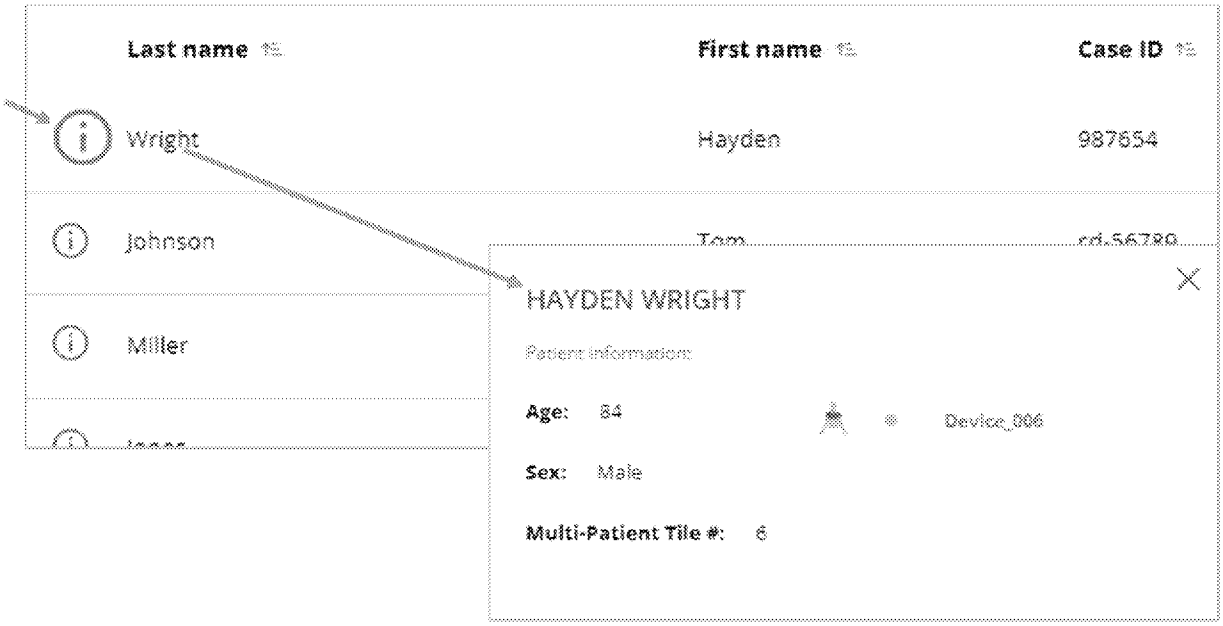
Individual Patient Page: Real Time View

Viewing one patient at a time

On the left navigation menu, click on "PATIENTS" to see the list of patients.



From the list of patients, select the patient's name you want to view. If you want to know additional details about the patient click on the "ⓘ" symbol to the left of the patient's last name to see additional information about the patient (Age, Sex, Multi-Patient Tile #, and Device name).



NOTE: If it is a new patient you wish to view and is not listed, you will need to first "ADD PATIENT", go to page 23.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHS@fda.hhs.gov or 301-796-8118

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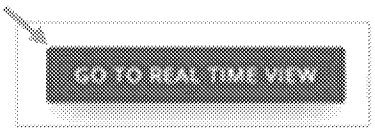
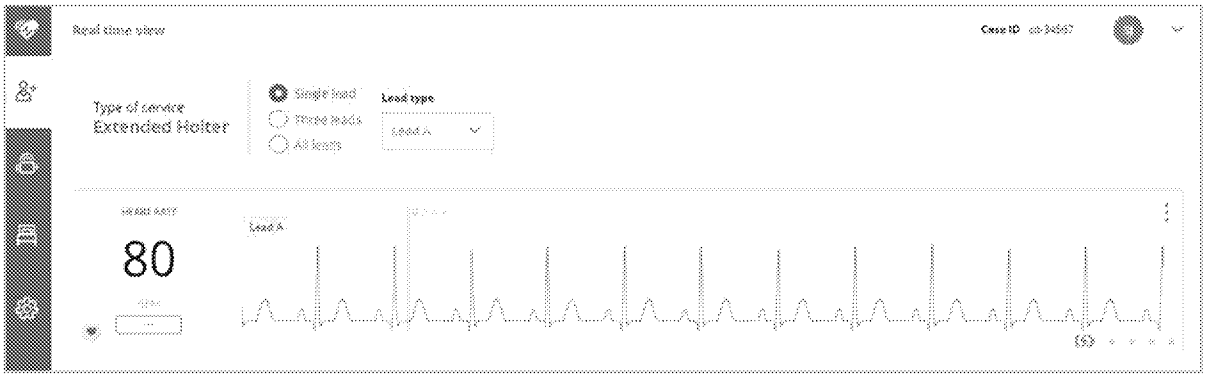
Real Time View

Once the patient's name is selected, their "Real Time View" is displayed. At that time, if you are not taken directly to the patient's real time view, on the left main menu select "Real time view" as pictured below.

NOTE: When you view a new different patient, you may be prompted to select "GO TO REAL TIME VIEW"





The following section will discuss all information shown and functionality available on this screen in detail.

At the top right of this screen, Case ID and patient initials are shown. When you pass the mouse over this information, there is a dropdown menu listing options for interaction with this patient's data as shown below.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHB@fda.hhs.gov or 301-796-8118

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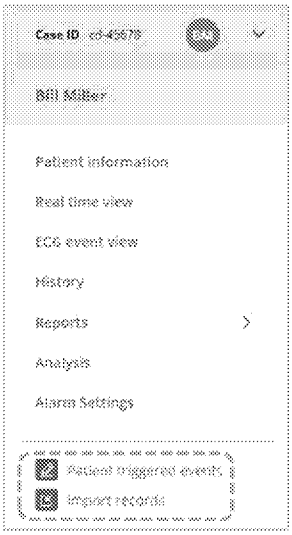
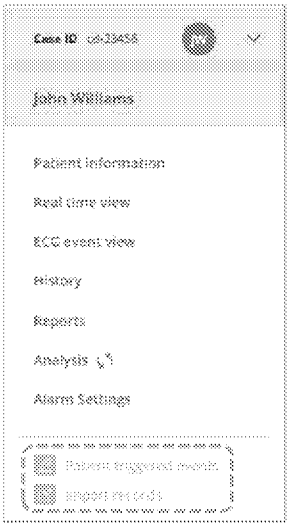
From this patient real time view page, you can view and manage “Patient triggered events” and “Import records”.

- “Patient triggered events” and “Import records” can also be accessed from Patient information, ECG event view, History, Reports, Analysis, and Alarm Settings.

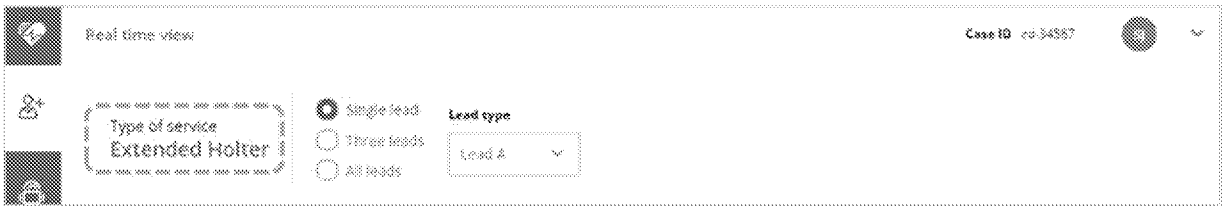


- If Analysis is in process “Patient triggered events” and “Import records” is not available and shaded in grey.



Type of Service Display

The “Type of service” selected to monitor the patient is shown in the upper left side of the screen (Holter, Extended Holter, Events, or Mobile Cardiac Telemetry). Detailed information about each type of service and how to make that selection is on page 26.



Questions? Contact FDAACDRHDOCSUB at CDRH-PDISTAFF@fda.hhs.gov or 301-796-8118
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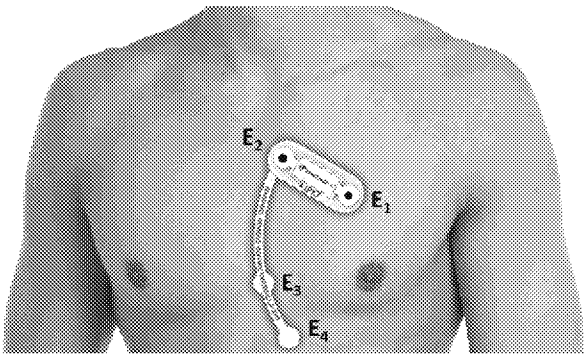
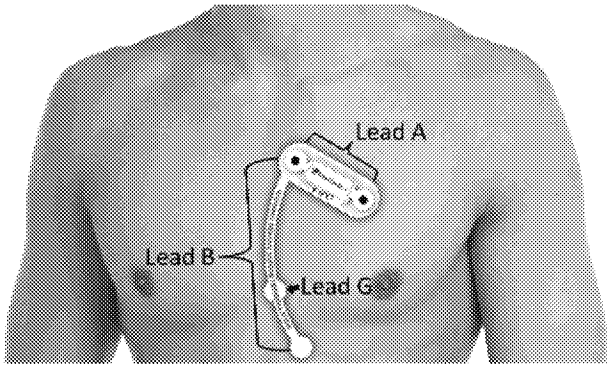
ECG Lead Display

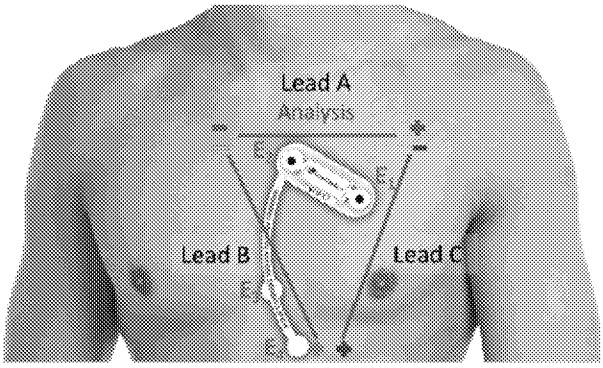
The four electrodes in the *7L Patch* transmit three vectors of ECG.
Seven ECG leads are computed and displayed (Leads A, B, C, D, E, F, G).
NOTE: Analysis is done on Lead A only.



ECG electrode identification



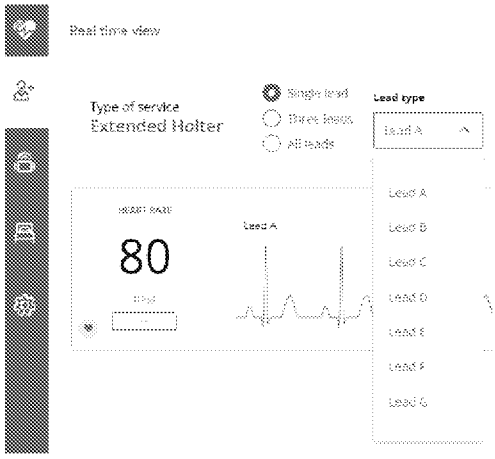
ECG channels transmitted



Polarity of measurements

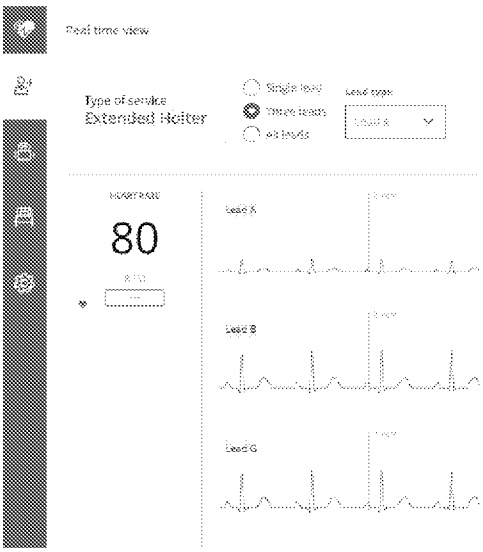
The ECG lead display format options are selected using a radio button. The choices of lead options available to view include:

- Single lead - you can select either A, B, C, D, E, F, or G. Use scroll bar to select all available leads.

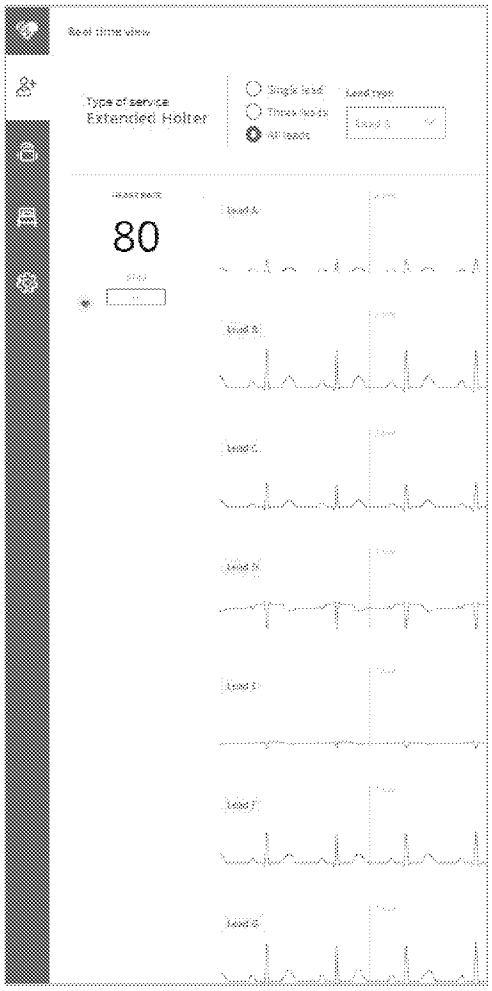


Questions? Contact FDAACDRH/OCE/DHB at CDRH-PolStaff@fda.hhs.gov or 301-796-8118

- Three leads - A, B, and G



- All seven leads - A, B, C, D, E, F, and G (Scroll down on the screen to view all leads)



Questions? Contact FDA/CDRH/OCE/DB at CDRH-BIOSTATS@fda.hhs.gov or 301-796-8118

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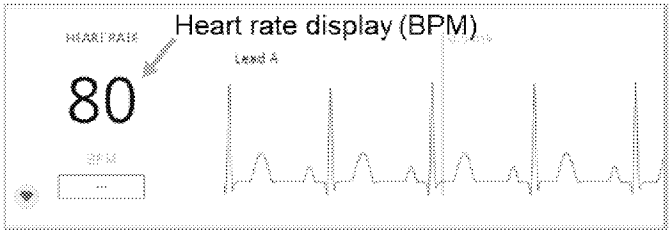
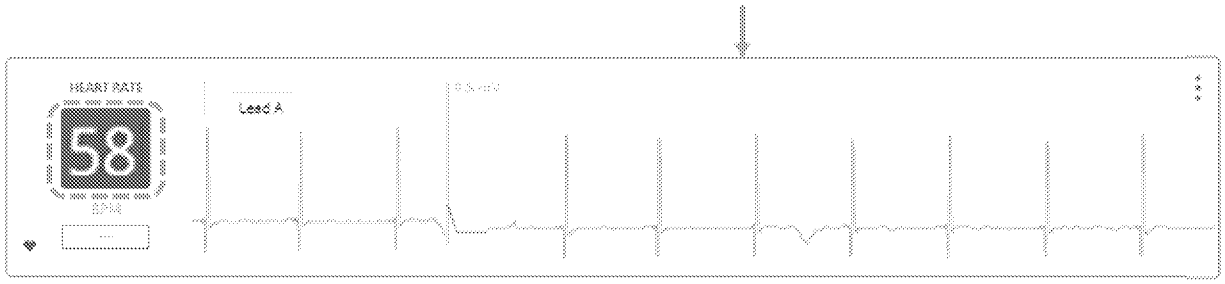
ECG Display

The lower section of the screen shows the real-time ECG. The number of leads and the specific leads selected are displayed.

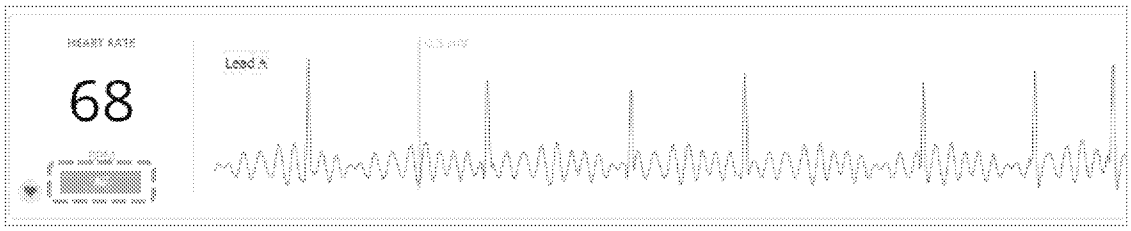
Heart rate (BPM) on the left



When the patient's heart rate is outside the set alarm limits, the patient tile is outlined in red, and the numerical heart rate box is shaded in red, and the high priority audio alarm sounds. In the example below, the patient's heart rate is outside the heart rate alarm limit setting. The patient tile is outlined in red, numerical heart rate display box shaded in red, and the high priority alarm sounds. See Alarms and Alarm Management section page 35 for additional information.

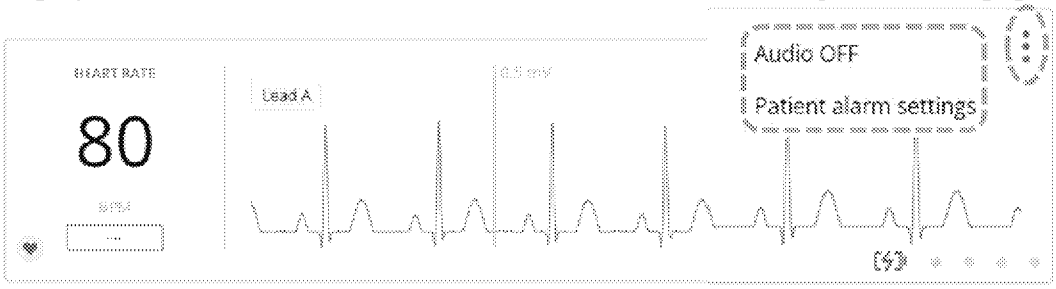


A visual alarm will be displayed in the case of atrial fibrillation. The following real time ECG view is an example of atrial fibrillation.



Navigation using Short Cut

A navigation shortcut using the three dots in the right upper corner of the ECG rhythm strip display selects "Audio OFF/Audio ON" or "Patient alarm settings" from the pop-up box.



Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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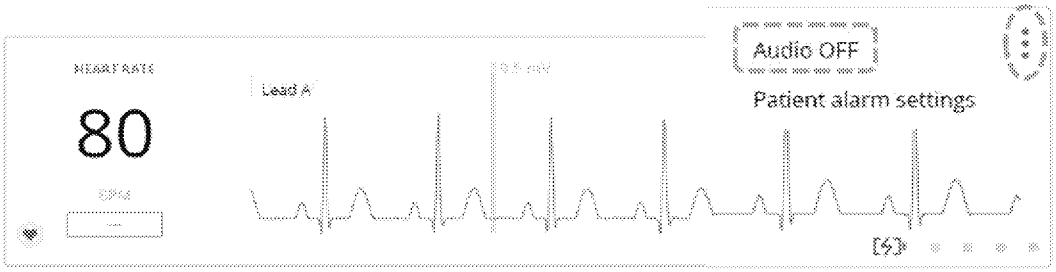
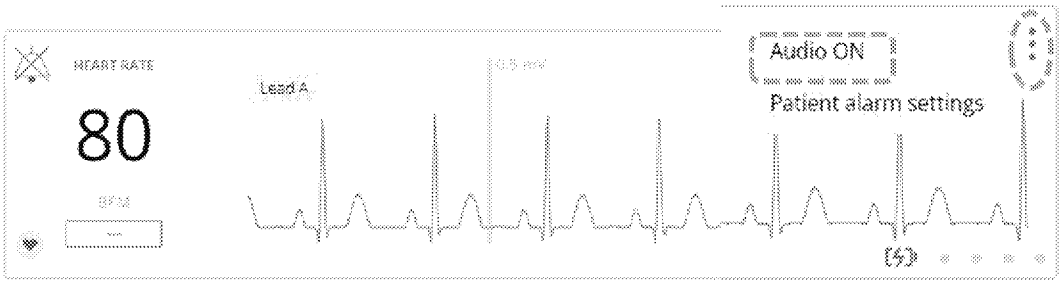
Short cut Audio OFF and Audio ON

In the right upper corner of the ECG rhythm strip display, clicking on the three dots brings up a pop-up box to select the alarm “Audio OFF” or “Audio ON” depending on the current audio alarm setting for the patient. In the strip below, the audio alarm is on and active. Therefore, the only option available to select is “Audio OFF” to turn off all audible alarms for this patient. Selecting “Audio OFF” for the patient, all auditory alarm sounds for that patient are turned off for five minutes



Audio OFF is indicated by a red “crossed bell” in the upper left corner of the patient tile. After five minutes of audio OFF, alarm audio turns ON automatically.



⚠	**WARNING: When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**

The SmartCardia 7L Platform checks the volume setting on the personal computer. If the volume is OFF or on Mute, a message will be shown in the top of the display.

If the volume is too low, the message will read "Low volume detected, please increase the volume of the computer".

Unmute and increase the volume of the computer to ensure auditory alarm signals can be heard.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118

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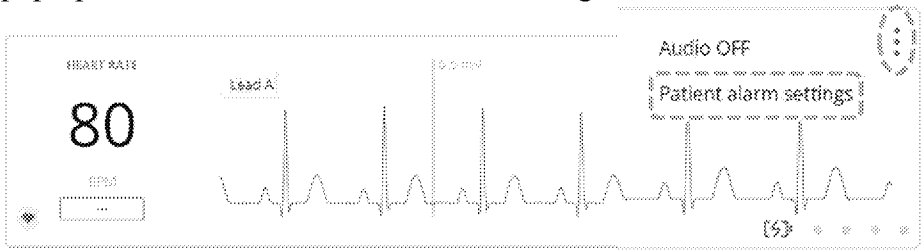
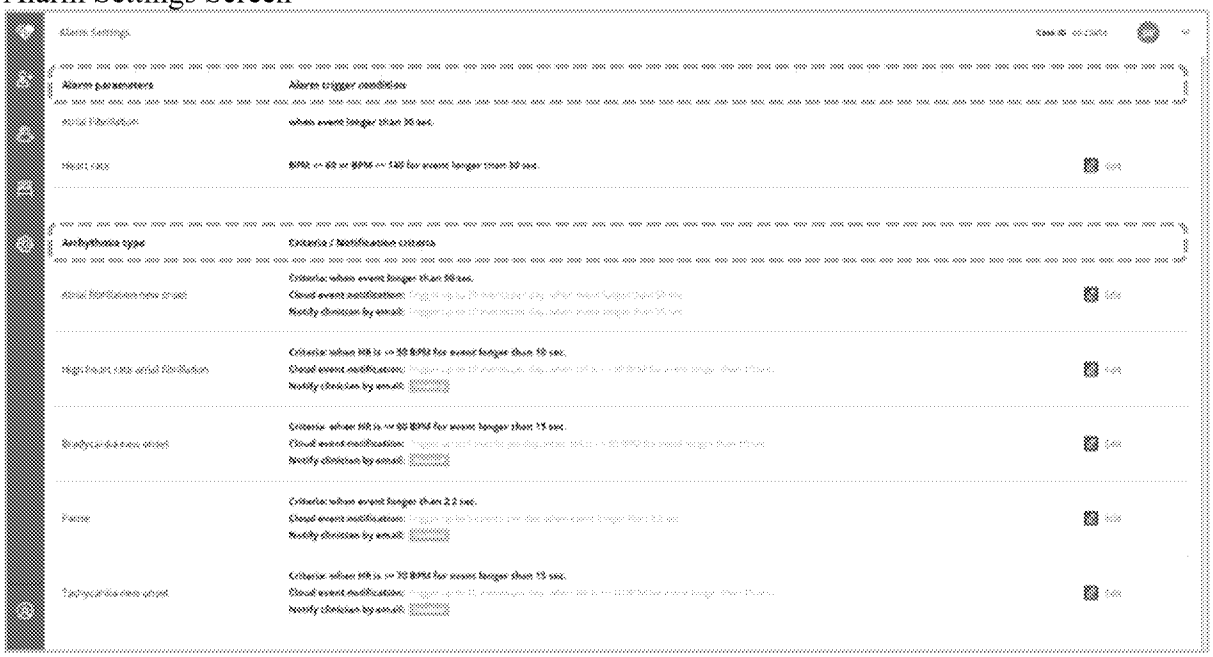
Short Cut to Patient Alarm Settings

In the right upper corner of the ECG rhythm strip display, clicking on the three dots brings up a pop-up box to select the “Patient alarm settings”.



Selecting “Patient alarm settings” takes you to the screen to adjust patient alarm parameters and arrhythmia notifications as shown below.

Alarm Settings Screen



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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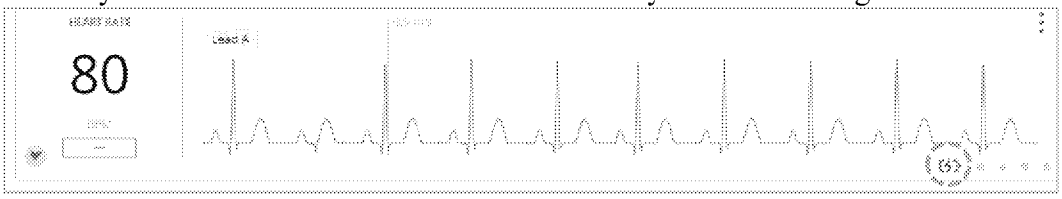
Battery Level Indicator

The device battery level of the *7L Patch / 7L Sensor* (device) worn by the patient is shown in the lower right corner of the ECG rhythm strip display. In the example below, the battery is critically low with 10% or less of the device battery level remaining.



Device battery is fully charged (100%)	
Device battery has 75% remaining	
Device battery has 50% remaining	
Device battery has 25% remaining	
Device battery level is critically low with less than 10% strength remaining	

NOTE: If the patient still needs monitoring, the patient should be contacted regarding direction to attach a new *7L Patch* according to facility protocol.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATTA@fda.hhs.gov or 301-796-8118

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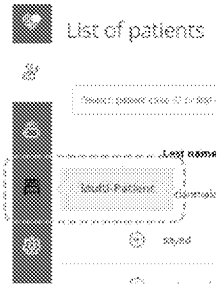
Multi-Patient View

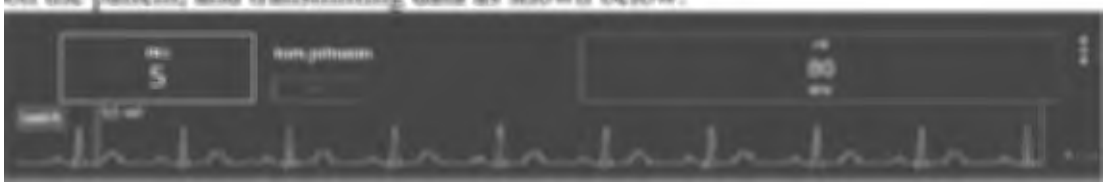
Multiple patient tiles can be viewed at one time. In this view, the clinician can view up to 12 patients at once on a single display screen. The data of many patients can be seen in a more detailed and comprehensive manner, similar to a hospital central monitoring unit. When a new patient is added they are automatically placed in a patient tile.
NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display.



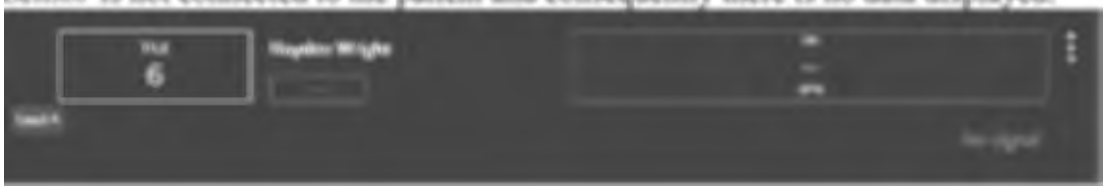
Select "Multi-Patient" on the left navigation menu to view all patients currently assigned to a patient tile.

In the Multi-Patient view, there are three variations of the patient tile screen display.

- The view when a patient is assigned to a patient tile, the *7L Patch* with the *7L Sensor* is on the patient, and transmitting data as shown below.



- This screen display below shows a patient is assigned to the patient tile but the *7L Sensor* is not connected to the patient and consequently there is no data displayed.



- This patient tile does not have a patient assigned.

	WARNING: When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.

Questions? Contact FDA/CDRH/OSEL/DAB at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118
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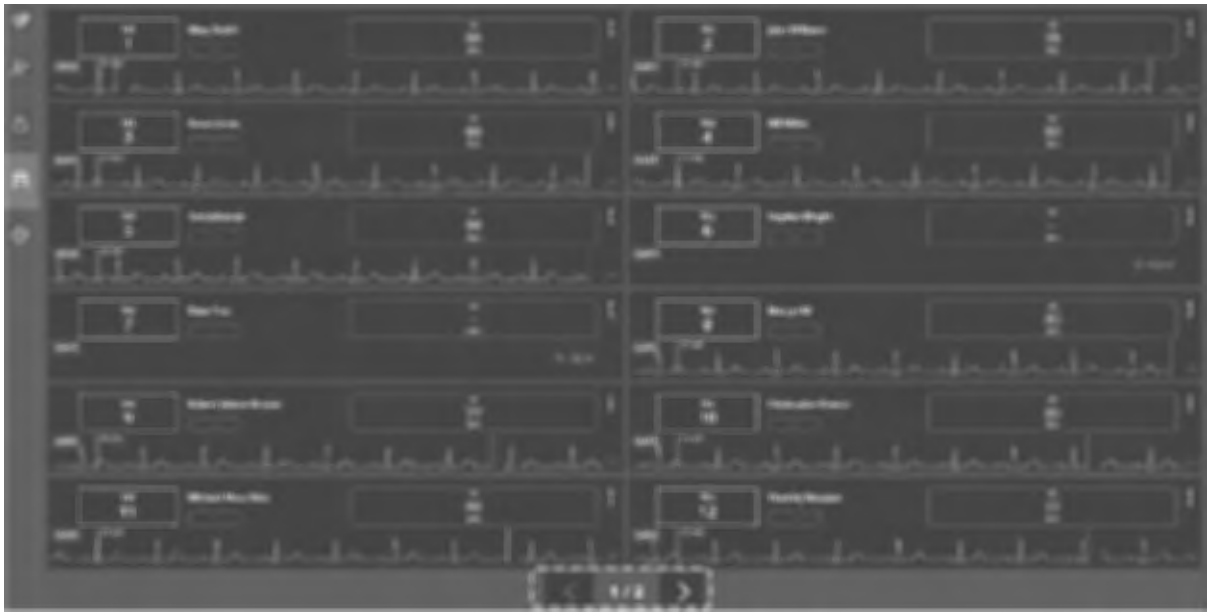
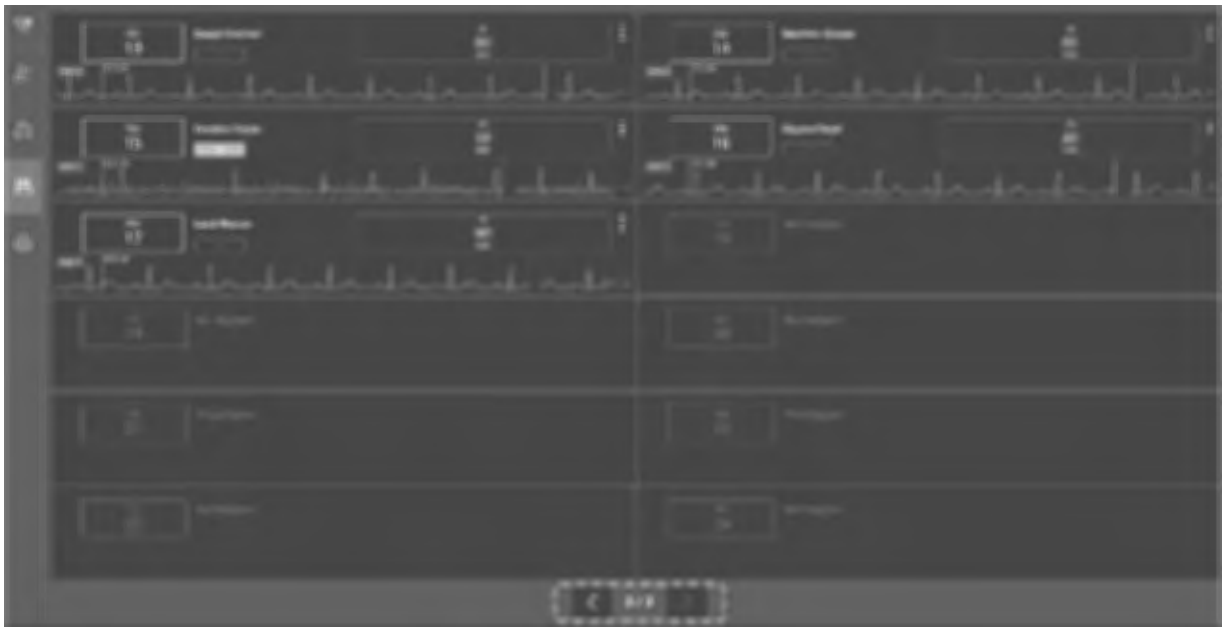
Multi-Patient View- using Multiple Displays

When monitoring more than 12 patients, ensure all patients are viewed at all times by opening another instance of the 7L Web Browser on additional displays.



Multi-Patient View- First instance of 7L Web Browser showing page one.
Display shows patient tiles 1-12



Multi-Patient View- Second instance of 7L Web Browser showing page two.
Display shows patient tiles 13-24

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATTS@fda.hhs.gov or 301-796-8118

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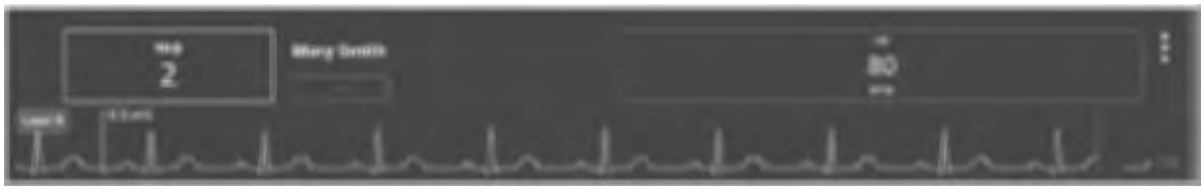
Patient Tile Display

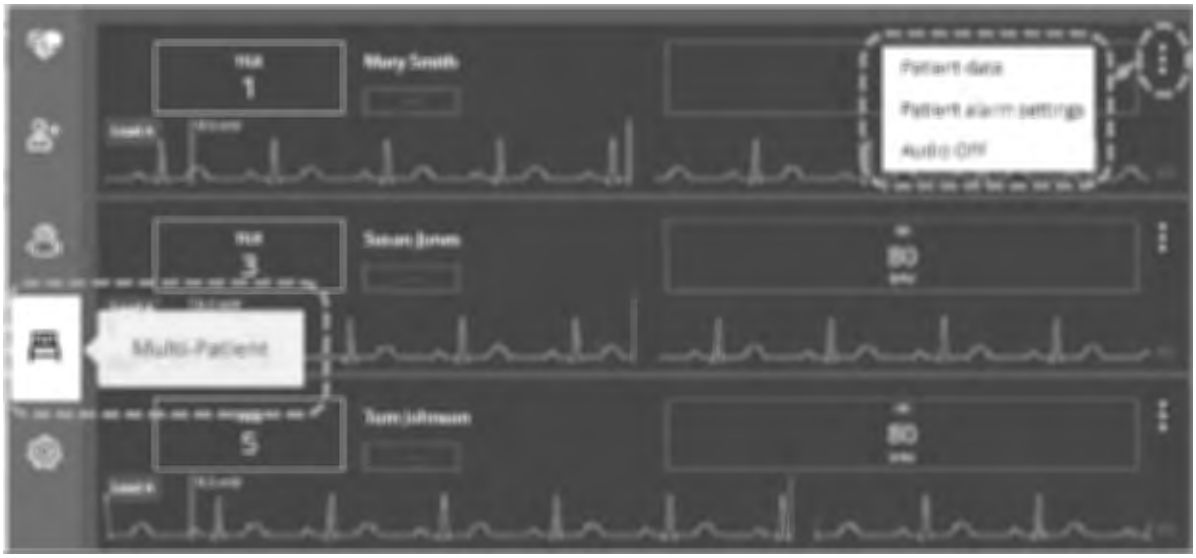
When a patient is assigned to a patient tile and the device is sending information in real time, the following information is displayed:

- Tile number
- Patient first and last name
- ECG signal
- Lead displayed
- Calibration pulse
- Heart rate beats per minute (BPM)



Navigation using Short Cut

There is a navigation shortcut using the three dots in the right upper corner of the patient tile display to select Patient data, Patient alarm settings, or Audio OFF/Audio ON.



Short Cut to Patient Data

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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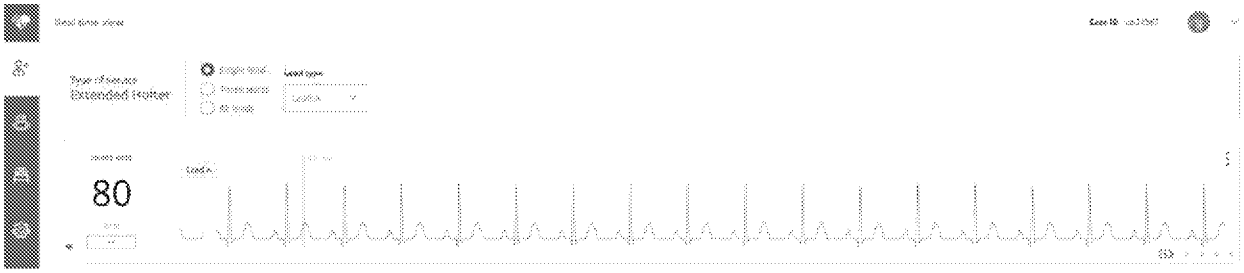
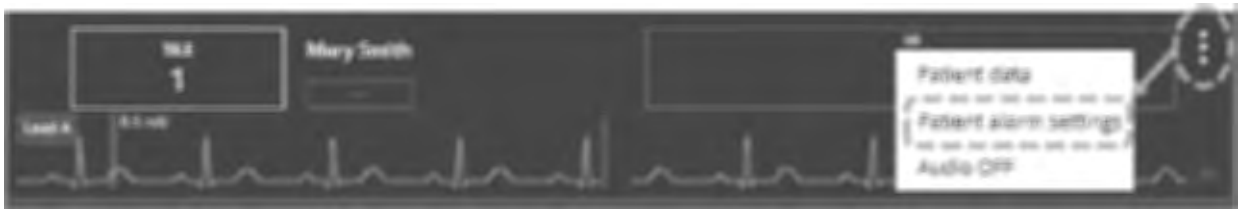
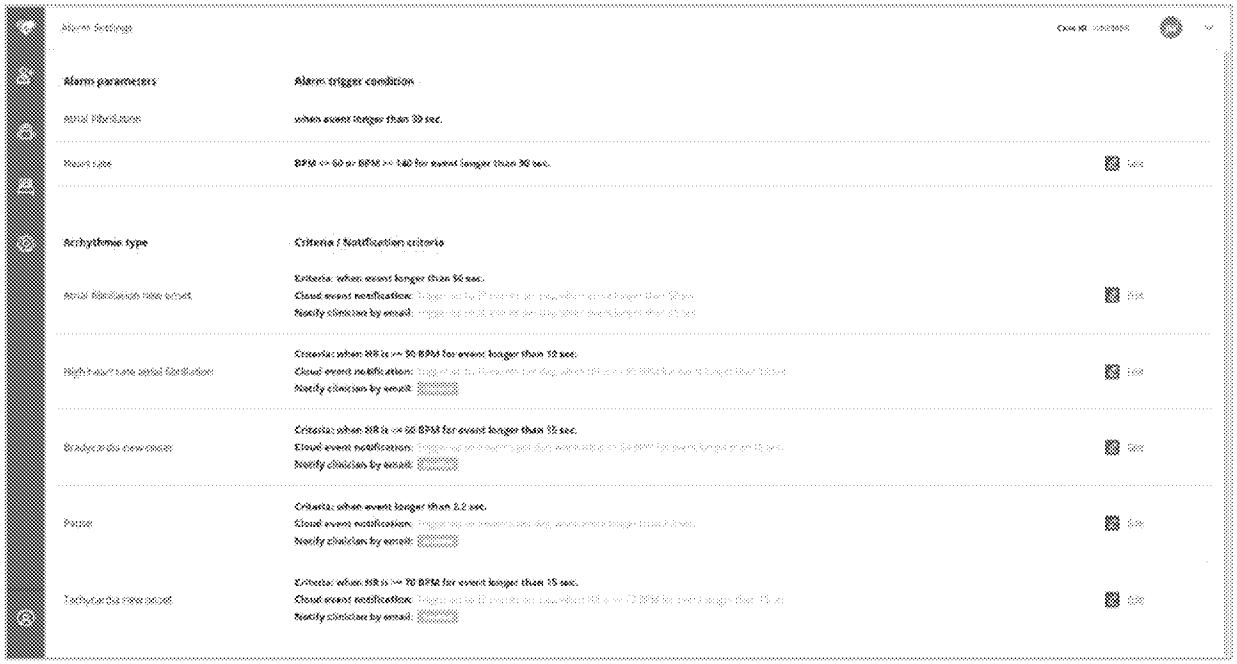
When you select “Patient data” the main patient information window opens displaying their “Real time view” of ECG. See page 43 for detailed information the patient’s real time view screen.



Short Cut to Patient Alarm Settings



Selecting “Patient alarm settings” takes you to Alarm Settings. Patient alarm and arrhythmia conditions and notifications can be adjusted as shown below. See Alarms and Alarm Management section on page 35 and Arrhythmia Event Notifications section on page 38 for additional information.



Questions? Contact FDA/CDRH/OCE/DHT8 at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118

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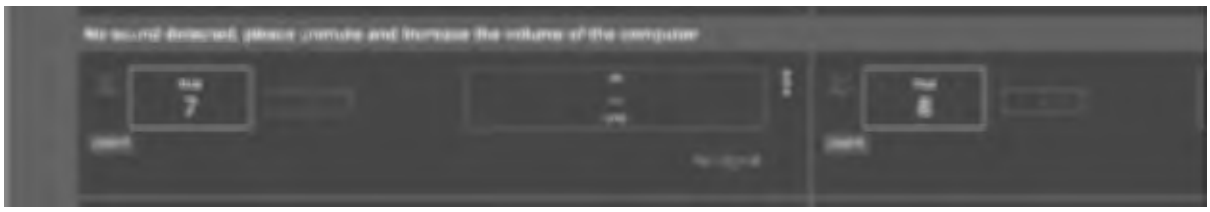
When you select “Audio OFF” all auditory alarm sounds are turned OFF for the selected patient. This is indicated by a red “crossed bell” in the upper left corner of the patient tile.

When Audio OFF is selected, the next time the menu is opened, it will show as Audio ON to turn on the auditory sound for all alarms. See page 49 for additional information.

⚠	**WARNING: When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**

The SmartCardia 7L Platform checks the volume setting on the personal computer. If the volume is OFF or on Mute, a message will be shown in the center of the display.



If the volume is too low, the message will read "Low volume detected, please increase the volume of the computer".

Unmute and increase the volume of the computer to ensure auditory alarm signals can be heard.

Battery Level Indicator

When the battery level of the *7L Patch /7L Sensor* worn by the patient has less than 10% charge remaining the battery icon is shown in red on the lower right side of the patient tile. If the patient still needs monitoring, the patient should be contacted regarding direction to attach a new *7L Patch* according to facility protocol.

Questions? Contact FDA/CDRH/OCE/DHT9 at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118
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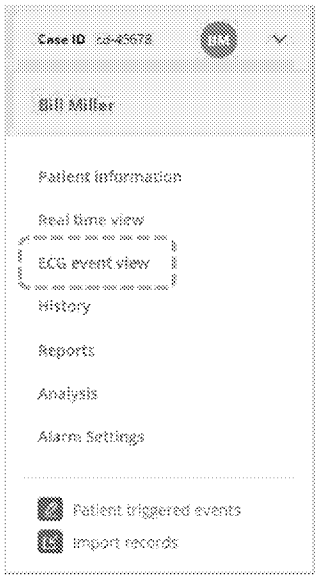
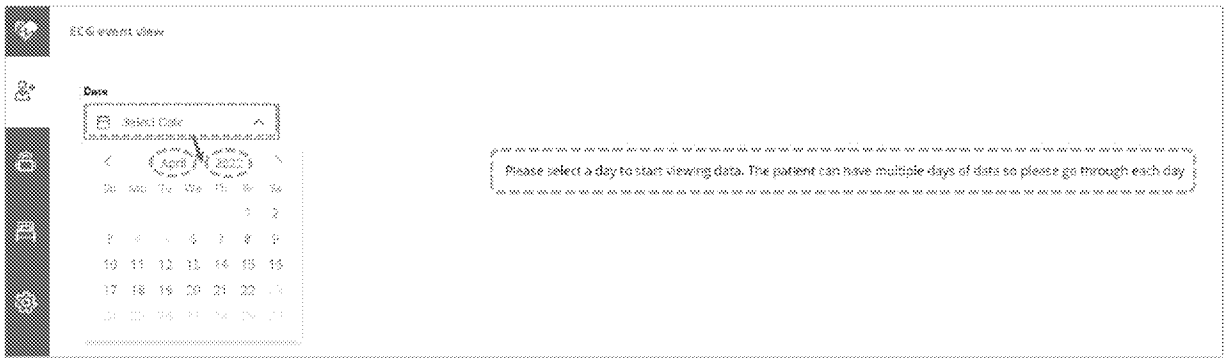
ECG Event View

On the patient page, select “ECG event view” on the expanded menu on the upper right side of the screen.



A screen will open to the calendar in the upper left corner and the message to select a day to start viewing data as shown below. The days where data is available are marked in black text, days when data is not available is grey text, and the current date is bold text. Use the calendar to enter the date to start viewing the data (to enter the year, select the year displayed then scroll to the one desired and select it. To enter the month, select the month displayed, then scroll to the appropriate one and select it.)



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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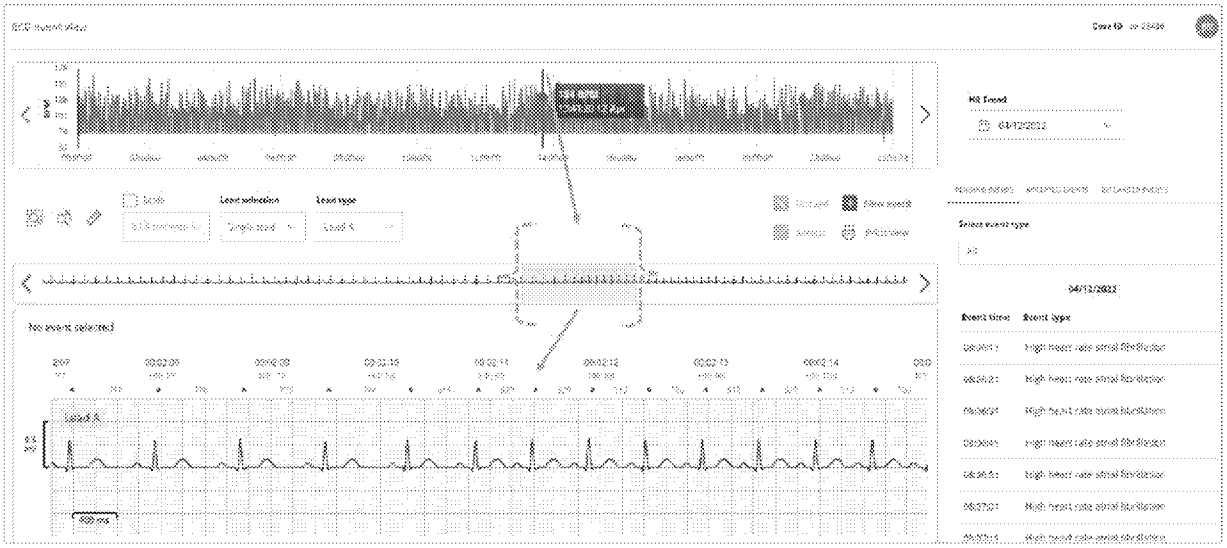
If there is available data, an image is shown as below.

Heart Rate Trend Display

At the top of the screen, there is a display of the heart rate trend shown over a 24-hour period. Clicking on any point in time there is data will show that selected section in the full disclosure bar display below and the rhythm strip from that point in time selected is also shown. The arrow keys on each side of the summary and full disclosure display provide scrolling backward or forward in time.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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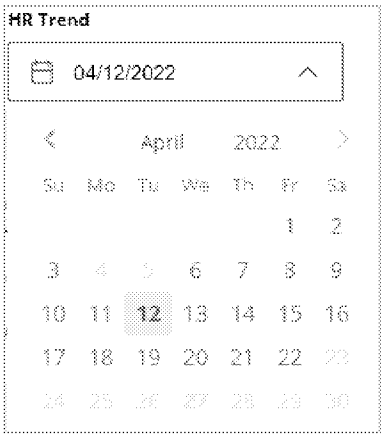
In this view with the data displayed, the calendar is in the upper right side of the screen. When the date box is clicked, a calendar appears. The days where data is available are marked in black text, days when data is not available is grey text, and the date currently being viewed is shaded in blue.



Review of Rhythm Strip

The tools below the HR Trend graph can be used to review and analyze the selected rhythm strip.

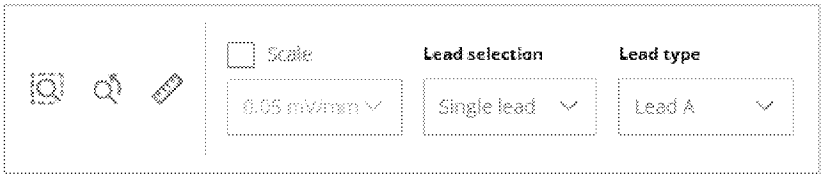
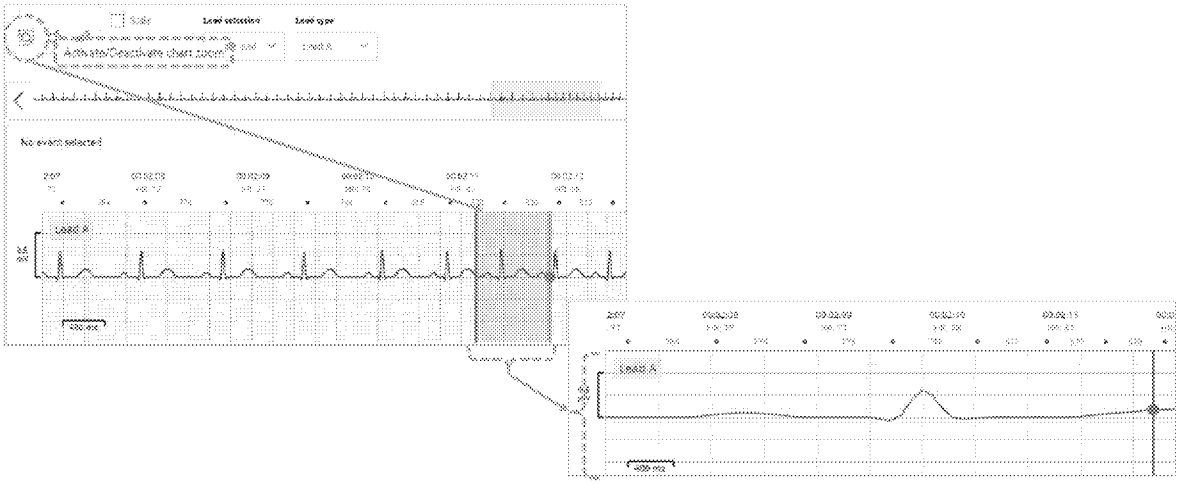


Chart Zoom

When Activate/Deactivate chart zoom is selected the icon turns red showing the tool is ready to use. On the rhythm strip, use a left mouse click at the beginning of the segment to enlarge and drag it over the area then left click to end. The zoomed in segment will display so that visual inspection can take place.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTAFF2@fda.hhs.gov or 301-796-8118

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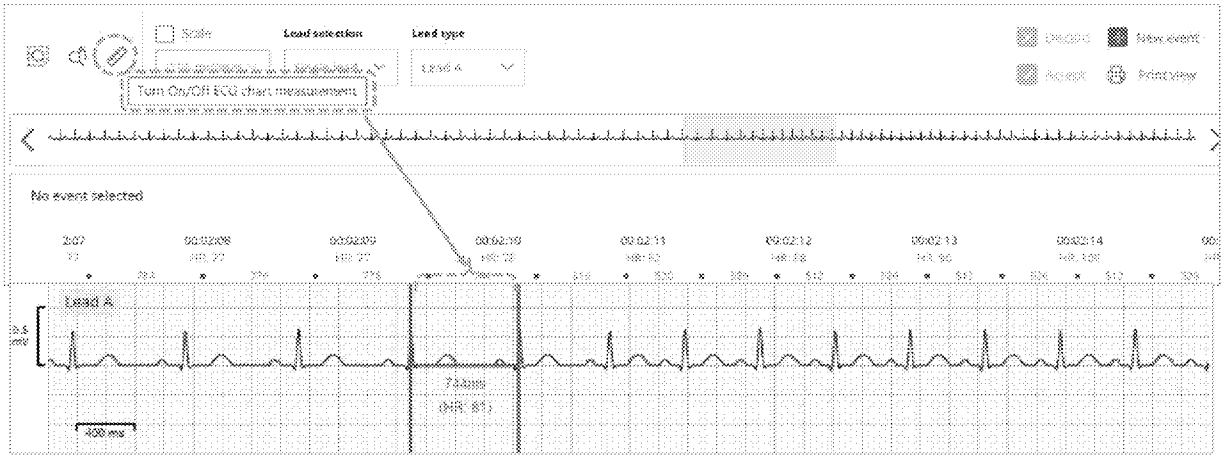
To return to the normal view, select the activate/deactivate chart zoom button again or select the restore chart zoom button.

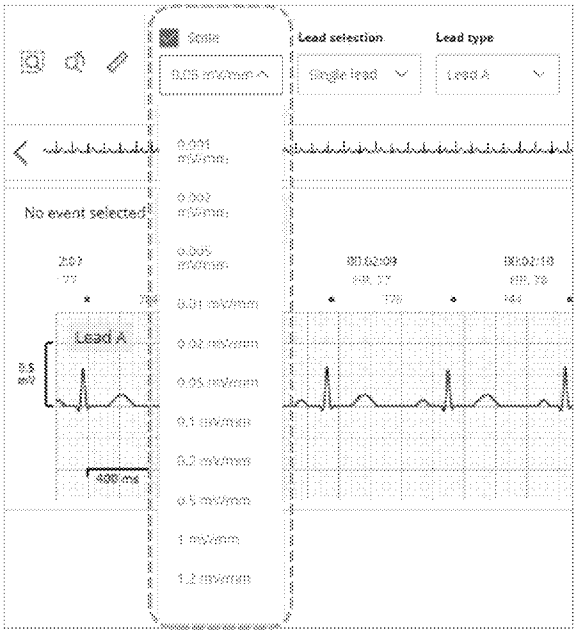
Measure



Heart rate can only be measured over one R-R interval. If you move the calipers to two R-R intervals, the heart rate will be one-half the actual rate.

Scale

The scale of each ECG graph is measured in millivolts per millimeter on the Y-axis. It is calculated automatically, but it can be changed by selecting the “Scale” box then choose the desired setting.



Questions? Contact FDA/CDRH/OHT5/DHP at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118

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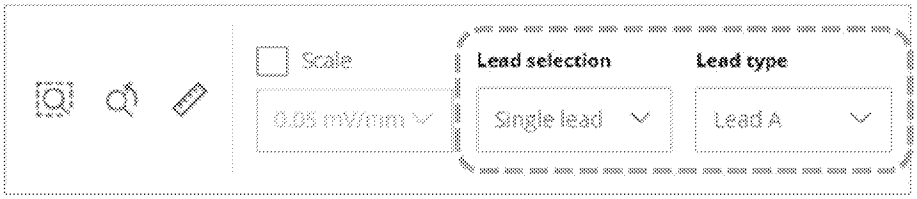
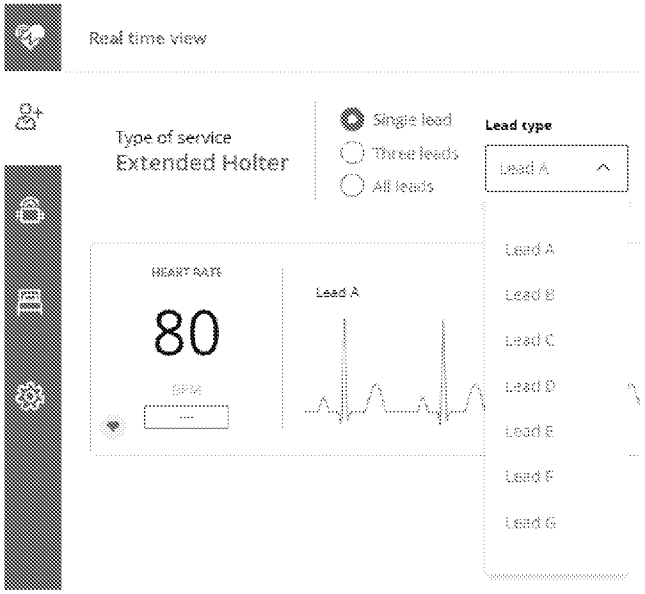
ECG Lead Display

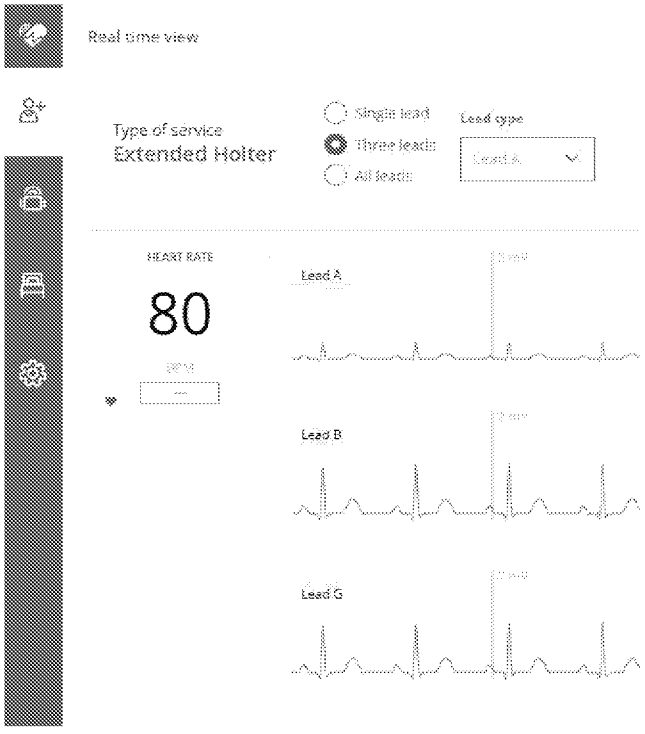
The ECG lead display format options are selected using a radio button.



- Single lead - you can select either A, B, C, D, E, F, or G



- Three leads -A, B, and G



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118

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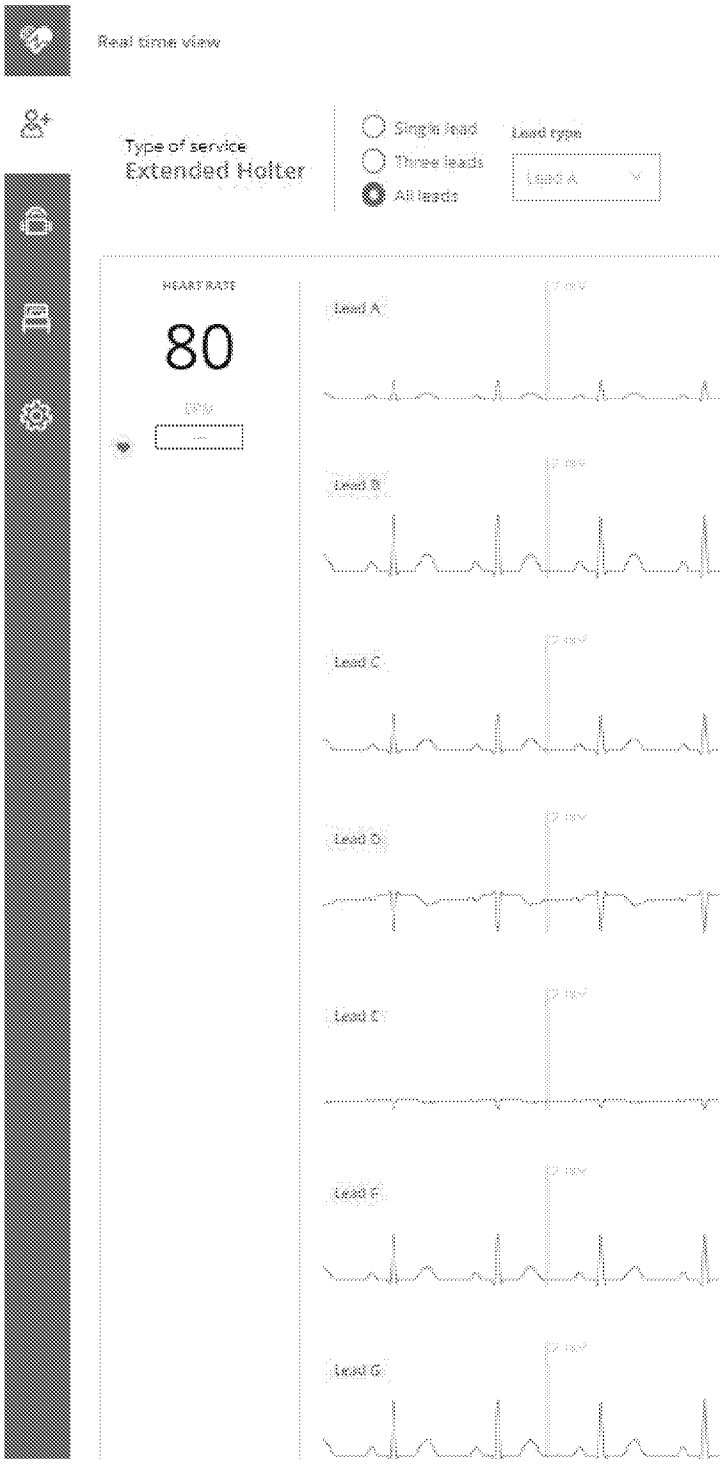
- All seven leads - A, B, C, D, E, F, and G (Scroll down on the screen to view all leads)



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118

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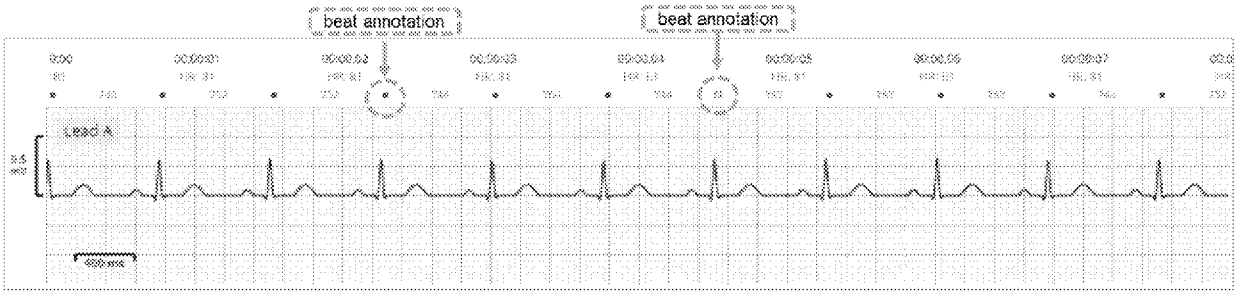
Beat Identification

The beat annotation is displayed as " ● " when a beat is detected by the 7L Sensor. Once Analysis processing is completed by the analysis service, beat types N, V, and SV are automatically detected by the analysis tool and labeled on the ECG. If the user wants to indicate the presence of a heartbeat that was not previously located, this new heartbeat must belong to one class. If the class cannot be determined, but the presence of the heartbeat must be explicitly indicated, the user can use the 'Indeterminate' class, which describes the beats that cannot be labeled clearly. The following table shows the list of heartbeats that can be marked on the ECG graph.

Label	Description	Definition
?	Unknown beat type	Clinician must always indicate a label classification Automatic annotation by SmartCardia analysis tool
N	Normal shape beat	Normal beat Automatic annotation by SmartCardia analysis tool
V	Ventricular Extrasystole	QRS complex arising from an ectopic focus in the ventricles of abnormal shape and duration. Also used to mark premature ventricular contractions (PVCs) Automatic annotation by SmartCardia analysis tool
SV	Supraventricular Extrasystole	Premature contraction arising from an ectopic focus above the bundle branches (includes the SA node, atria, and AV junction) Automatic annotation by SmartCardia analysis tool
I	Indeterminate Single Beat	Abnormal beat that cannot be identified

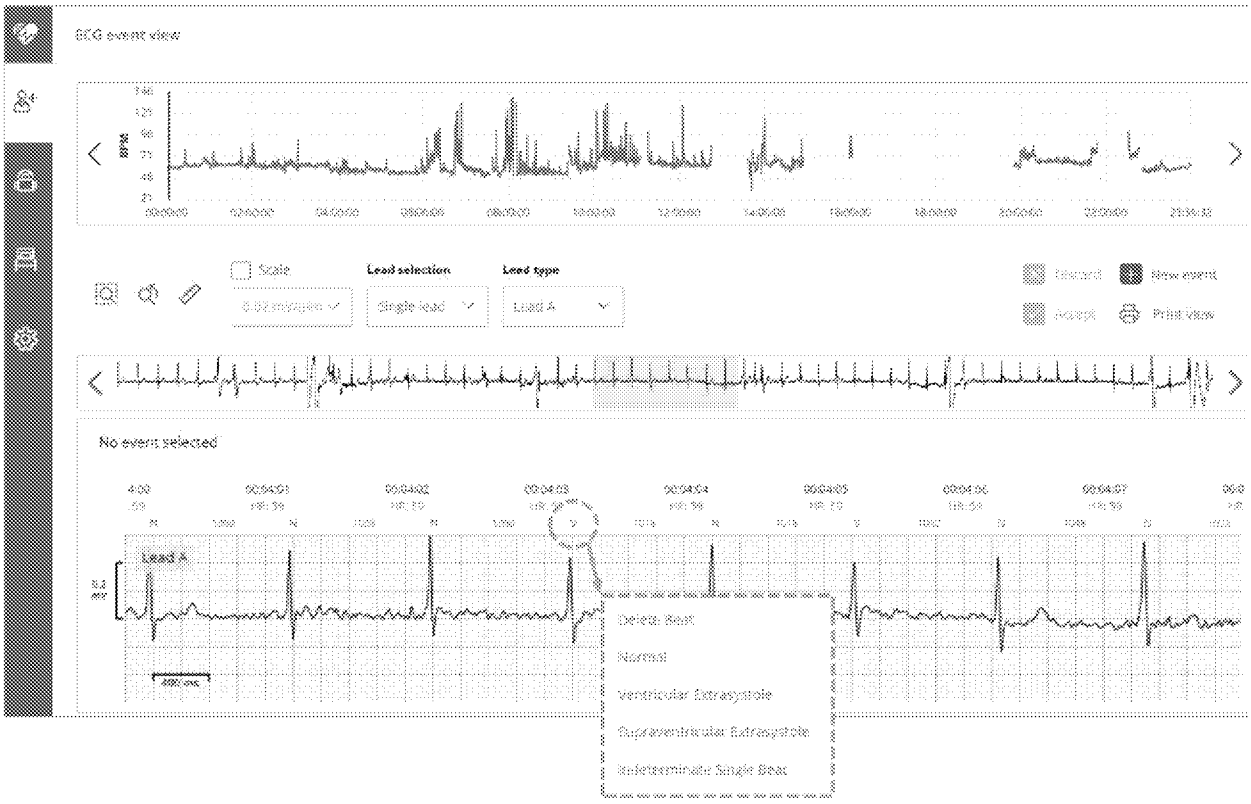
Beat Annotation

In one lead, three leads, and seven lead ECG views, the annotation for each beat is located at the top of the ECG graph. The annotation is either a letter label such as ?, N, V, SV, I, or " ● ".

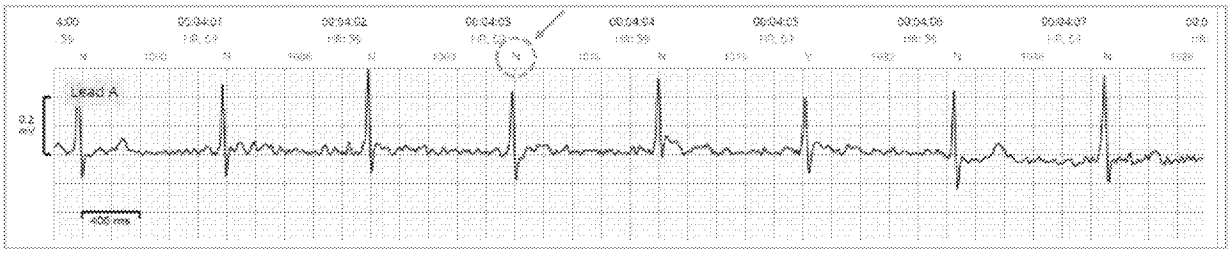


Clicking the mouse on any annotation brings up a pop-up box to delete or change the annotation for that beat. Choices include Delete Beat, Normal (N), Ventricular Extrasystole (V), Supraventricular Extrasystole (SV), and Indeterminate Single Beat (I).

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118



Once the new annotation is selected it replaces the one that was previously shown.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATHB@fda.hhs.gov or 301-796-8118

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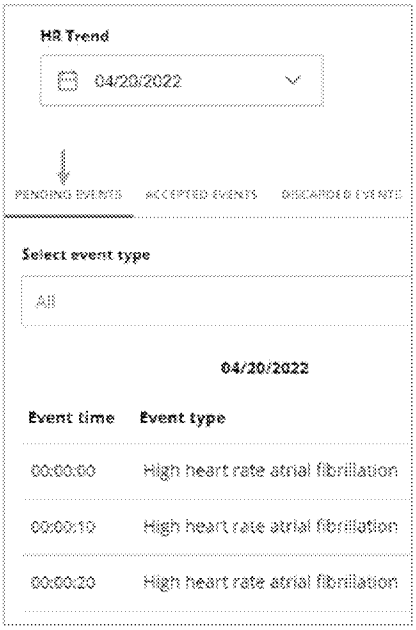
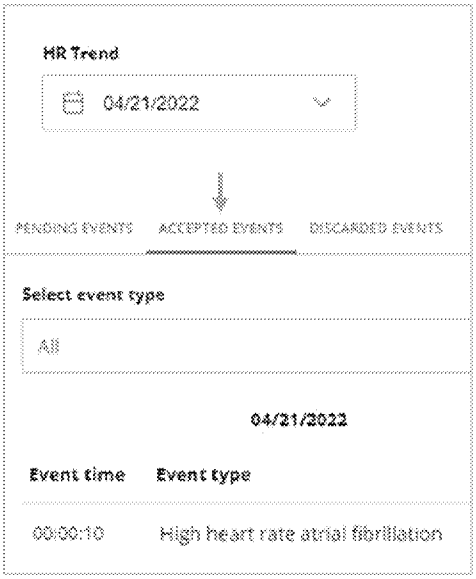
List of ECG Events

On the right-hand side of the screen is the list of events. The event date, time, and type of event are listed. There are tabs to view PENDING EVENTS, ACCEPTED EVENTS, and DISGARDED EVENTS. Select each one to view the respective list of events. Click on the box below “Select event type” to bring up the drop-down list of various arrhythmia events to filter the events listed.

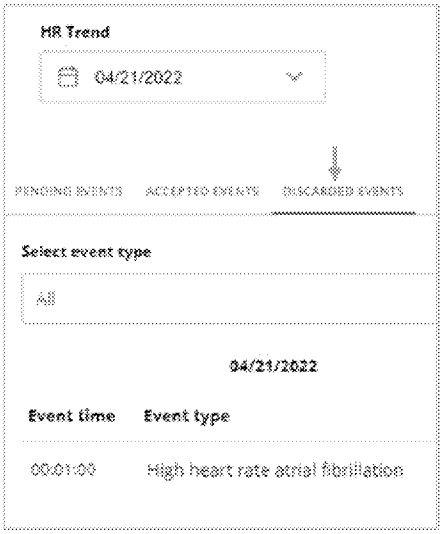
PENDING EVENTS



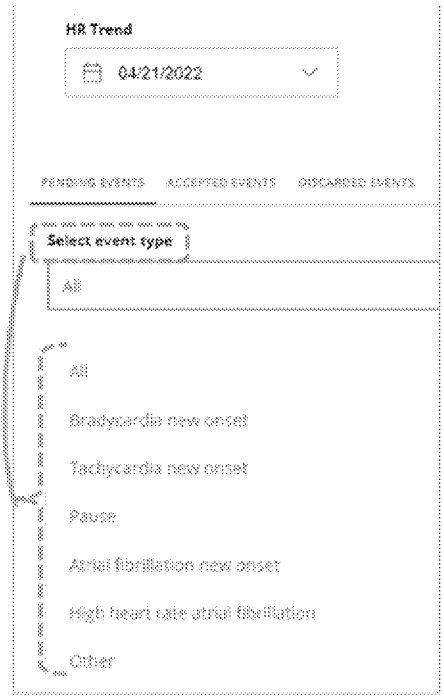
ACCEPTED EVENTS



DISCARDED EVENTS



Select event type to view



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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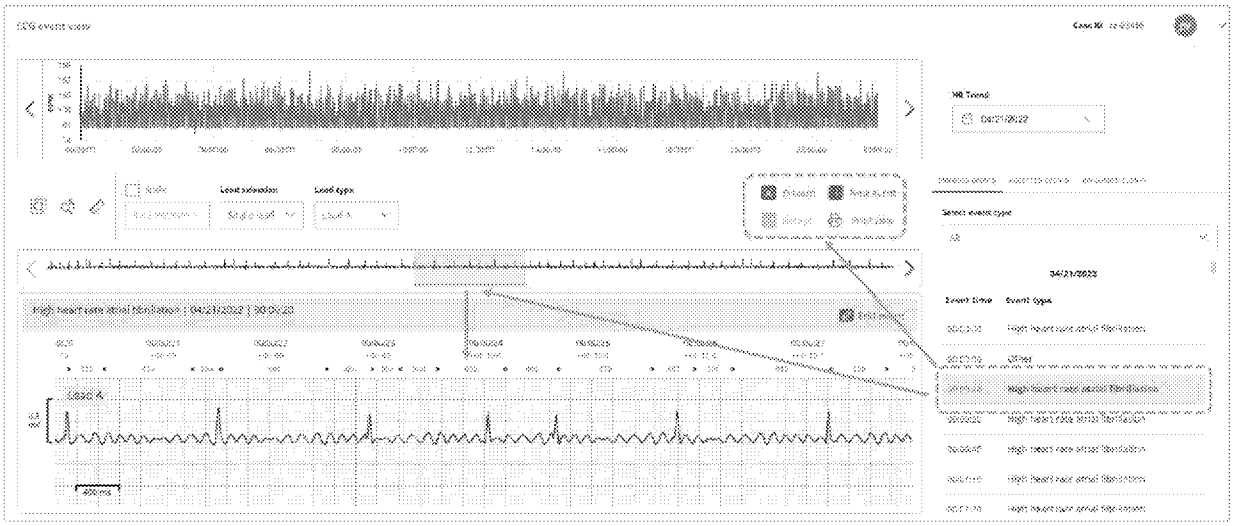
Select the event to review, analyze, and change any annotated beats. The event selected is shaded in blue. Notice the red line under the selected segment in the full disclosure bar indicating this is a listed event.



When an event first occurs, it is pending. After review of the event, it is either accepted or discarded by selecting the appropriate button.

In the following list of events, the red bell indicates that the clinician was notified of that event by email.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118

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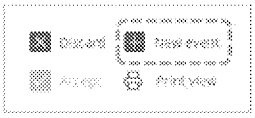
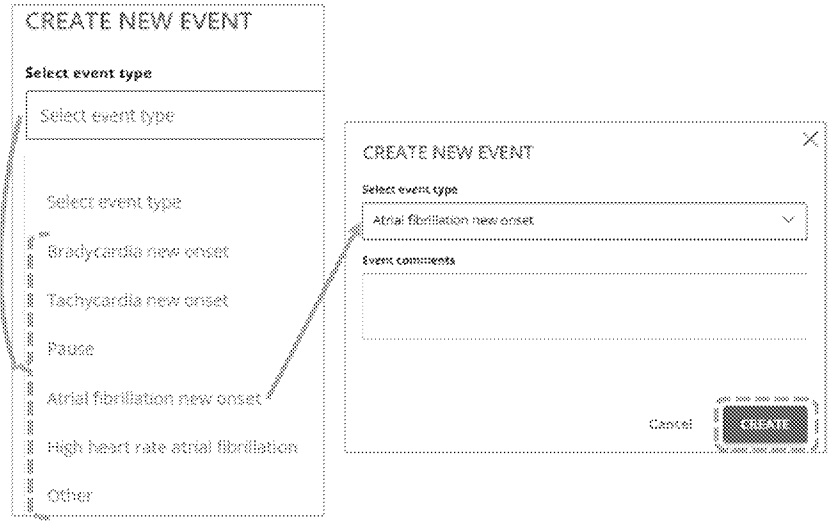
Create New Event

To document a new ECG event, select the “New event”.

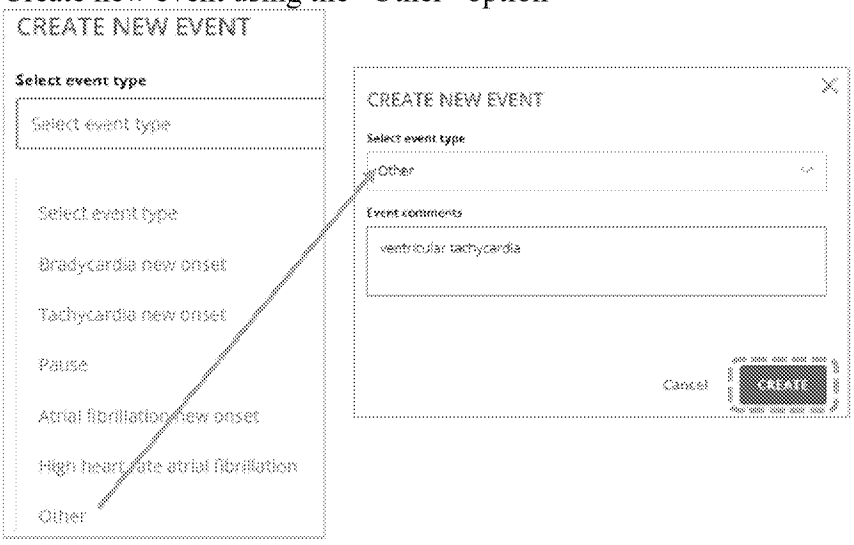


Select event type from drop-down menu and add any comments, then select “CREATE”. This new event will be listed under PENDING EVENTS. It can be reviewed and analyzed then either accepted or discarded.

Create new event from list of arrhythmia types



Create new event using the “Other” option



Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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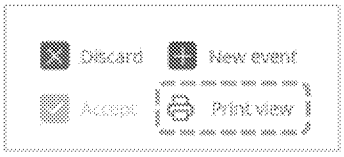
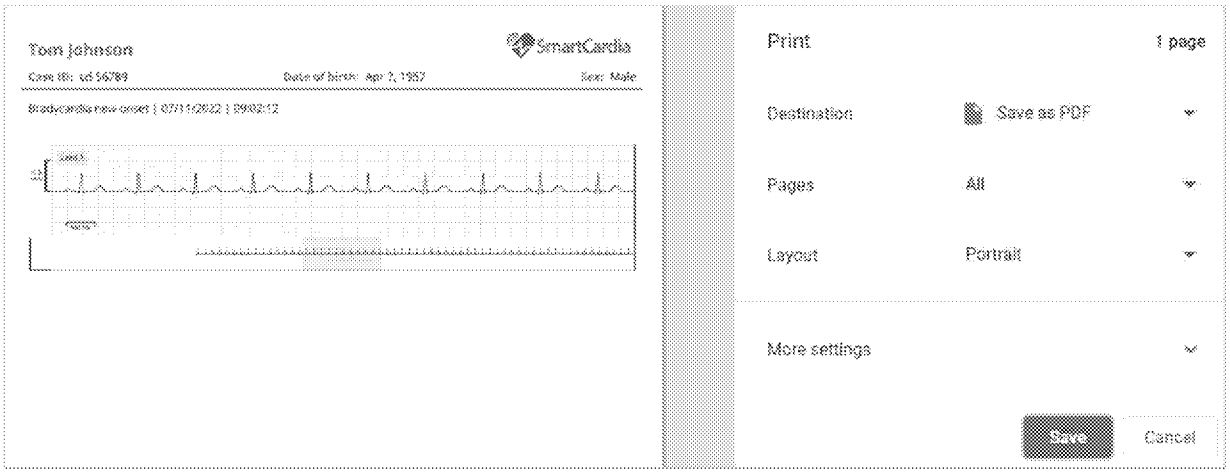
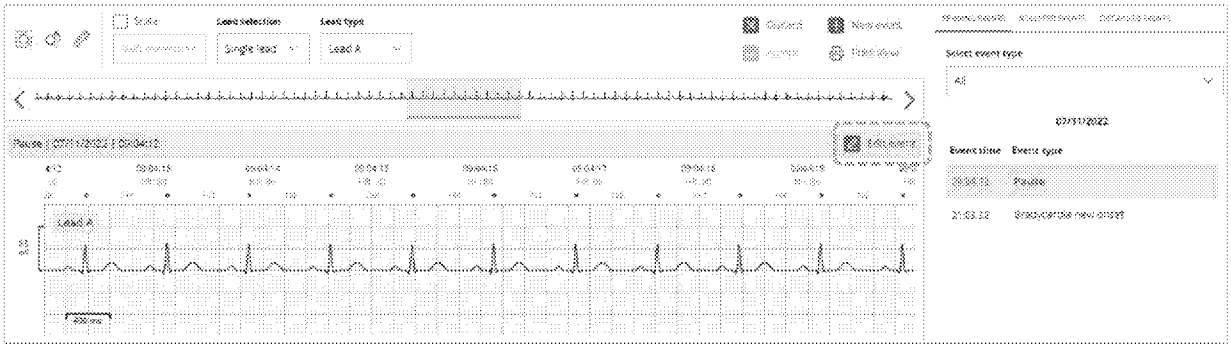
Print View

Print view can be selected and print the copy or cancel print

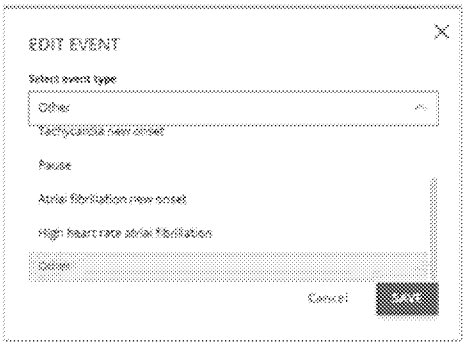


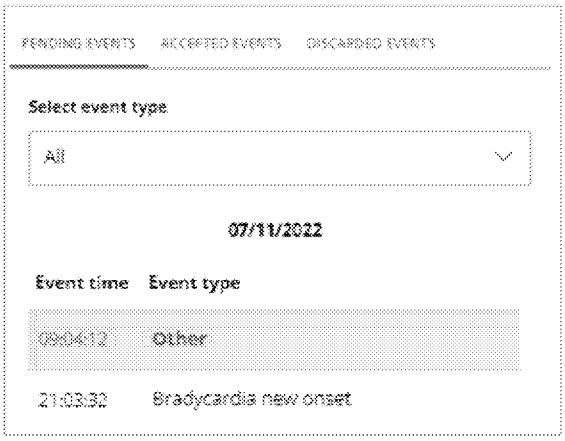


Edit Event



Select Edit event, choose the event type, and SAVE to complete the edit.





Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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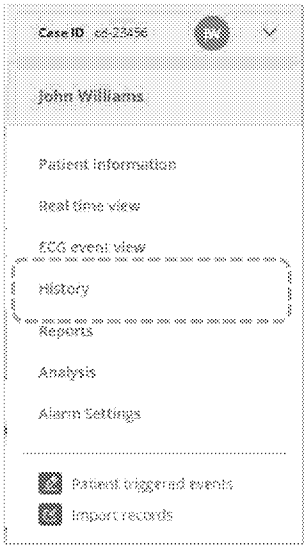
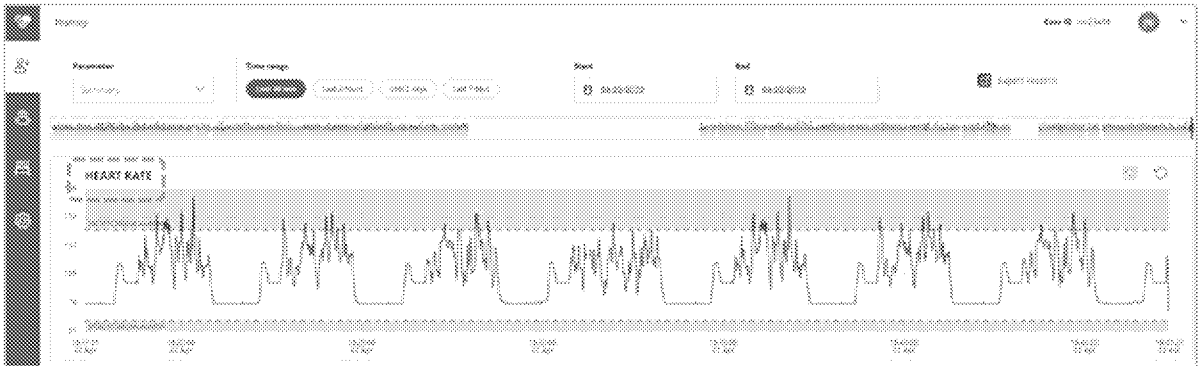
History

On the patient page, select “History” on the expanded menu on the upper right side of the screen.



The summary view displays heart rate when data is available.



Parameter and time range are two sections in the header at the top of the screen. In addition, the start and end date to review can be selected.

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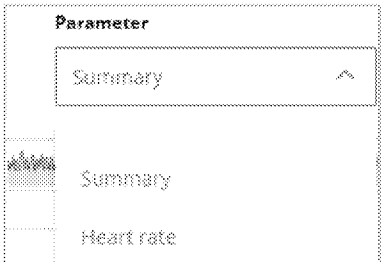
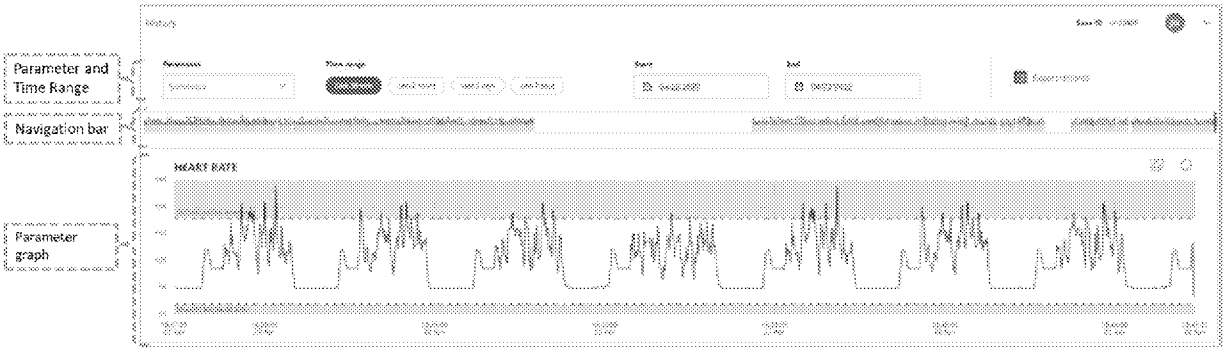
Parameter

At the top of the list is the summary option which displays heart rate graphs all in one view. Selecting the parameter box provides the option to view only the heart rate graph.



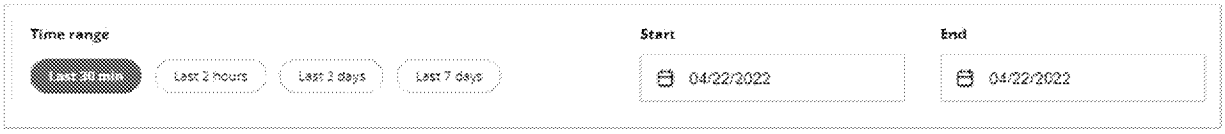
The summary and parameter page contains three elements:

- Header with the sections of parameter, time range, start and end date
- Navigation bar that displays the time of data
- Parameter graph



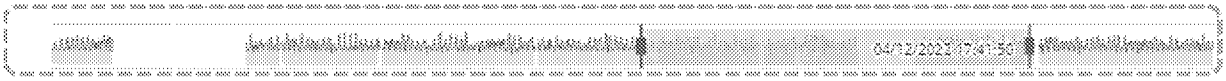
Time Range

In the time range section, data can be displayed for the last 30 minutes, 2 hours, 2 days, or 7 days. The calendar can also be used to select the start and the end dates of the data to display.



Navigation Bar

The bar shown just below symbolizes the graph of heart rate values in the period of the patient's stored data. The section appears blank if there is no data and shaded in gray when there is data. Sliding the blue bars can adjust the time of the data displayed.



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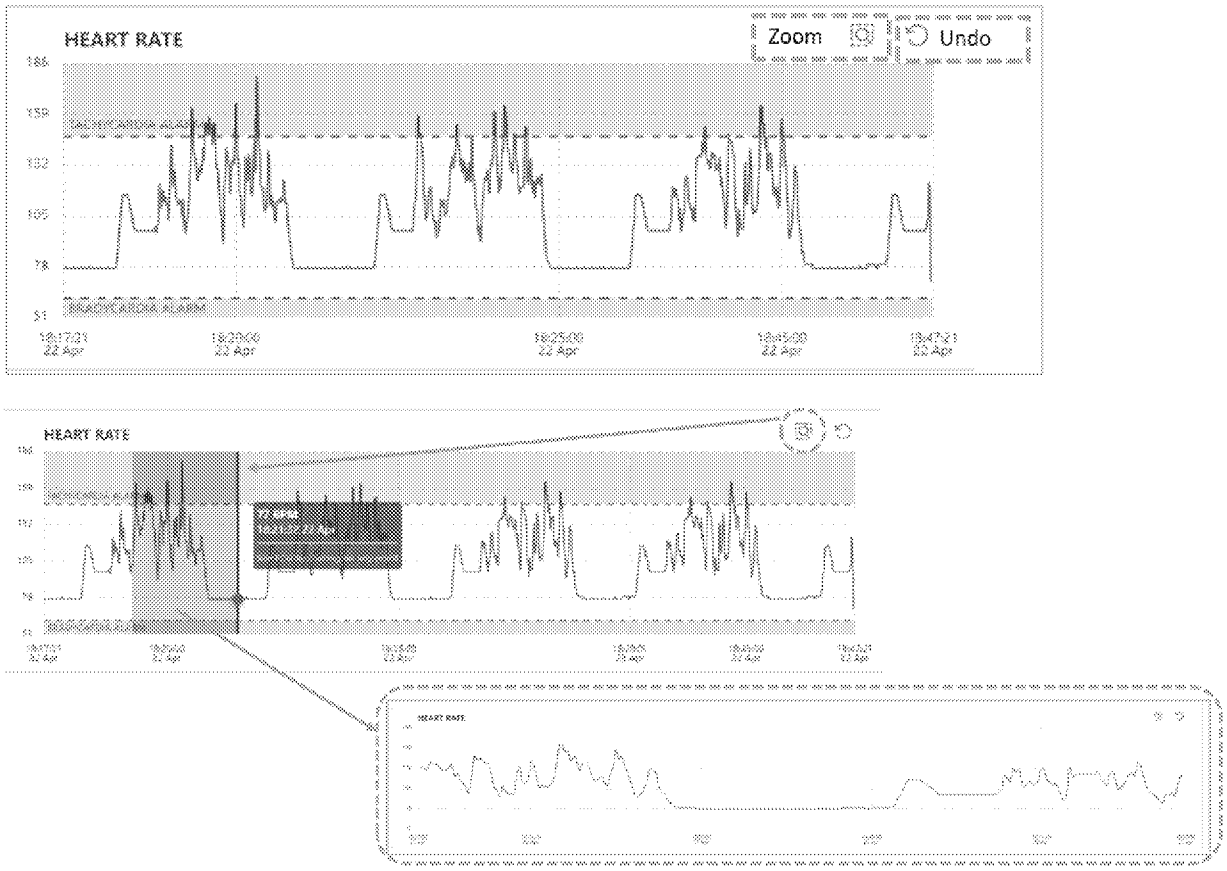
Parameter Graph

The summary view includes a parameter graph of the heart rate graph all in one view. In the graph, the x-axis shows the dates, and the y-axis shows the units of the parameter. If there is no data, the graph is blank. When data is available and inside the set limits, it is displayed in gray and data outside of the set limits is red. The threshold limits for the parameter are marked in the graph.

Chart Zoom

The parameter graph has the same format with the tools to review the graph in detail at the top right corner (Zoom, Undo, and Restore). The user can zoom in on an area of interest by activating the "Zoom" function (icon turns from grey to blue). Once it is active mark a point on the graph and drag it to the desired place. The undo function returns to the original time.



In the history summary, the graph displays a line, when the user moves the mouse over it, the line indicates the point of time in the plot. Moreover, if the user clicks in the plot, a pop-up window appears where the user can see 30 seconds of ECG centered at the click point.

When the user passes the mouse over the graph, the following information is observed:

- Heart rate
- Time and date

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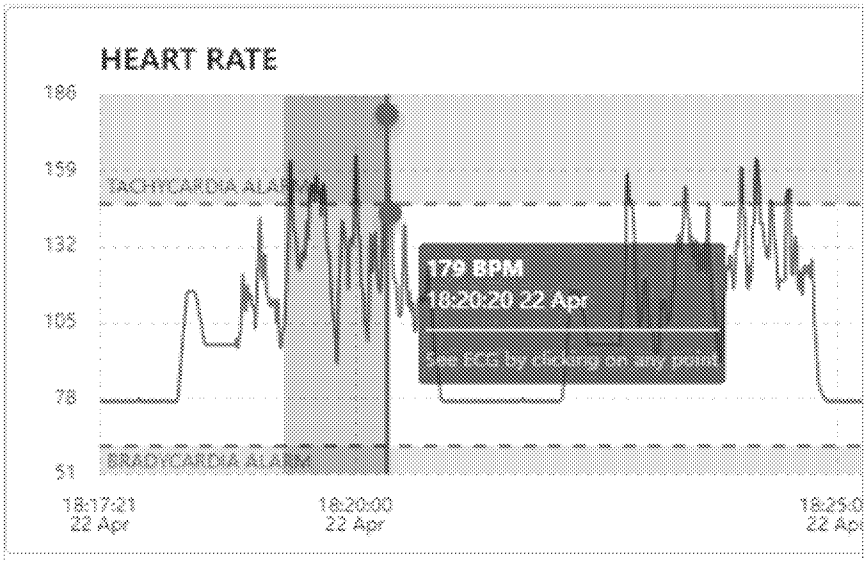
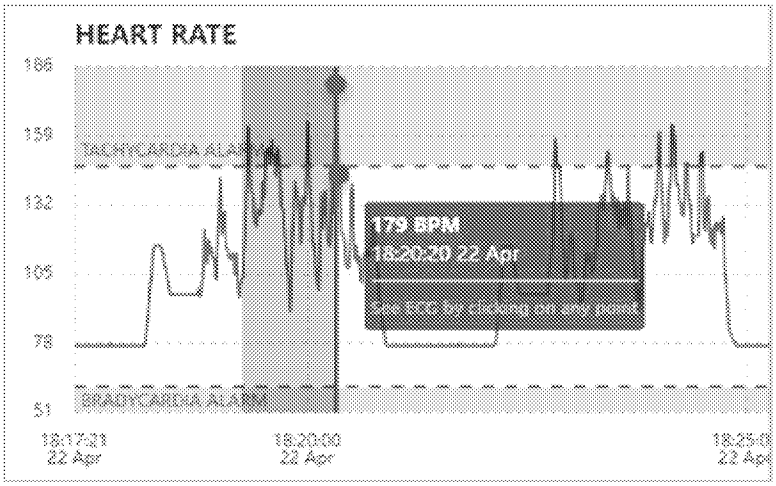
The heart rate graph is displayed in beats per minute (BPM). The red dotted line indicates the thresholds for tachycardia and bradycardia, respectively. The area above is shaded in red, indicating tachycardia alarm. Similarly, the area below is shaded in red indicating bradycardia. When the mouse is moved over the graph, the information box displays the heart rate value at that time with the date and time listed.



Clicking on one of the blue circles in the graph or on the bar line in the picture below, brings up the ECG graph observed at that precise moment and is displayed in the following picture below the summary graph.



The blue line in the middle of the rhythm strip indicates the exact time selected on the parameter graph. Selecting the arrows on either side of the displayed rhythm move forward or backward in time to review the ECG data.

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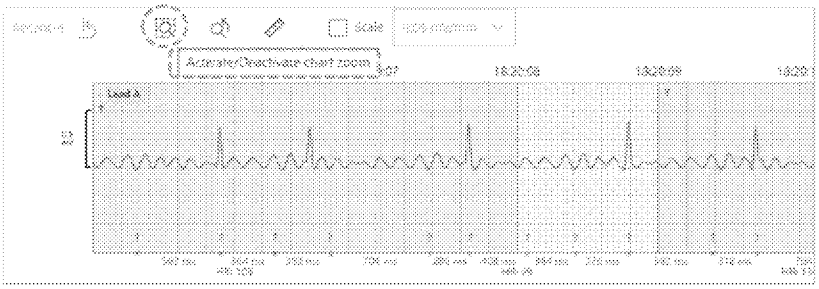
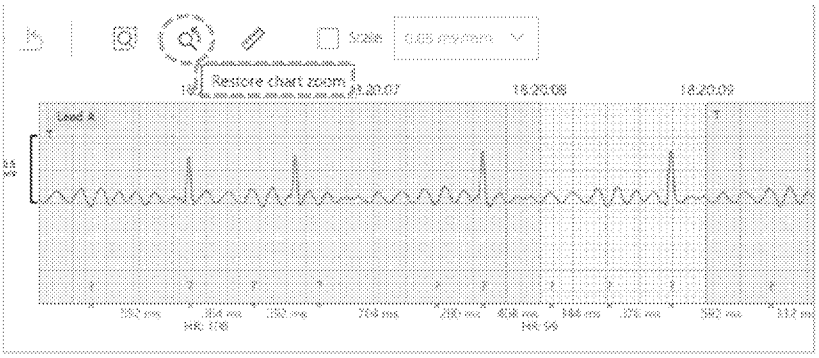
The yellow shading indicates an alarm condition is present. When two or more alarm conditions occur, the yellow shading is darker. The section at the end of the strip that is not highlighted indicates the ECG is within set thresholds and no alarm occurred.

The following functions found in the upper left corner are available to review the ECG rhythm strip:

- Activate/deactivate chart zoom



- Restore chart zoom



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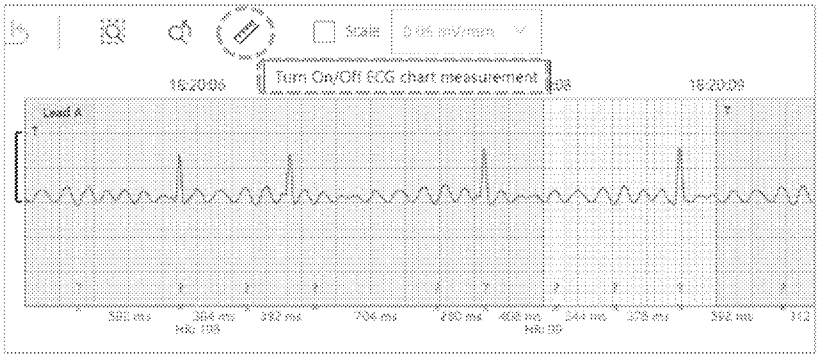
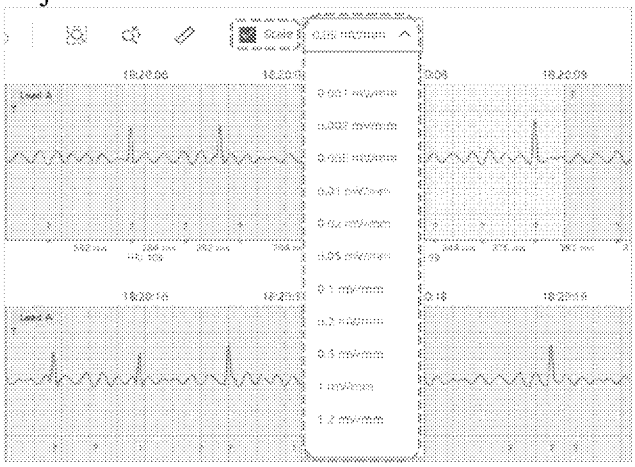
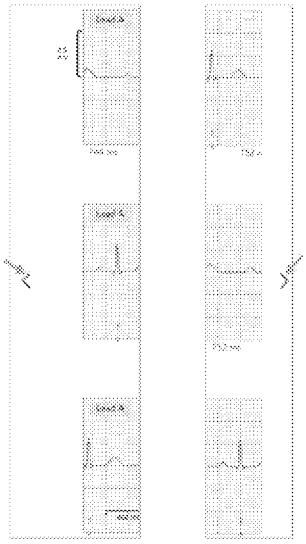
- Turn on/off ECG chart measurement



- Adjust scale as needed



To view more data scroll through the ECG using the arrow keys.



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The “Recentre” (Recenter) button in the upper left corner can be used to return instantly where previously clicked.

At the top left corner of the rhythm strip the rhythm is identified with AFIB or an initial for the rhythm type.

Rhythm Types

The following chart lists the rhythm labels, description, and any related notes. Unless stated in the "Note" column, the rhythm is not automatically marked by the 7L Platform and can only be manually marked by a clinician/technician.

Label	Description	Note
NSR	Normal Sinus Rhythm	
A	Artifact or Noise	Extra spikes, waves, or complexes in signal
AFIB	Atrial Fibrillation	Automatic annotation by SmartCardia analysis tool
VFIB	Ventricular Fibrillation	
AFL	Atrial Flutter	
VFL	Ventricular Flutter	
MAT	Multi-focal Atrial Tachycardia	

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Label	Description	Note
VT	Ventricular Tachycardia	Automatic annotation by SmartCardia analysis tool
T	Tachycardia	Automatic annotation by SmartCardia analysis tool
Vx1	Isolated Ventricular Heartbeat	Also called VEB Automatic annotation by SmartCardia analysis tool
Vx2	Ventricular Couplet	Also called V Couplet Automatic annotation by SmartCardia analysis tool
Vx3	Ventricular Triplet	Also called V Triplet Automatic annotation by SmartCardia analysis tool
VRUN	Ventricular Run	Run of 4 or more VEBs. Automatic annotation by SmartCardia analysis tool
V2	Ventricular Bigeminy	Automatic annotation by SmartCardia analysis tool
V3	Ventricular Trigeminy	Automatic annotation by SmartCardia analysis tool
SVx1	Isolated Supraventricular Heartbeat	Also called SVEB Automatic annotation by SmartCardia analysis tool
SVx2	Supraventricular Couplet	Also called SV Couplet Automatic annotation by SmartCardia analysis tool
SVx3	Supraventricular Triplet	Also called SV Triplet Automatic annotation by SmartCardia analysis tool
SVRUN	Supraventricular Run	Run of 4 or more SVEBs. Automatic annotation by SmartCardia analysis tool
SV2	Supraventricular Bigeminy	Automatic annotation by SmartCardia analysis tool
SV3	Supraventricular Trigeminy	Automatic annotation by SmartCardia analysis tool
AV1	AV Block (First degree)	
AV2	AV Block (Second degree)	
AV3	AV Block (Third degree)	
P	Pause	Automatic annotation by SmartCardia analysis tool
B	Bradycardia	Automatic annotation by SmartCardia analysis tool
ASYS	Asystole	
PM	Pacemaker Rhythm	
MaxHR	Maximum HR	*Meta-label* to indicate that the segment contains an example of maximum heart rate of the recording Automatic annotation by SmartCardia analysis tool
MinHR	Minimum HR	*Meta-label* to indicate that the segment contains an example of minimum heart rate of the recording Automatic annotation by SmartCardia analysis tool
REPORT	Printable Strip	*Meta-label* denoting that this strip is of interest for a report

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Heartbeat Types

The type of heartbeat is shown in blue in the lower line of the graph. The red x indicates a beat was detected.

The beat types N, V, SV, and ? are automatically detected by the analysis tool, while the user can manually add /edit the rest. If the user wants to indicate the presence of a heartbeat that was not previously located, this new heartbeat must belong to one class. If the class cannot be determined but the presence of the heartbeat must be explicitly indicated, the user can use the 'Indeterminate' class, which describes the beats that cannot be labeled clearly. The following table shows the list of heartbeats that can be marked on the ECG graph.

Label	Description	Definition
?	Unknown beat type	Clinician must always indicate a label classification Automatic annotation by SmartCardia analysis tool
N	Normal shape beat	Normal beat Automatic annotation by SmartCardia analysis tool
V	Ventricular Extrasystole	QRS complex arising from an ectopic focus in the ventricles of abnormal shape and duration. Also used to mark premature ventricular contractions (PVCs) Automatic annotation by SmartCardia analysis tool
SV	Supraventricular Extrasystole	Premature contraction arising from an ectopic focus above the bundle branches (includes the SA node, atria, and AV junction) Automatic annotation by SmartCardia analysis tool

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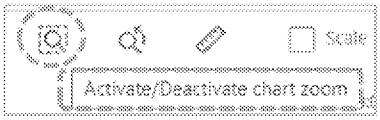
Label	Description	Definition
M	Missing QRS. This occurs in a heartbeat when the QRS complex is not present or not visible.	QRS complex is not present or not visible for a heartbeat
P	Paced beat	Beat from artificial pacemaker
F_V	Ventricular Fusion Beat	More than one electrical impulse fires at the same time in the ventricles causing the resulting complex to be varied in configuration and height
F_A	Atrial Fusion Beat	More than one electrical impulse fires at the same time in the atria with the resulting complex varied in configuration and height
X	Phantom Beat	Unclassified beat
I	Indeterminate Single Beat	Abnormal beat that cannot be identified

Chart Zoom

The chart zoom function can be activated and deactivated using these tools.

- Activate/Deactivate chart zoom



- Restore chart zoom

In the example below, the chart zoom icon is red indicating it is activated. The darker yellow shaded area was selected by placing the mouse cursor on the beginning point to review and dragging it to the last point to review.

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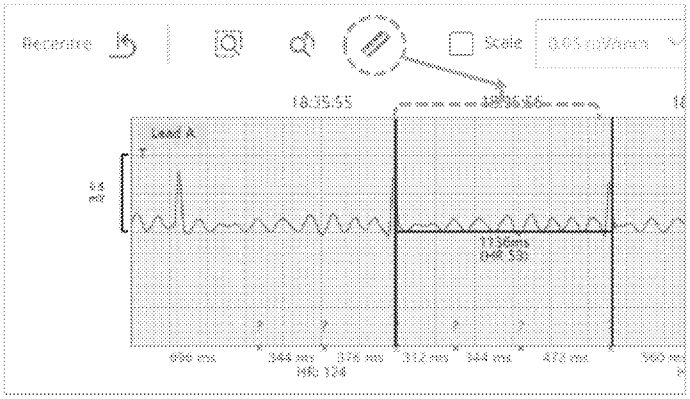
The example below shows the top strip with the highlighted beats using the zoom function. The second strip shown, is the normal view which can also be expanded using the zoom function if desired.

ECG Chart Measurement

ECG chart measurement can be turned on to analyze the ECG in more detail. The gray icon indicates the measurement function is off and red shows measurement is on as pictured below. The location of R peaks and the time between consecutive R peaks can be measured in milliseconds and heart rate is shown. The amplitude can also be measured in mV and displayed in the information box.



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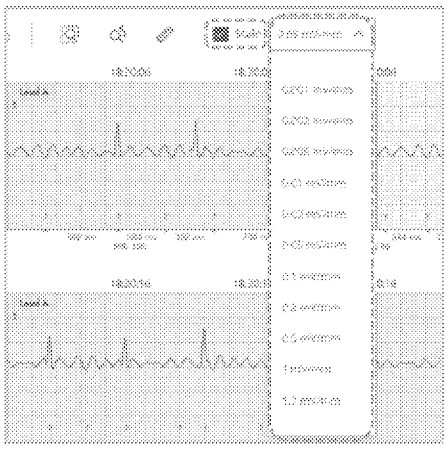
Scale for Display

The scale for rhythm display can be adjusted as desired.



After review of the detailed ECG chart view use the X to exit this screen to return to the graph view.

Export Records

From this view in “History”, clinicians can export the signals of a patient in the SmartCardia files’ format (*.SC). These files can be uploaded (imported) again to the same patient.

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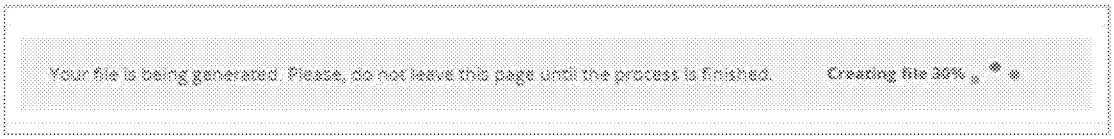
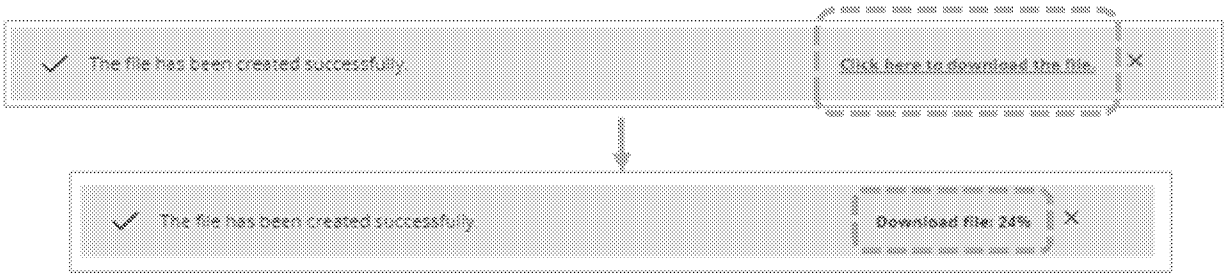
To create a *.SC file with the signals of a patient, a clinician must select the time range using the navigation bar. They can also use the buttons at the top-left corner to select one of the pre-defined options (last 30 minutes, last 2 hours, last 2 days and last 7 days with data). Select “Export records”

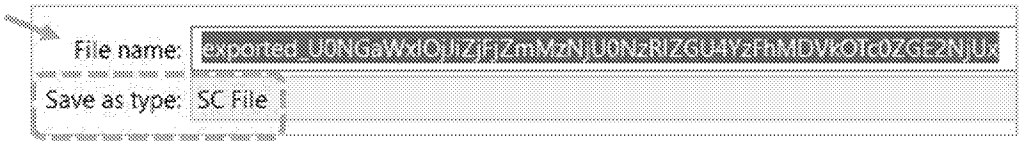
When selecting a large amount of data, the following message will show the progress of file generation and reminder to not leave this page until the process is finished.



Once the process finishes and the file is ready to be downloaded, the user will see a notification with a link. Clicking on that link will start the download process. A message will state the progress of the file download.



Clinicians must select the path and the name of the recording, and the file will be downloaded.



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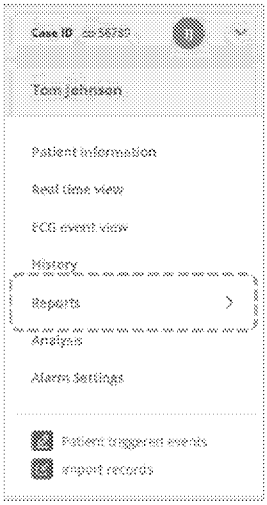
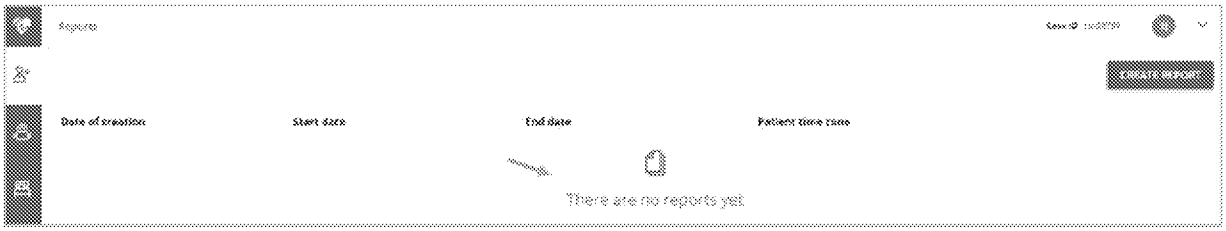
Reports

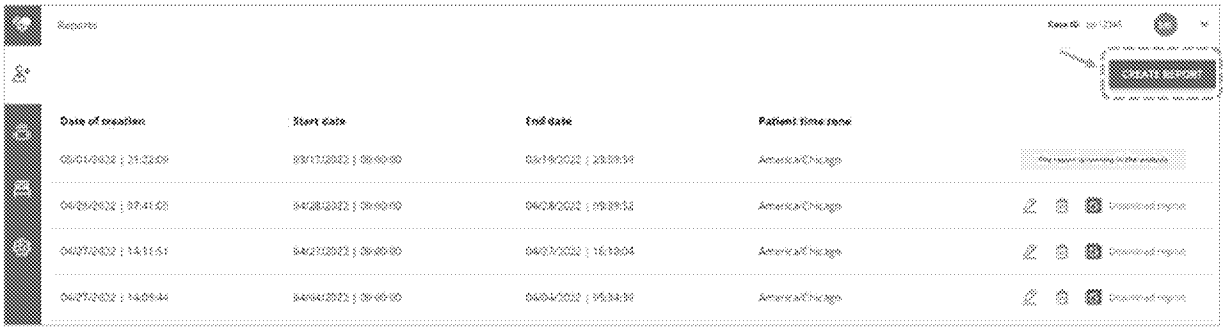
Reports of Analysis done for a patient can be managed by selecting “Reports” from the expanded menu on the upper right side of the screen.



If there are no reports available for the patient, there is a statement on the list of reports page that says, ‘There are no reports yet’.



This page below displays the list of reports that have been generated for the patient.
To generate a new report, select “CREATE REPORT”.



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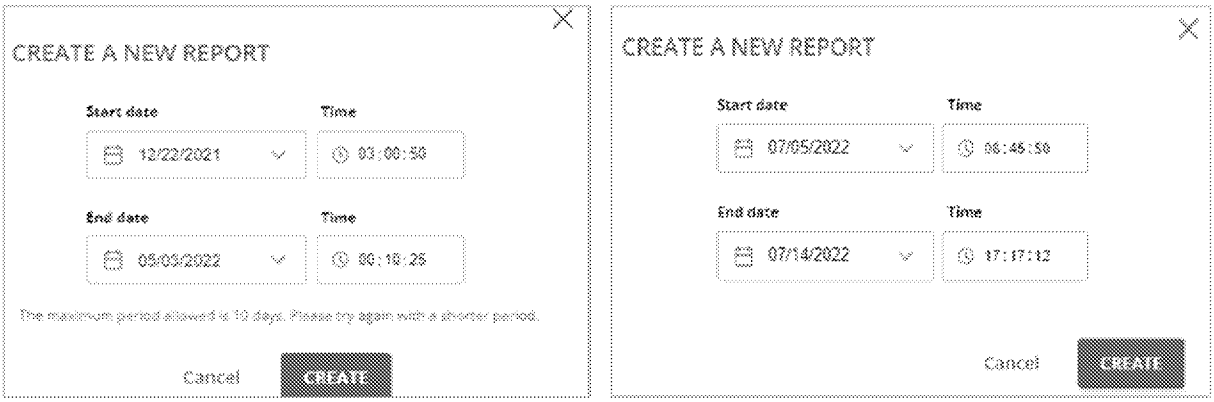
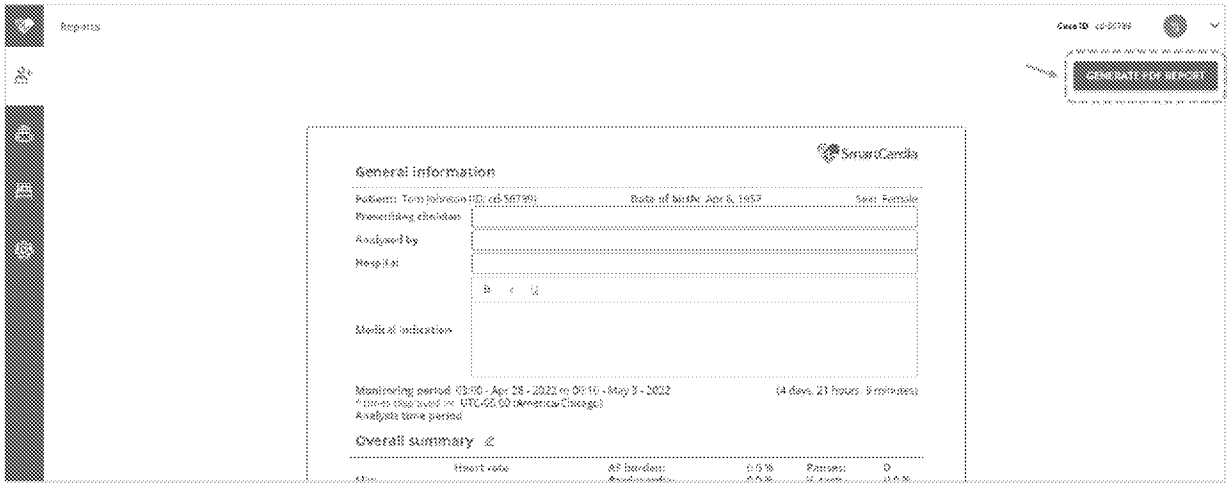
In the pop-up box, enter the start date and time along with the end date and time. Ten days is the maximum number of days possible for the report time period.

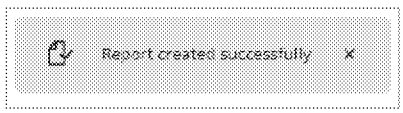
NOTE: The first screen shot below is an example when you try to enter more than ten days for the report time period. Once the date information is corrected the “CREATE” button changes color from gray to blue and is active.



Once “CREATE” is selected the report is created and displayed with the option to “Generate PDF Report”.



The report was created successfully, and the report is now added to the list of reports.



NOTE: If a long period of time is requested, it will take longer to create the report.

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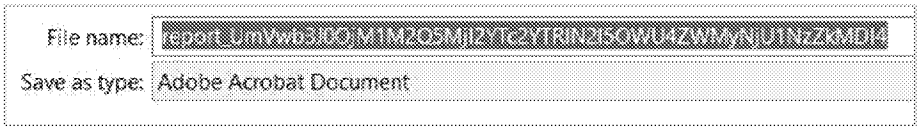
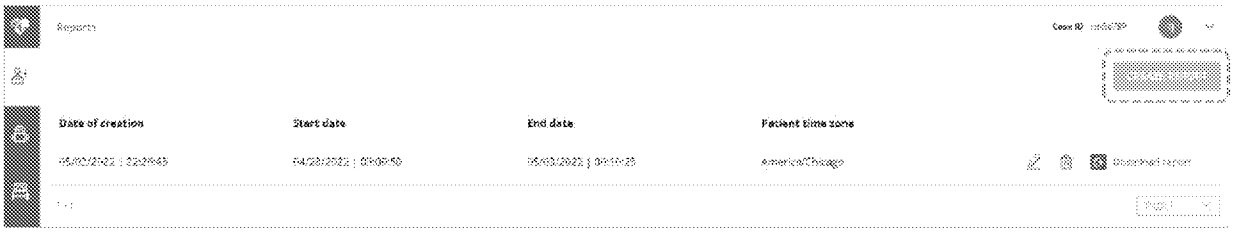
The report list has column headers of the creation date, the selected start and end date of the report, and patient time zone. For each report listed, there is a button to edit, delete, or download the report.

The edit function provides the ability to add and edit a comment on each report. Once edits are complete, select “GENERATE PDF REPORT”.

The report can be deleted or download as a PDF file.



NOTE: The “CREATE REPORT” button is shaded in gray and not active while Analysis is in process for the patient, as shown in the example below. During that time, the only function available is to work with an available report.



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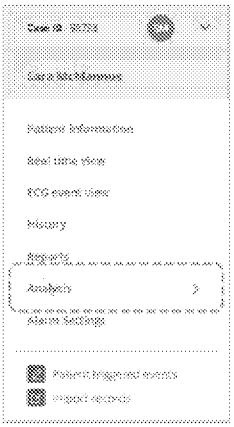
Analysis

Selecting Analysis provides a software tool to perform marking of long electrocardiogram (ECG / EKG) recordings. This was created with special emphasis on the ease of use for the clinician. The application has been developed to mark ECG recordings sampled at different resolutions and voltage levels, enabling the marking of heartbeat types, the underlying rhythm as well as episodic rhythm changes and artifacts. Analysis also provides processing functionalities to perform semi-automatic detection of different abnormalities aiding the marking process.

There are two ways to get to the Analysis function.

- From the "PATIENTS" list, select the patient's name that you want to perform analysis.



- From the "Multi-Patient" view, on the patient tile of the patient that you want to perform analysis, click on the three dots in the upper right corner of the patient tile.

Select Patient data in the pop-up window, then go to the options for that patient in the upper right side of the screen and select "Analysis".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ.STATUS@fda.hhs.gov or 301-796-8118

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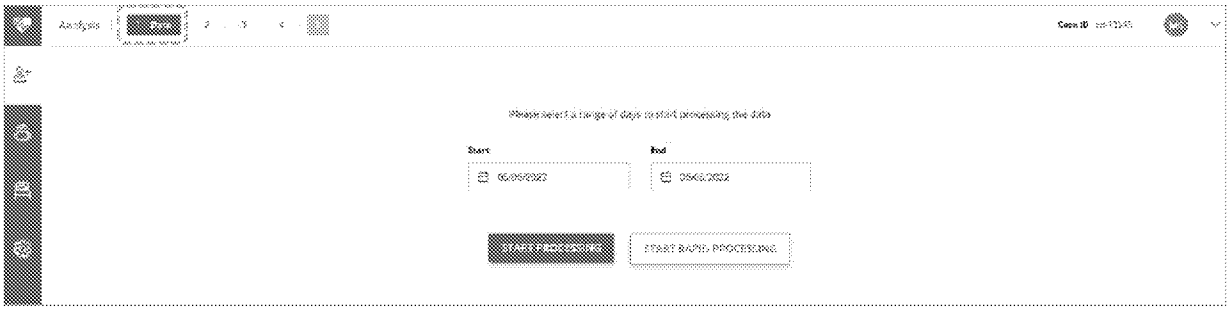
Holter Report Preparation- Standard Processing

Processing the data is done in five steps

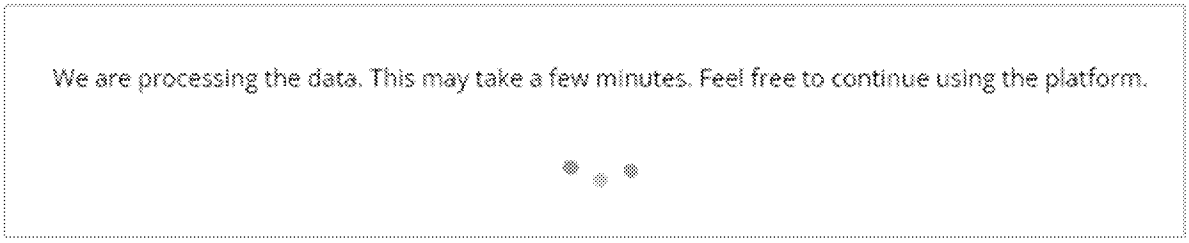
Step 1 Date

- Select the range of days to start processing the data. Use the calendar to set the start and end dates.
- Click on “START PROCESSING” or “START RAPID PROCESSING”



If analysis was done previously a pop-up asks if you want to do a new analysis.

If YES is selected in this case, data processing begins.



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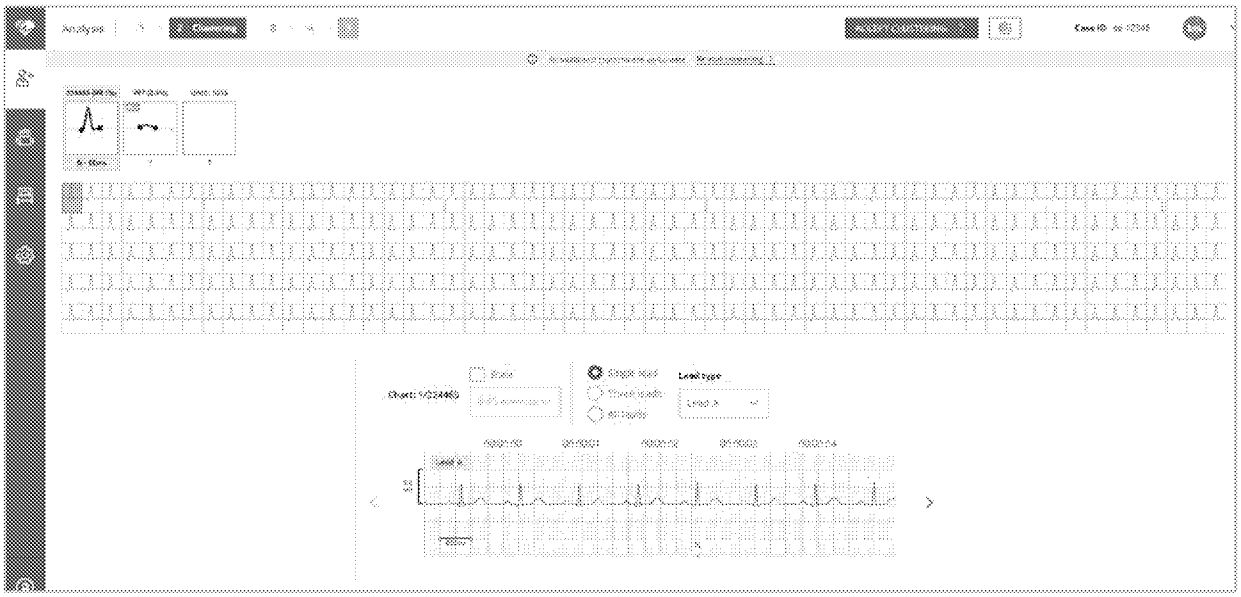
Step 2 Clustering-Beat clustering analysis



Reviewing the heartbeat clusters

Each cluster represents a group of heartbeats (QRS complexes) that are similar in morphology. The clusters are presented in descending order according to the number of heartbeats belonging to the cluster.

The template of each morphology is shown in a square.

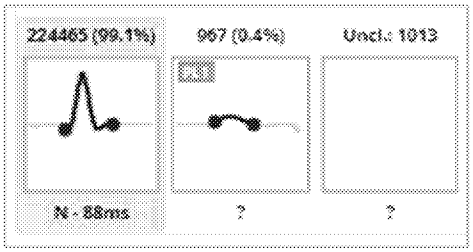
Above the cluster square is displayed:

- Number of the same morphology QRS beats
- Percentage of their occurrence

If a cluster has premature QRS complexes, the relative degree of prematurity will be shown in the upper left corner. The prematurity of the beats inside the cluster is indicated in three levels:

- Premature (PL1)
- Very premature (PL2)
- Extremely premature (PL3)

Below the cluster square is an estimation of the QRS length of the template as well as a tentative suggestion for the label to apply to the cluster.



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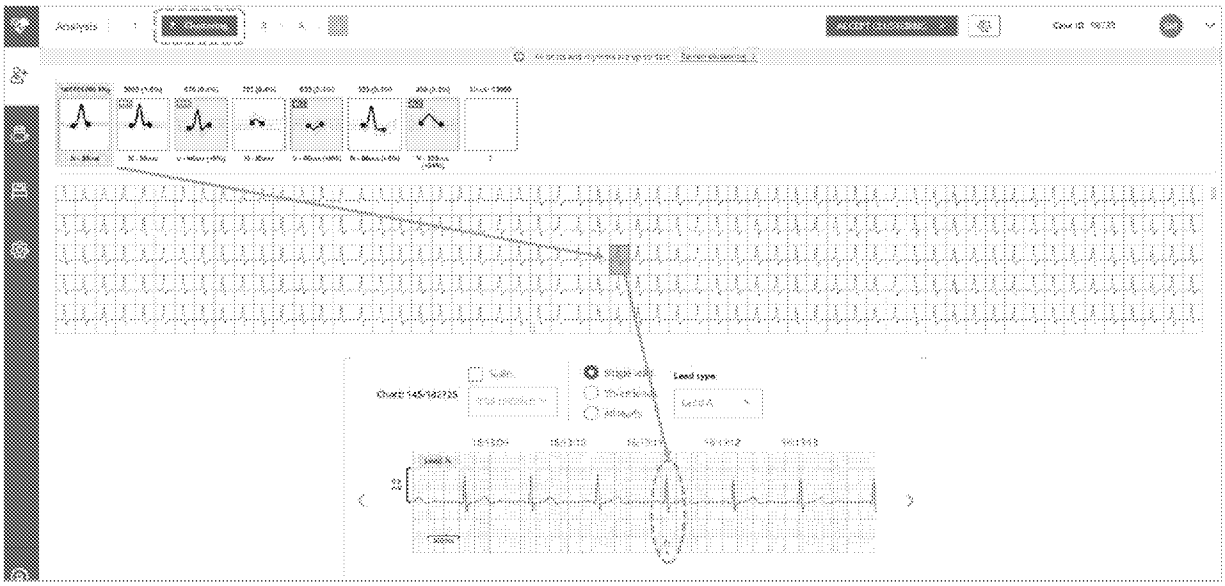
The background of each template is color coded:

- Green for Normal clusters (denoted with the label 'N')
- Yellow for any other type
- White for clusters of unknown type (denoted with the label "?")

QRS and ECG Preview

For each cluster, the individual heartbeats can be reviewed in greater detail.



ECG Time and Voltage Scales

As in a standard ECG rhythm strip, on the horizontal dimension (time axis), each 1mm box corresponds to 0.04 seconds (40 milliseconds) and each 5mm box corresponds to 0.2 seconds (200 milliseconds). In other words, the ECG is displayed at 25 mm per second. On the vertical dimension (voltage axis), the tool adapts the scale to optimally display the ECG signal. This ratio is expressed in millivolts per millimeter (mV/mm) and is indicated in the Scale pop-up selector.

While the tool automatically adapts this scale when changing from signal to signal (e.g., after loading a new file), the ratio can be manually changed by the user selecting the desired value using the pop-up selector for scale.

ECG preview leads

The ECG lead display format options are selected using a radio button. The choices of lead options available to view include:

- Single lead - you can select either lead A, B, C, D, E, F, or G

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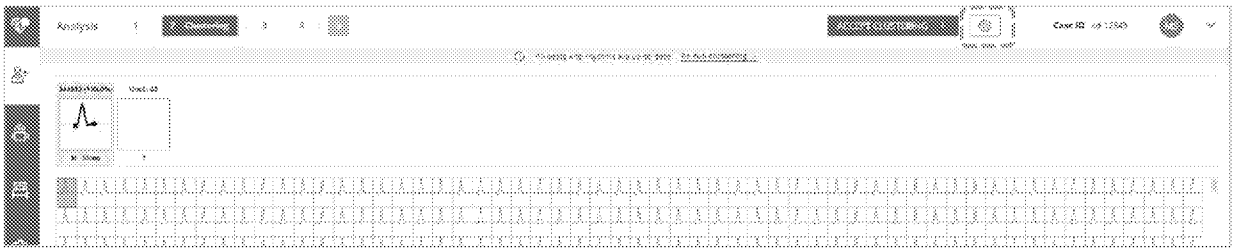
- Three leads - A, B, G
- All seven leads - A, B, C, D, E, F, or G (Scroll down to view all leads)

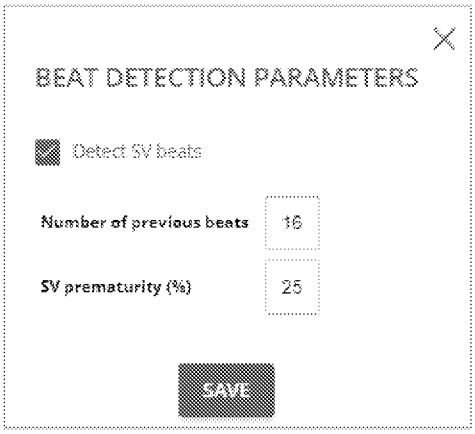
Beat detection parameters

Adjustments can be made to the parameters for beat detection.

- Click on the gear icon at the top right of the screen to the right of ACCEPT CLUSTERING

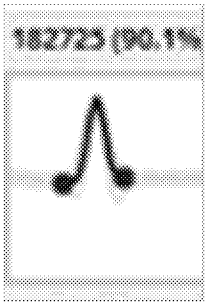


In the "pop up" box, BEAT DETECTION PARAMETERS make any adjustments to detect SV beats, number of previous beats and SV prematurity %. And "SAVE" changes.



Navigation through heartbeat clusters

Click on the square of the desired heartbeat (QRS) cluster to look at in detail. A blue box will outline the cluster.



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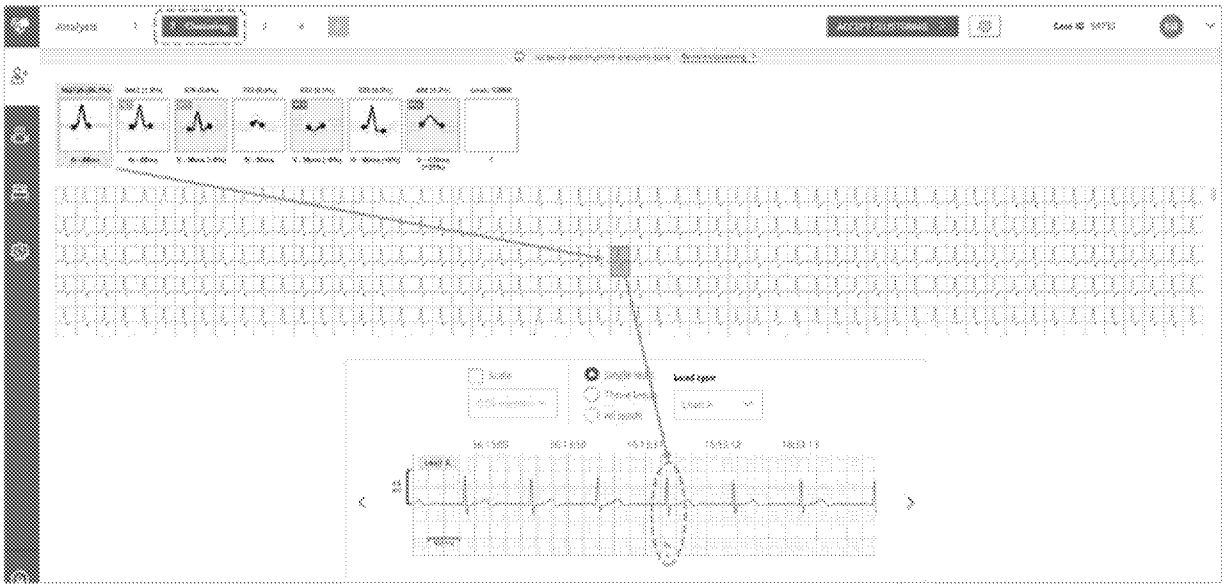
The first heartbeat of the recording belonging to this group will be highlighted on the top of the full disclosure ECG view and on the enlarged rhythm strip. Heartbeats are sorted by how similar they are to the template of the clusters where they belong, rather than chronologically.



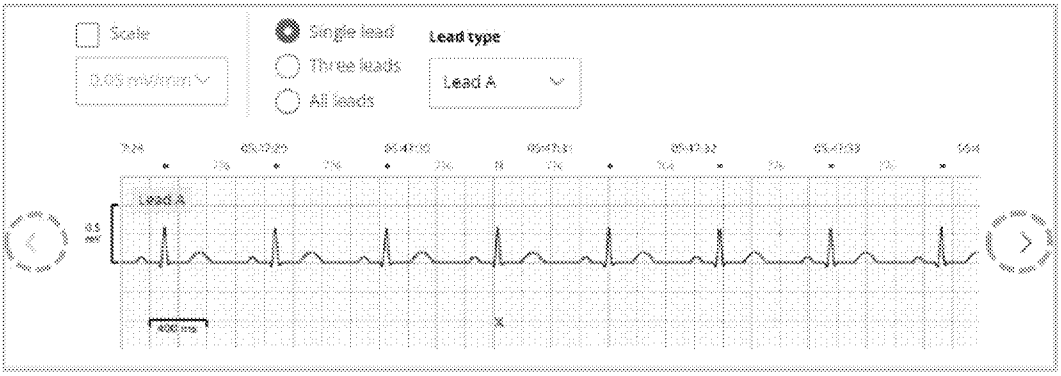
There are multiple ways to inspect the heartbeats belonging to a selected heartbeat cluster:

- Select the cluster to review
  - In the cluster screen, continue clicking on the selected heartbeat cluster to see each heartbeat in the ECG full disclosure and ECG preview strip
  - In the full disclosure ECG view (All complexes belonging to the cluster are displayed in the full disclosure view)
    - Click on any point to display that period of time in the rhythm strip view
    - Use the scroll bar on the right side of the screen to move through the ECG complexes

    NOTE: The beat highlighted in red on the full disclosure view is shown on the rhythm strip with the QRS complex beat annotation about the center of the strip.

OR

- On the rhythm strip, use the right/left arrow keys to move forward or go back in time



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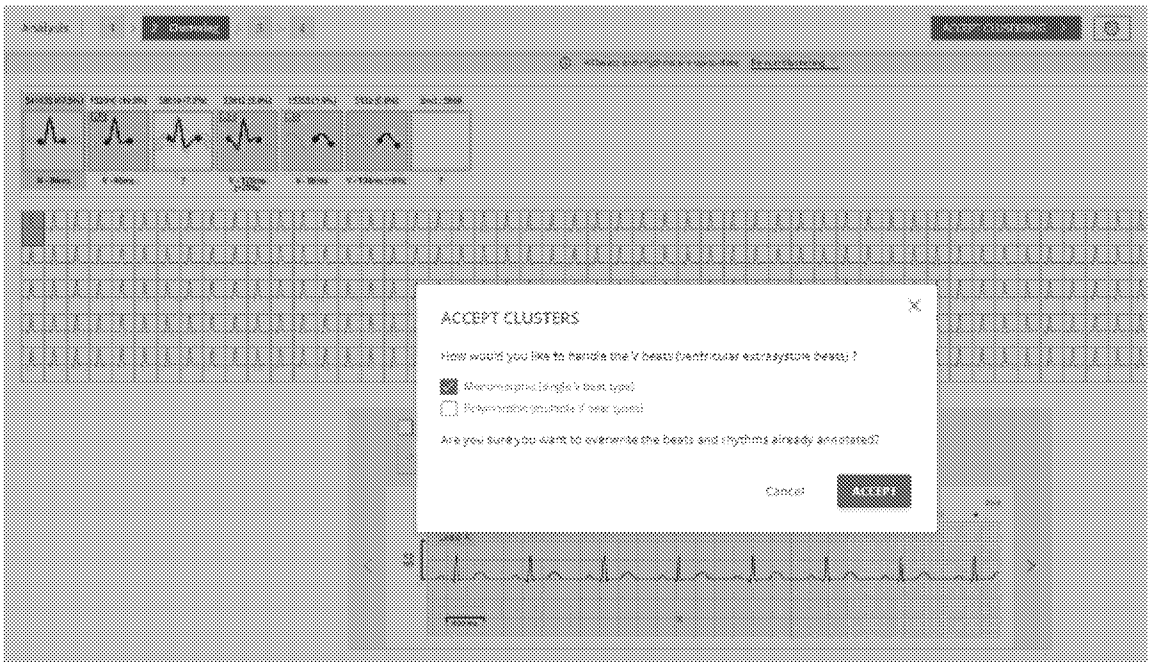
Accept Clustering

Select “ACCEPT CLUSTERING”.

In the “pop up” box, ACCEPT CLUSTERS choose how to handle the V beats (ventricular extrasystole beats)

- Monomorphic single (V beat type)- classify all V beats into one category/cluster
- Polymorphic multiple (V beat type)- classify V beats into more than one category/cluster



Step 3 Report selection

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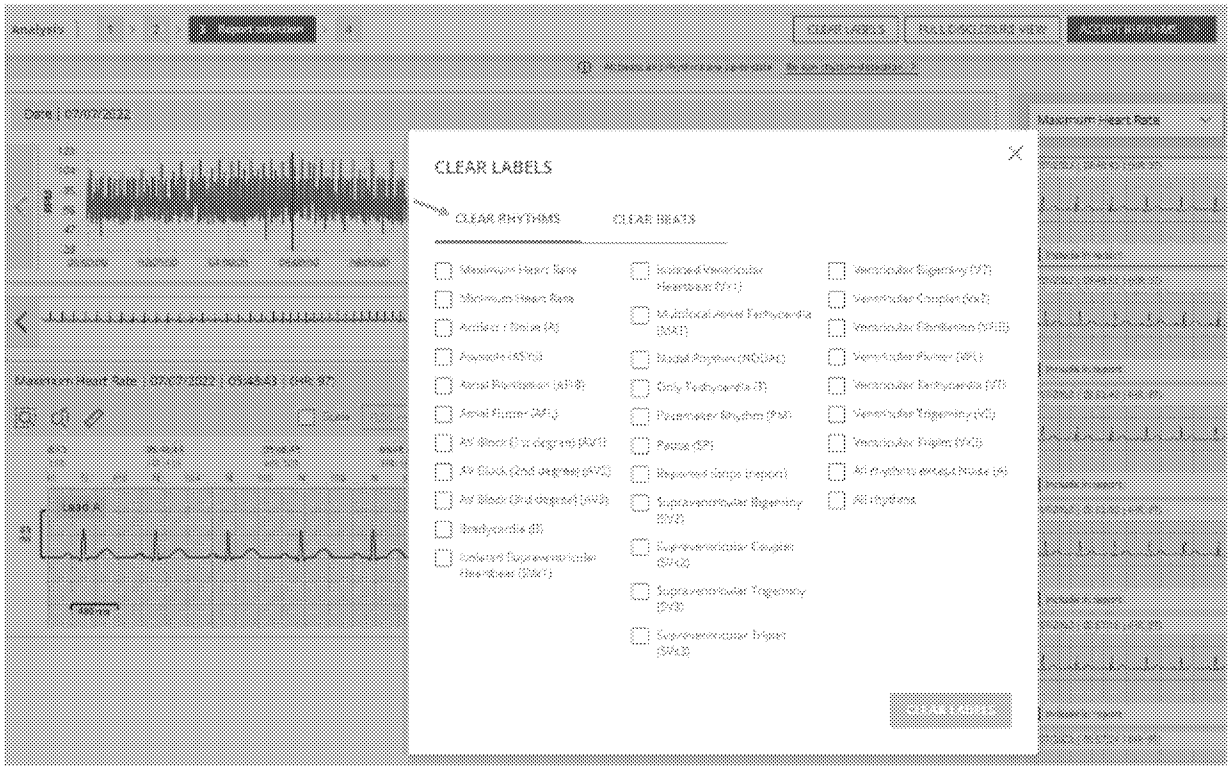
Rhythm detection can be repeated if needed. Select “Re-run rhythm detection” in the top middle of the screen.

Labels for rhythms and beats can be cleared by selecting “CLEAR LABELS” in the upper right corner.

In the pop-up box, select the item to delete which will be shaded in blue, then select “CLEAR LABELS”

CLEAR RHYTHMS



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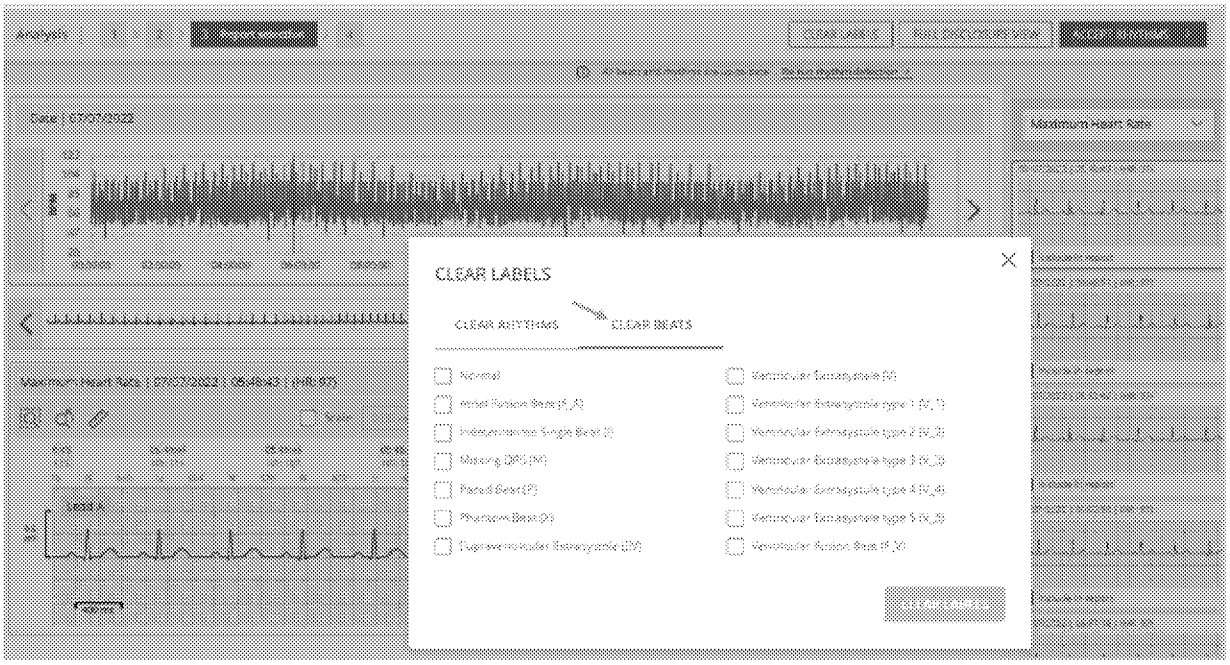
CLEAR BEATS



To view all available rhythms, use the scroll bar on the right side of the screen. In the various rhythm categories, there may be additional rhythms to view.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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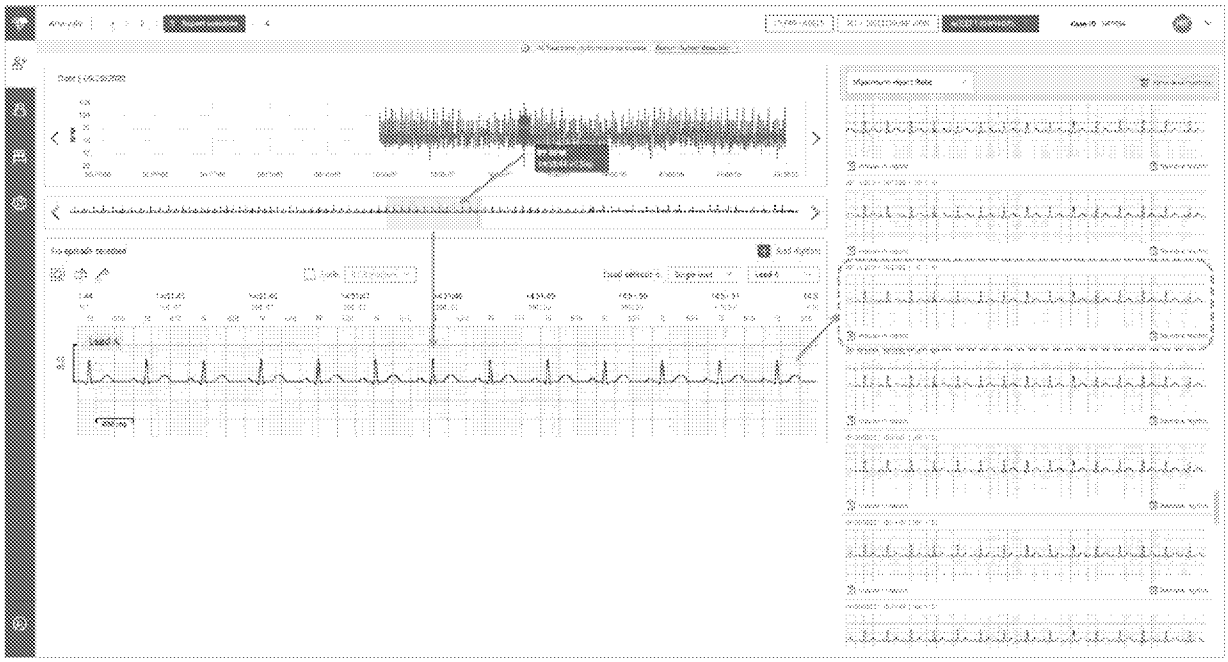

All rhythm strips can be removed from the report by selecting “Remove all rhythms”. Individual rhythm strips can be included or removed from the report using “Include in report” or “Remove rhythm”.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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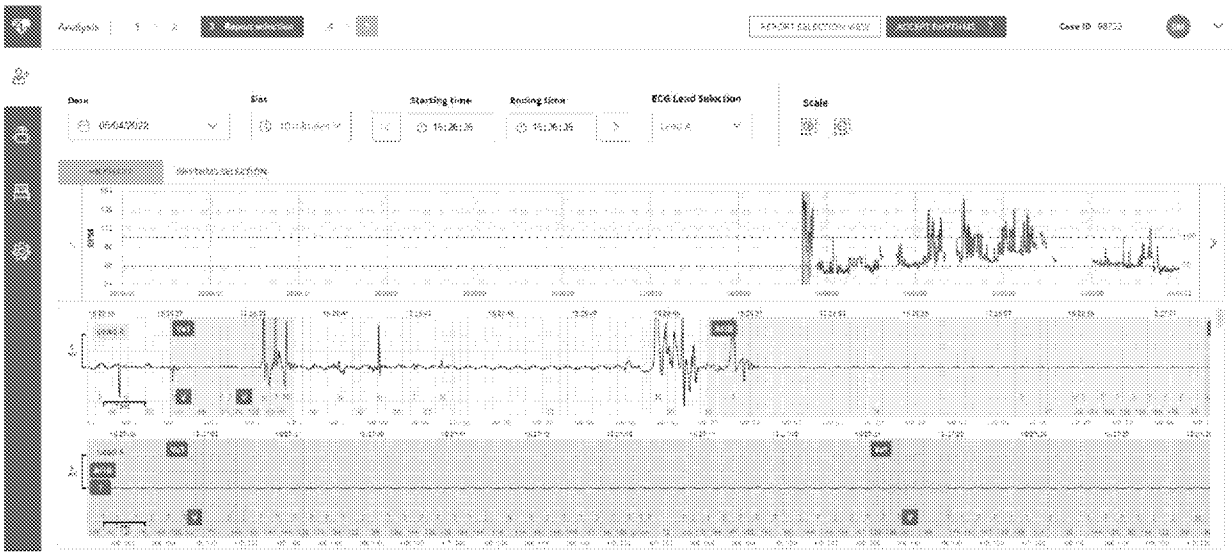
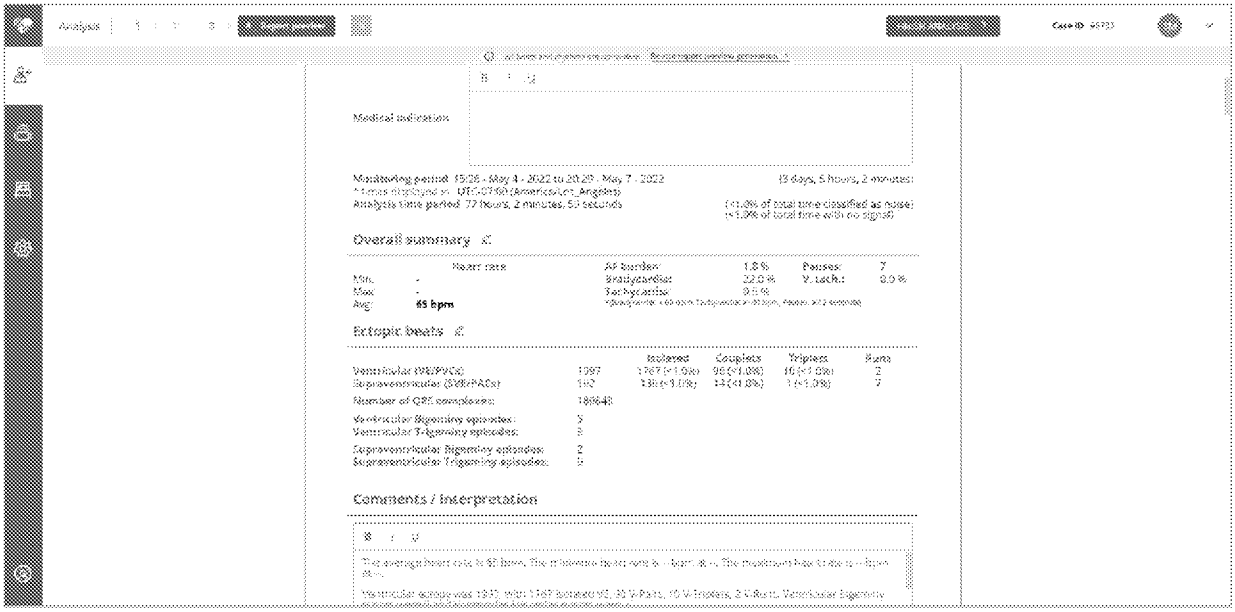
Full Disclosure View



When finished with review, select “ACCEPT RHYTHMS”

Step 4 Report preview

- The report is displayed, and you can scroll through all pages to review.
- Select “FINISH ANALYSIS”



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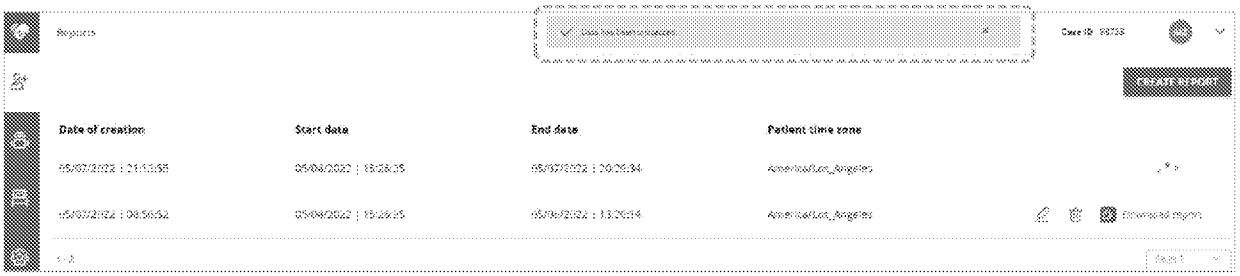
Step 5 Finished



Holter Report Preparation- Rapid Processing

Select “START RAPID PROCESSING” to begin analysis.

Using Rapid Processing skips user interaction in Step 2 Clustering-Beat clustering analysis and takes you directly to Step 3 Report selection.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ.STATUS@fda.hhs.gov or 301-796-8118

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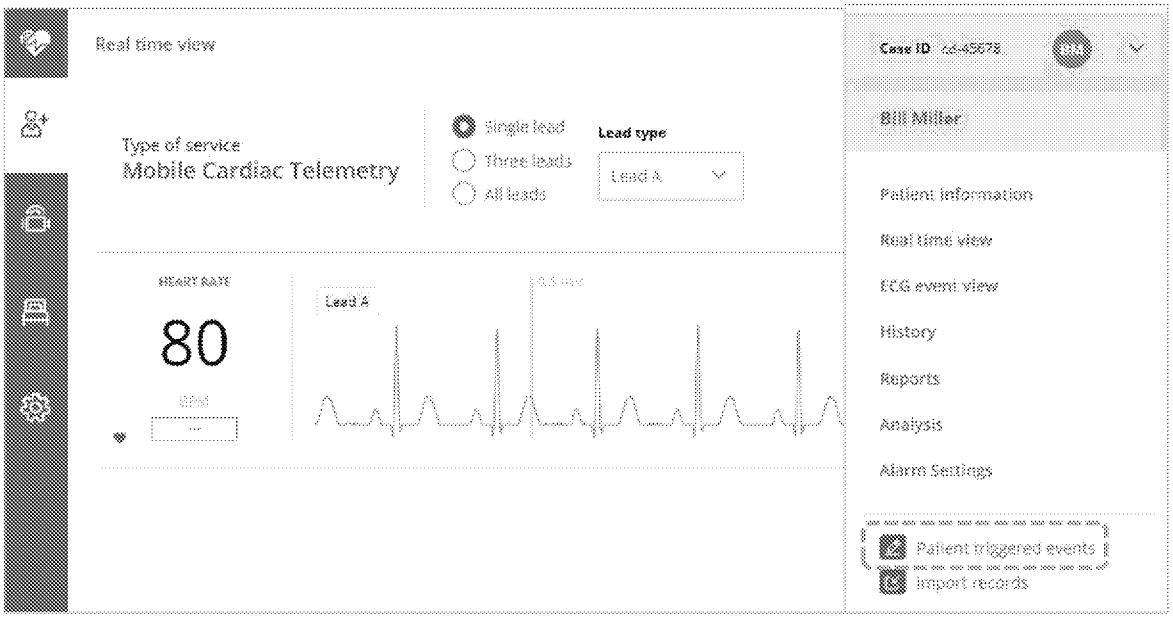
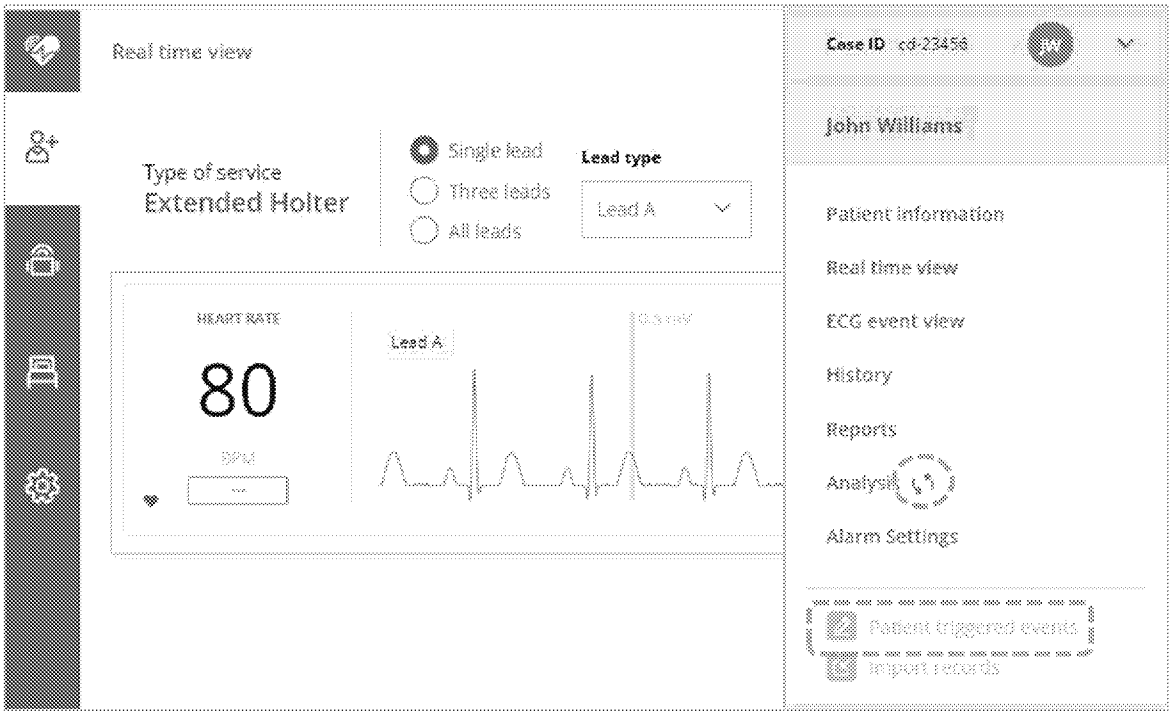
Patient Triggered Events

Patient triggered events can be reviewed from any individual patient page options (Patient information, Real time view, ECG event view, History, Reports, Analysis, and Alarm Settings).



If Analysis is in process “Patient triggered events” is not available and shaded in grey.



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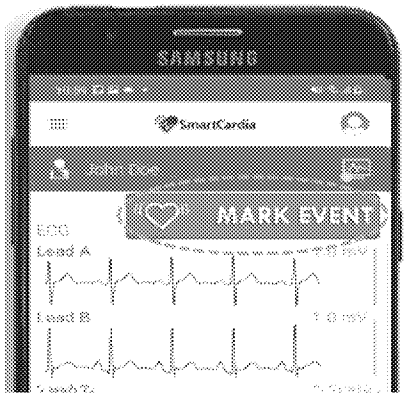
Patient triggered events can be added to the list by the patient or clinician

- The patient can select "MARK EVENT" on the SmartCardia *Phone* and select:
  - event duration
  - symptoms occurring

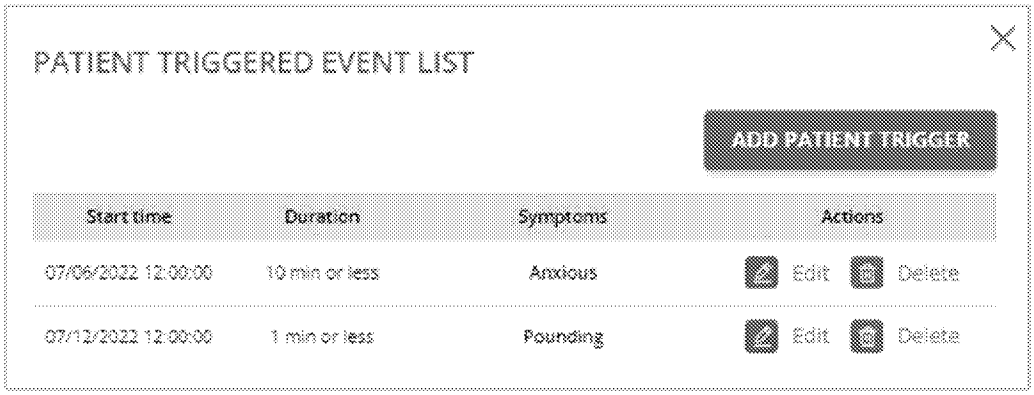


7L Web Browser

- This triggered event is automatically listed in "ACCEPTED EVENTS" in ECG event view
- All triggered events appear in the report

- Clinicians can manually add the patient triggered event information as shown in the two different patient triggered events list screens below

  - If the patient has triggered events, the event time, duration, and symptoms are listed. Triggered events on this event list can be edited or deleted.



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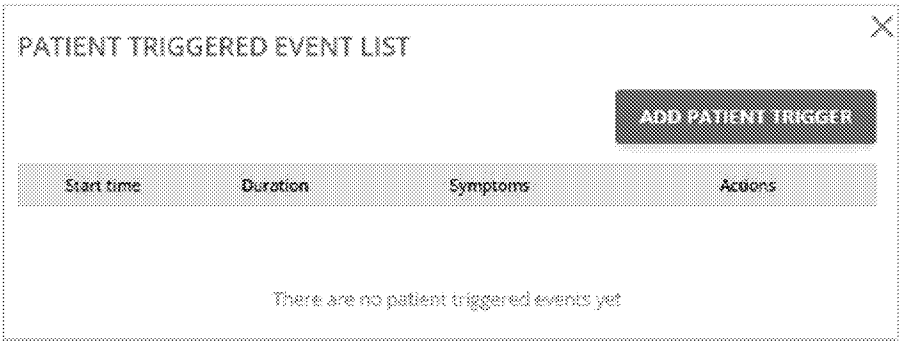
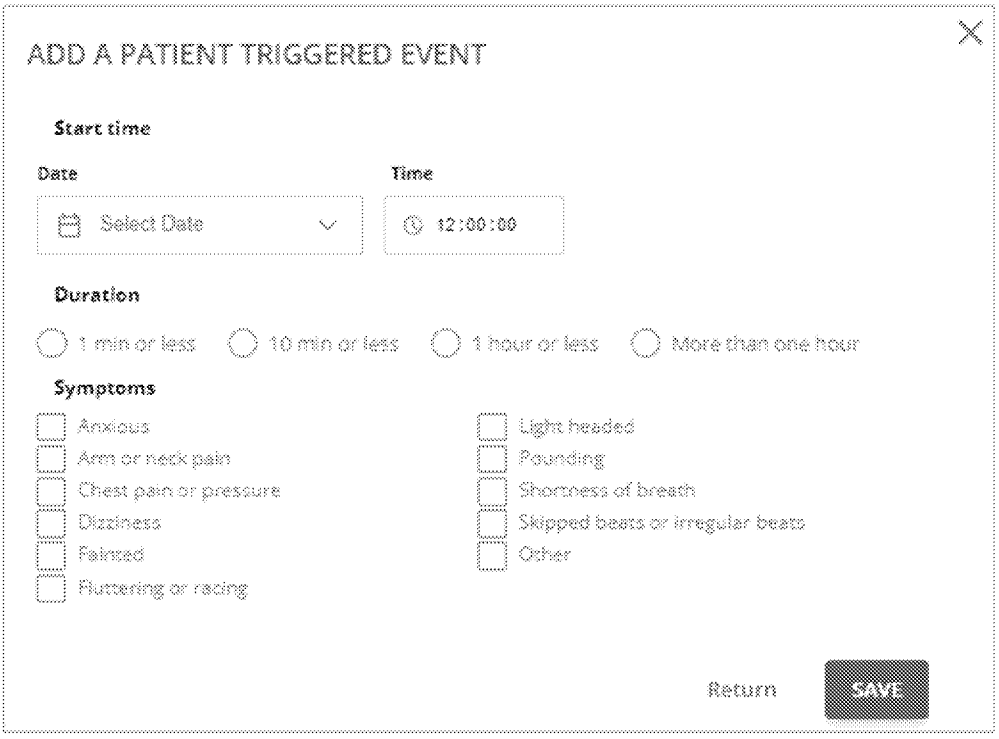
- If this patient has not marked any events or none have been added by the clinician, the list will be empty with the message “There are no patient triggered events yet”.



In both above situations if there are no patient triggered events yet or if events are listed, patient triggered events can be added.

Select “ADD PATIENT TRIGGER”

Enter all event information. Once the information is complete select “SAVE” and the event will be added to the list of triggered events for the patient.



Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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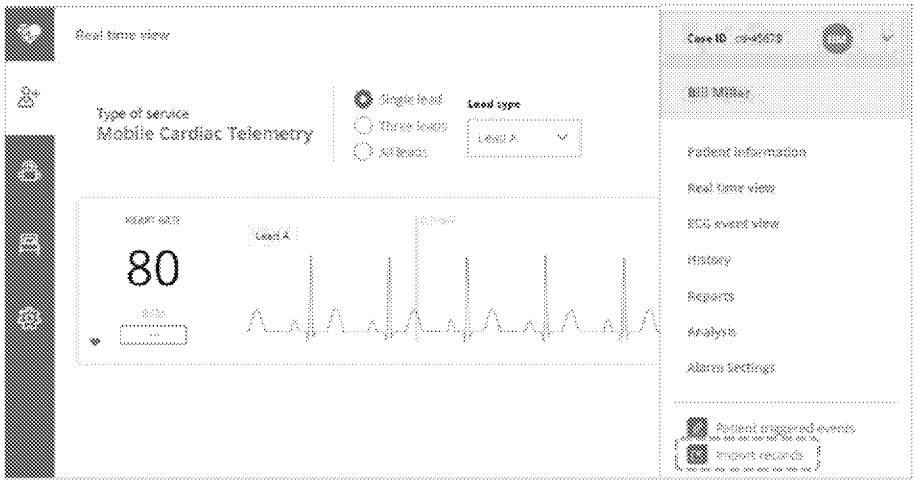
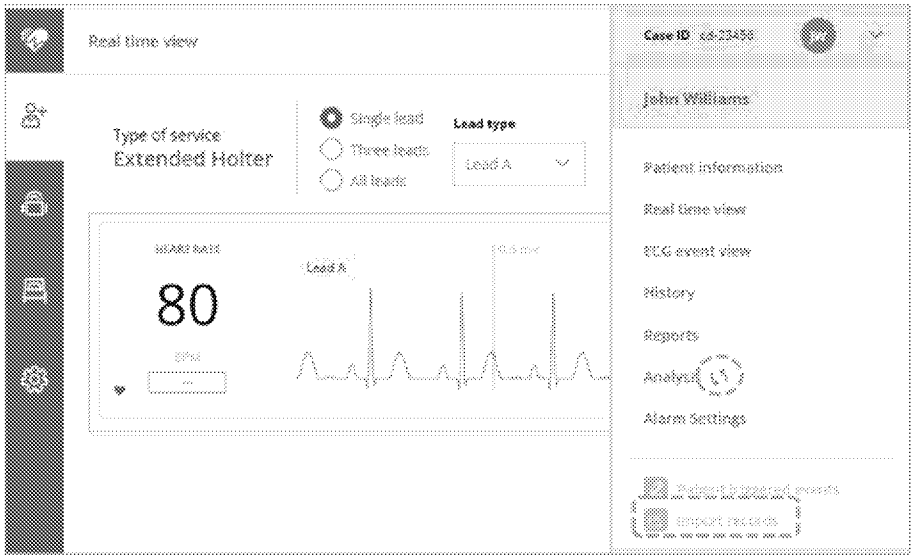
Import records

Import records can be done from any individual patient pages (Patient information, Real time view, ECG event view, History, Reports, Analysis, and Alarm Settings). Patient data can be added or combined with a record that already exists.



If Analysis is in process “Import records” is not available and shaded in grey.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118
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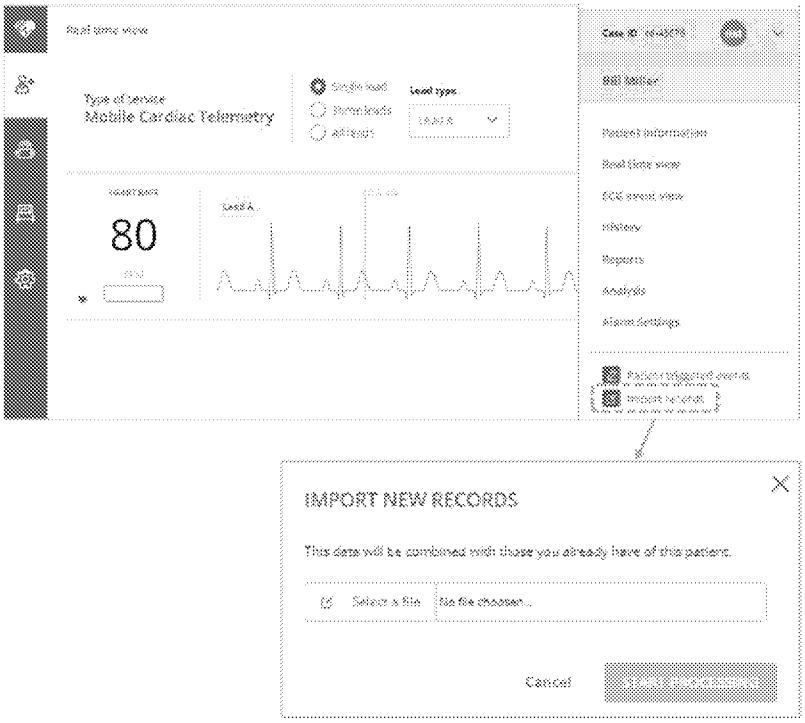
Select “Import records”



Click on the “Select a file” button to search for the file to add. **The file must have the extension “.sc”.** If a file is selected that does not have that extension, an error message is displayed.

Once the file is chosen, the file will begin uploading. The green line and digital information show the progress of the file upload.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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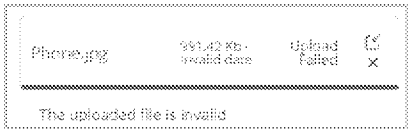
Steps when uploading the data file:

- Error
  A red message means there was an error in the operation with the message: “Upload Failed. The uploaded file is invalid.”
  NOTE: check file name and extension for correct format (.sc) See page 110.



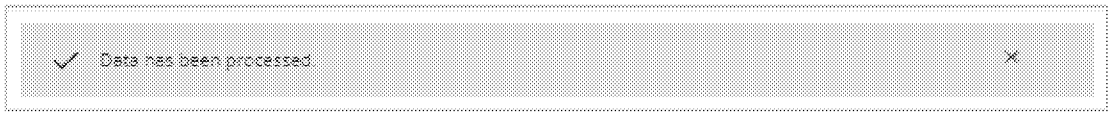
- Once upload is complete, record saved (name of record, file size/date/time, and complete with the option to delete) is displayed
- Select “START PROCESSING” Now ready to import additional new records

- In process

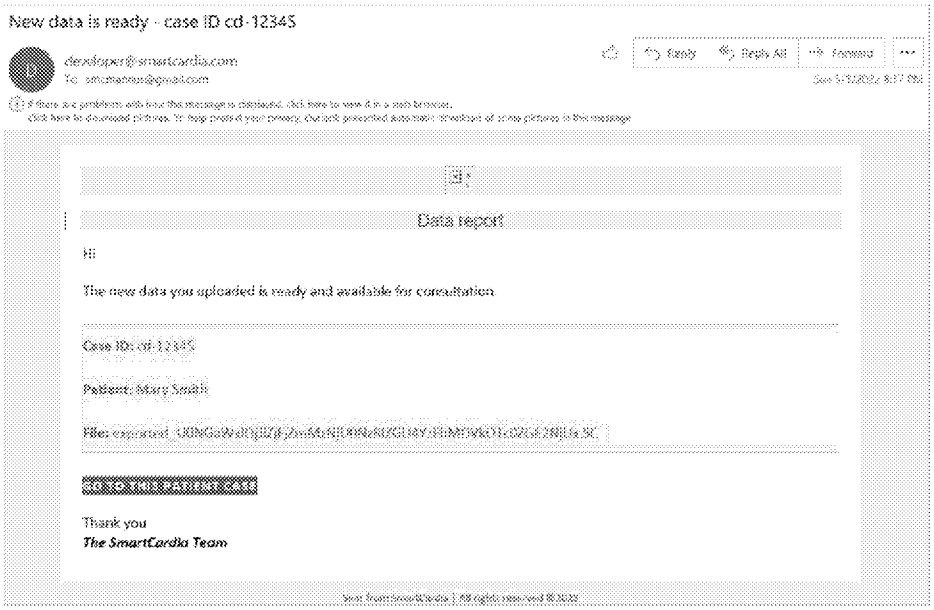
  The message in blue text, “Processing new data. Feel free to continue using the platform” indicates the operation is in process

- Successful import of record

  The message “Data has been processed” In the green box means the operation is successful



An email is sent to the clinician with notification the new data file is ready for import.



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Manage Devices

The Devices section of the *7L Web Browser* provides two functionalities for the clinician. They include review and editing the list of devices and to add a device.

List of Devices

This list has all *7L Sensors* currently in use or available to use for a new patient.

List of devices

The search bar allows the user to search for a device by MAC address or device name.

The following information is displayed and can be sorted:

- MAC address of the *7L Sensor*
- Name of the device
- Date of the last association with the patient
- Patient name which the device is assigned

Identification of the device location on the chest of the patient

The “Edit” button is used to change the name or MAC address of the *7L Sensor*

The “Delete” button removes the *7L Sensor* from the list of devices (only available for devices that are not assigned to a patient).

Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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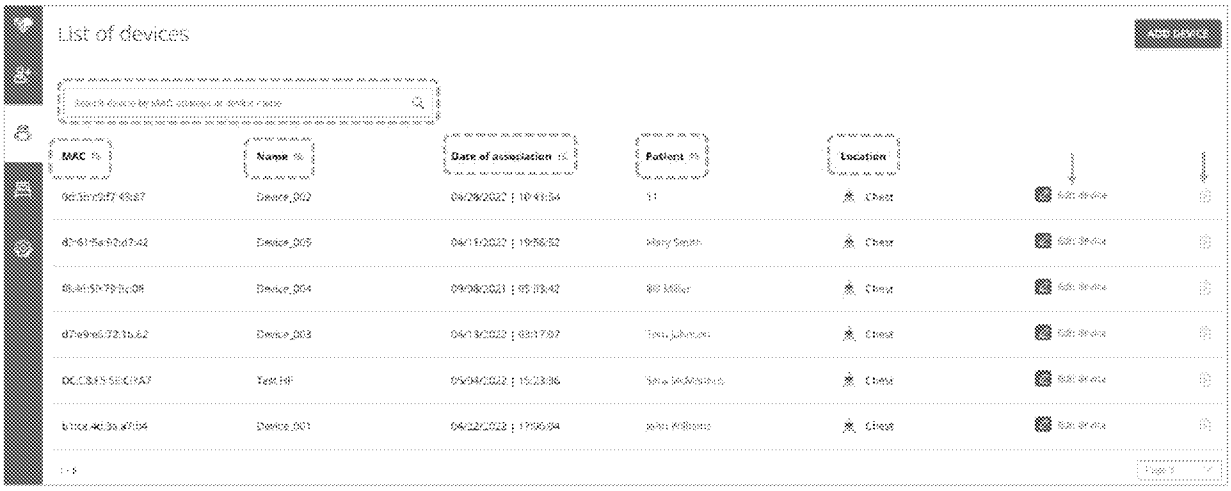
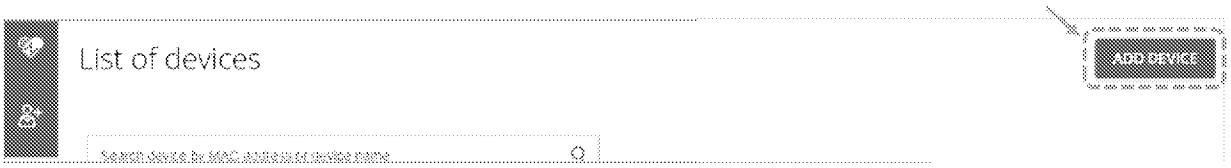


NOTE: To remove or add an association between a *7L Sensor* and a patient, the user must go the patient information page. Easily get there by selecting the patient's name on the list, select patient information and select "Assigned Devices" then "Unassign device" or "Assign device".

Add a New Device

If a new *7L Sensor* (device) needs to be added to the SmartCardia 7L Platform use the following process. Each *7L Sensor* has a unique MAC address that will be added along with the device name designated by your practice. For example, the device name could be CD01, CD02, etc.



Select the "ADD DEVICE" button in the upper right corner.

- Type the name for the new *7L Sensor* device (must not currently exist)
- Enter the MAC address that is found on the surface of the *7L Sensor* that is inserted into the *7L Patch*
- Select "SAVE"
- A notification is displayed with the message "Device added"
- The new device is now added to the list of devices and available for patient use

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Discontinuation of Monitoring

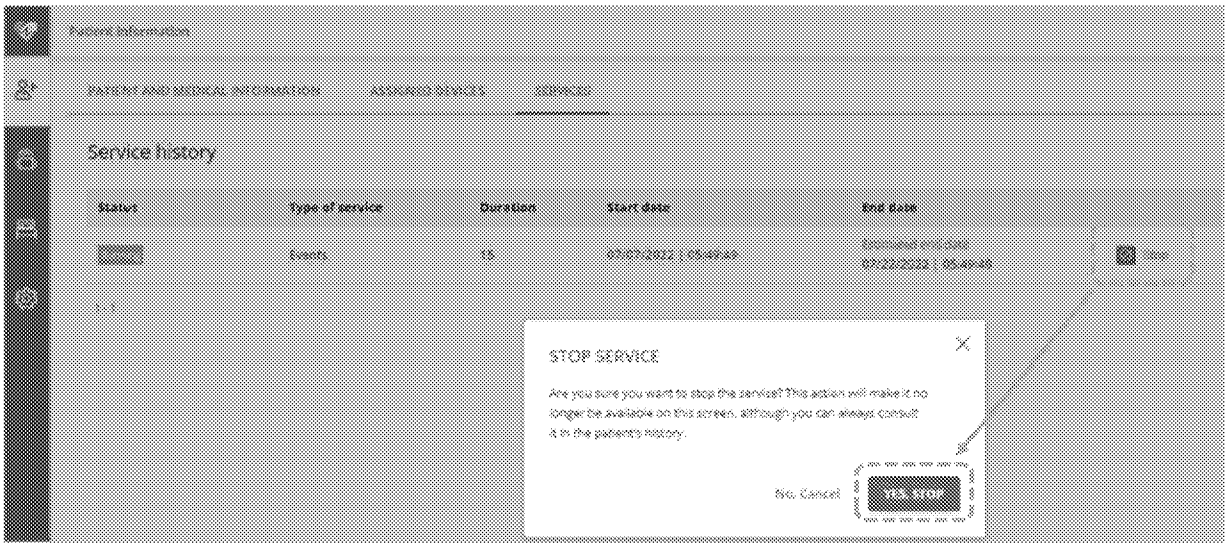
At the conclusion of the monitoring service, the patient returns the SmartCardia *7L Sensor*, *Phone*, and medical grade charger using the pre-addressed, pre-paid mailing envelope for reprocessing.

Follow the process of your practice to review, analyze, and prepare patient reports.

On the patient information page, select “SERVICES” tab.

Under Service history, for the current running service, select “Stop”.

In the confirmation pop-up box, select “YES, STOP”



The confirmation message, “Type of service has been stopped” is briefly displayed on the screen and status shows “Finished”.

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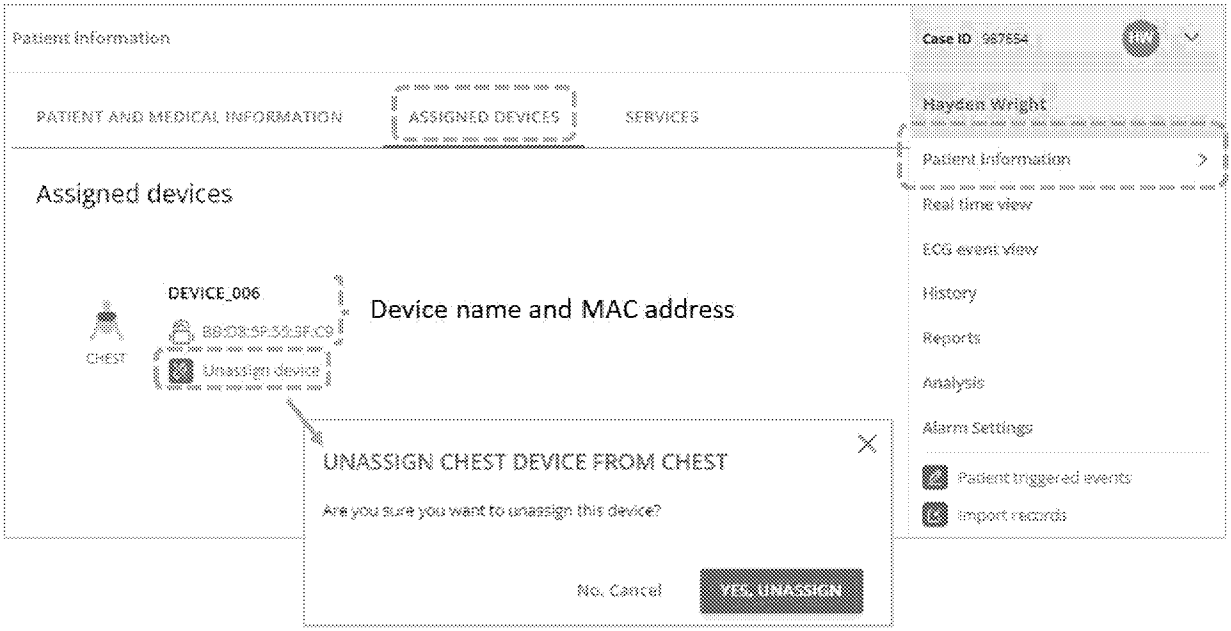
Next step is to unassign device.

On the patient information page, select “ASSIGNED DEVICES”, then select “Unassign device”.

In the pop-up box select “YES, UNASSIGN” to stop monitoring the patient.



A notification message is posted that the device was unassigned successfully.

NOTE: Monitoring is stopped for the patient. All patient information, data, and reports remain available in the practice data base.

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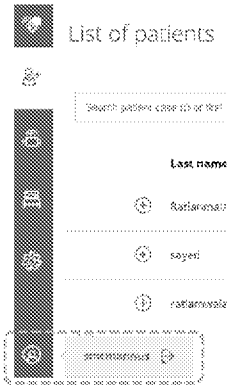
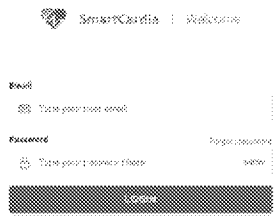
Clinician Logout

The last image of the main left navigation menu is the clinician logout option.



When “Logout” is selected the application closes and the SmartCardia Welcome LOGIN screen is displayed.



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Troubleshooting

7L Sensor, 7L Patch, and SmartCardia Phone

Problem	Cause	Correction
When logging into the SmartCardia *Phone* an error occurs	Unknown	Contact SmartCardia Customer Support
Problem	**Cause**	**Correction**
Related to the Bluetooth-ECG does not display on SmartCardia *Phone*	• *7L Patch* battery is low • *SmartCardia Phone is too far away from 7L Patch*	Always use new *7L Patch* (batteries are part of the *7L Patch*)
Problem	**Cause**	**Correction**
SmartCardia *Phone* is not connected to the SmartCardia backend server	• SmartCardia *Phone* lost its cellular connection or is out of range of cellular communication	Make sure the SmartCardia *Phone* has good cellular signal strength. Move location if necessary

7L Web Browser

Problem	Cause	Correction
Unable to login using the clinician's credentials (email and password)	• Clinician's account is not activated • Clinician's email is not correct • Clinician's password is not correct	Contact SmartCardia Customer Support team to: • Activate the account • Update the clinician's email • Set a new password
Problem	**Cause**	**Correction**
Invalid web certificate *7L Web Browser* says site is insecure, web certificate is invalid	The *7L Web Browser* has cached the old certificate	Remove the browser cache and reload the page

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Viewing Clinical Data

Problem	Cause	Correction
Missing functionality- Some of platform functions are not working properly. Artifacts are presented, problems with style, etc.	• User is not using supported Google Chrome browser (version 93 or higher) • Web browser has cached the old code	• Use Google Chrome version 93 or higher (do not use beta or alpha releases) • Remove browser cache and reload page
Problem	**Cause**	**Correction**
Real-time signals are not shown on clinical data page	• Patient is not connected to the server • Patient does not have the *7L Patch* on their chest	• Make sure the patient is connected and sending data to server • Confirm Bluetooth is activated on SmartCardia *Phone* • Verify no error is displayed on SmartCardia Mobile application • Put *7L Patch* on chest
Problem	**Cause**	**Correction**
Signal amplitude is too small, and signal cannot be visualized properly	Poorly positioned *7L Patch* High Body Mass Index (BMI)	• Reposition *7L Patch* • Manually change scale to smaller one so signal display will be higher amplitude
Problem	**Cause**	**Correction**
Text labels and controls overlap or appear partially	Screen size is too small, or resolution is too low	• *7L Web Browser* was designed to run in a system with minimum resolution of 1024x768 pixels • Use higher resolution in Operating System or use larger screen
Problem	**Cause**	**Correction**
Real-time signals are not shown on multi-patient view	Patient does not have the *7L Patch* on the chest	Put *7L Patch* on chest

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Reports

Problem	Cause	Correction
The generation of the reports never finishes	The server is processing other user's reports	Wait a few minutes until the server finishes processing the rest of the reports
Problem	**Cause**	**Correction**
Unable to download a PDF report	The browser is blocking the file downloads browser allows the file downloads	• Verify the report is being downloaded to a write-allowed location • Try to download the report to another location
Problem	**Cause**	**Correction**
Unable to open a PDF report	• PDF document is corrupted • User is trying to open document using a non-PDF reader application	• Open PDF report using PDF reader, like Adobe Acrobat Reader

Files

Problem	Cause	Correction
Unable to save a file	User does not have necessary write permissions	Make sure user has proper permissions to write to file and access directory where file is stored
Problem	**Cause**	**Correction**
Unable to upload a data file	The file does not have the extension ".sc". If a file is selected that does not have that extension, an error message is displayed.	Check file name and extension for correct format (.sc)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118
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Patient Use

Problem	Cause	Correction
Contact between skin and *7L Patch*- Quality of ECG signal is poor	• Skin was not cleaned well or *7L Patch* isn't attached correctly • Out-of-date *7L Patch* was used and no longer works well	Clean skin, clip or shave hair if needed, and attach new *7L Patch*
Problem	**Cause**	**Correction**
Quality of ECG signal is poor	Amplitude of ECG wave is small in Lead A, which is difficult for analysis	Reposition or replace *7L Patch*

We are here to help

Customer Support (800) 363-8151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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System Administrator Set-up for the Organization

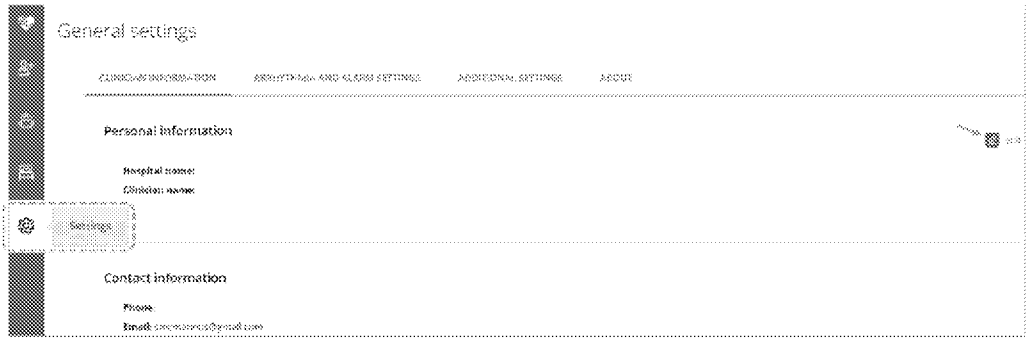
Initial Set-up for Clinician First Use

Registration of Clinicians on SmartCardia 7L Platform

- Contact SmartCardia Customer Support (800) 363-8151 to register clinicians to use the 7L Platform
- Viewing and report privileges for each clinician will be established

Settings

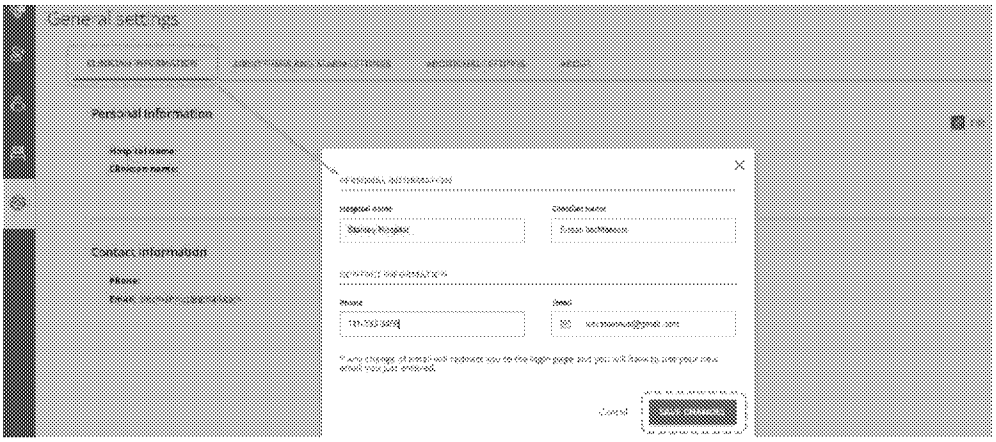
The administrator for each practice facility can edit the system general settings for their organization. On the left menu select the gear icon to access “Settings”.



Clinician Information

- Select the “Clinician Information” tab to edit clinician personal and contact information
- Select “Edit” on right side to make changes to hospital name, clinician name and phone
- Enter required information - Hospital name, Clinician name, and Phone. Email will be already entered. (Any change of email will redirect you to the login page and you will have to use your new email you just entered)
- Select “Save Changes” or “Cancel”

NOTE: To add new clinician, contact SmartCardia customer support at 800-363-8151



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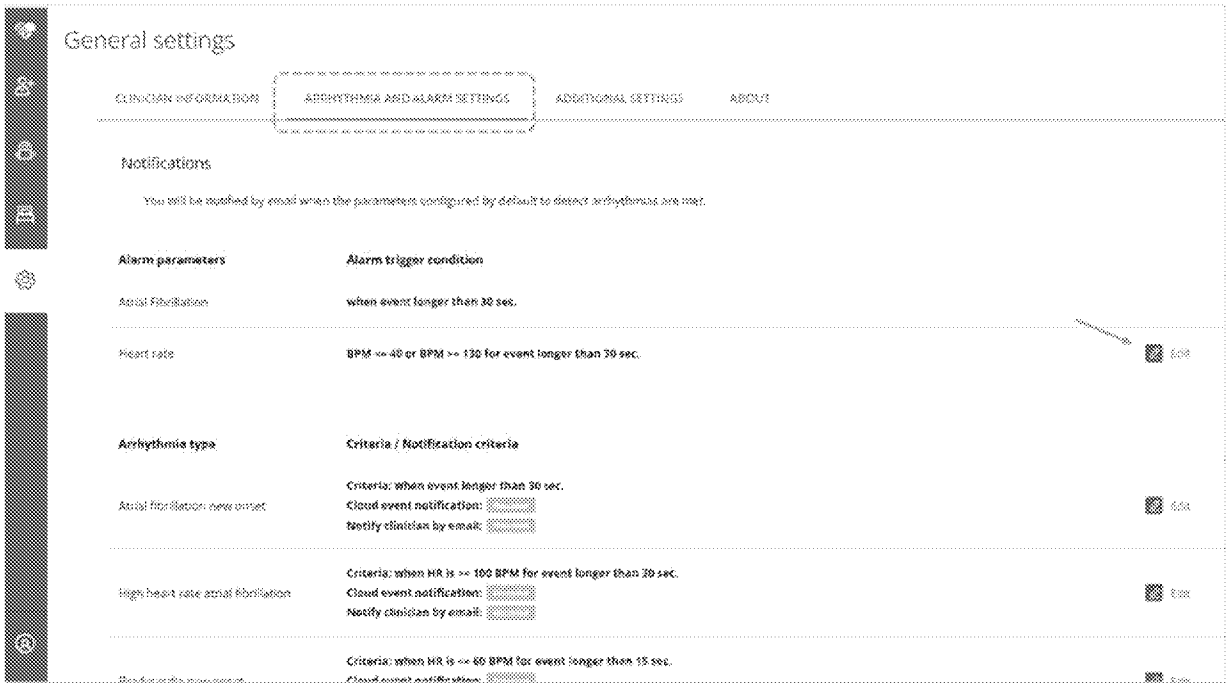
Configure Default Alarm and Arrhythmia Event Notification Settings for Organization

Alarms and arrhythmia event notifications are pre-set by the manufacturer and can be modified to meet the practice requirements. It is important to review settings and modify these to meet the practice requirements of the organization.

NOTE: Alarms and event notifications can be customized for individual patients based on their clinical condition and provider orders.

To set the hospital/practice alarm and notification settings:

- Select the "Arrhythmia and Alarm Settings" tab to adjust alarm, notification, and report settings
- See Alarms and Alarm Management page 35 and Arrhythmia Event Notification page 38 for detailed information



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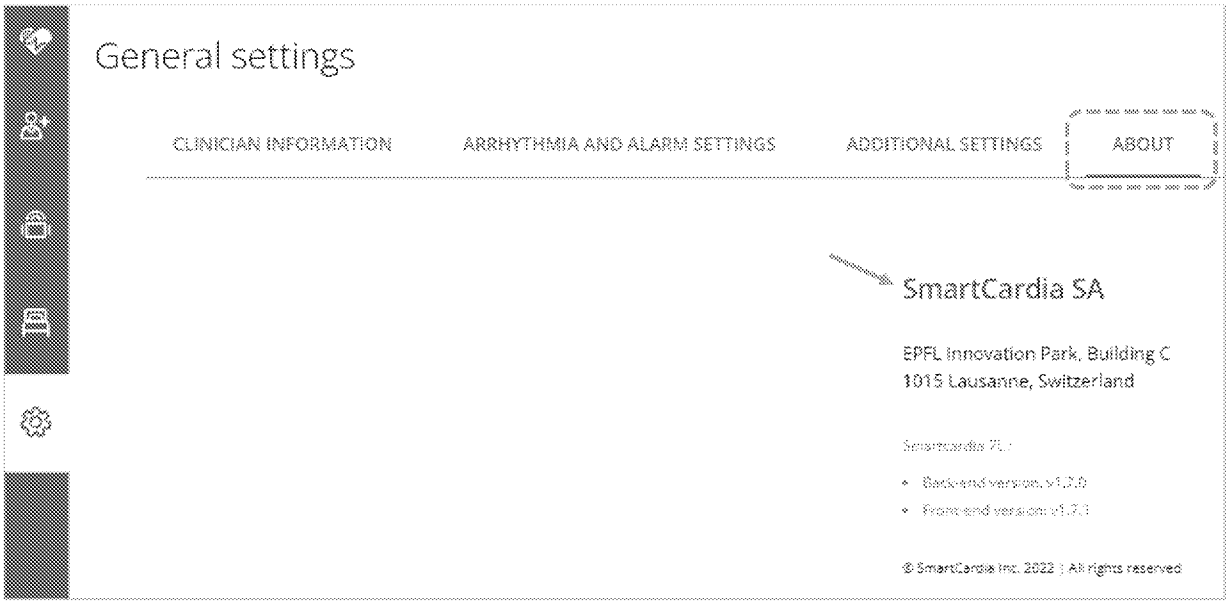
About

The About section provides SmartCardia SA corporate address and software version information.



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Product Specifications

Physical and Environmental

Physical and Environmental	
Size	7L Sensor: 1.97 x 1.18 x .39 inch; (50 x 30 x 10mm) 7L Patch (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14mm)
Weight	7L Sensor and 7L Patch: Less than 3.52oz. (100 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C)
	Operating: +41 to +104°F (+5 to + 45°C)
Humidity	Storage and transport: relative humidity up to 90%, non-condensing
	Operating: 10 to 95% at +41 to 95°F (+5 to +35°C) (non-condensing) / 700 – 1060 hPa
Safety	Type BF
Water Ingress	IPX7 (waterproof)
Battery Life	Up to 14 days, depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30 - 200	Beats per Minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Manufacturer Default Alarm Settings			
Parameter	Low Limit	High Limit	Alarm Delay
Heart Rate	40	130	0 seconds
Atrial Fibrillation	When event is longer than 30 sec.		NA

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Parameters

Body Measurements	Shown As	Range	Units	Accuracy	Comment
Heart Rate	HR	30 - 200	Beats per minute (BPM)	± 3 BPM	HR is computed every 2.048 seconds and the displayed value is updated every 2.048 seconds as the average of the last 6 beat-to-beat intervals
Atrial Fibrillation	AF	N/A	N/A	N/A	Computed every 10 seconds using last 30 seconds of ECG data

ECG Arrhythmia Definitions

Arrhythmia Definitions	
Normal Sinus Rhythm	Normal rhythm of the heart, originating in the sinoatrial (SA) node with a regular rhythm and heart rate of 60-100 beats per minute (BPM)
Bradycardia	Regular rhythm and heart rate below 60 BPM
Tachycardia	Regular rhythm and heart rate more than 100 BPM
Sinus Pause	SA node does not discharge an impulse for ≥ 2 seconds
Supraventricular Bigeminy	Every other beat is a premature supraventricular contraction
Supraventricular Trigeminy	Every other beat is a premature supraventricular contraction
Supraventricular Couplet	Two consecutive premature supraventricular beats
Supraventricular Triplet	Three consecutive premature supraventricular beats
Multi-focal Atrial Tachycardia (MAT)	Atrial tachycardia (heart rate greater than 100) originating in three or more different atrial ectopic pacemaker sites, P waves differ in size, shape, and direction
Nodal Rhythm	Regular rhythm arising from the atrioventricular (AV) node typically the QRS complexes are narrow
Atrial Fibrillation	Absence of P waves, with disorganized electrical activity in their place, and irregular R–R intervals due to irregular conduction of impulses to the ventricles.
Atrial Flutter	Absence of P waves, presence of characteristic "flutter waves". Individual flutter waves may be symmetrical, resembling p-waves, or maybe asymmetrical with a "sawtooth" shape.

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Ventricular Bigeminy	Every other beat is a premature ventricular contraction
Ventricular Trigeminy	Every third beat is a premature ventricular contraction
Ventricular Couplet	Two consecutive premature ventricular beats
Ventricular Triplet	Three consecutive premature ventricular beats
Ventricular Tachycardia	Originates in an ectopic pacemaker in the ventricles characterized as a wide complex (QRS duration greater than 120 milliseconds) and heart rate greater than 100 BPM
Monomorphic Ventricular Beat	QRS morphology is the same from beat to beat
Polymorphic Ventricular Beat	QRS morphology changes from beat to beat
Ventricular Flutter	Sinusoidal waveform without clear definition of QRS and T waves with loss of organized electrical activity with a rate over 250-350 BPM
Ventricular Fibrillation	Arrhythmia originating in multiple ectopic pacemakers in ventricles characterized by many fibrillatory waves and no QRS complexes
Asystole	Absence of any contractions
AV Block (First degree)	All normal P waves are followed by QRS complexes, but the PR interval is longer than normal (> 0.20 seconds)
AV Block (Second degree)	Some normal P waves are followed by QRS complexes, but some are not. Type I- PR interval progressively lengthens with each beat until atrial impulse is not conducted and QRS complex is dropped, AV nodal conduction resumes with next beat, and the sequence is repeated. Type II- PR interval remains constant with beats intermittently not conducted and QRS complexes dropped
AV Block (Third degree)	No relationship between P waves and QRS complexes (AV dissociation) the P wave rate is greater than the QRS rate
Pacemaker Rhythm	Arrythmia produced by an artificial pacemaker

Definitions from public source domain

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Attachment A: Alarm System Disclosures

Alarm System Description

The SmartCardia 7L Platform is a Distributed Information System (DIS) that communicates alarm conditions in real time for Heart Rate and Atrial Fibrillation. It provides alarm signals at a remote location but does not contain a mechanism for confirmation of receipt of the alarm signal.

	WARNING: The alarm system in the SmartCardia 7L Platform is a distributed information system and cannot be relied upon to indicate the clinician has received the alarm signals as there is no feedback mechanism for the clinician to acknowledge such receipt.

Alarm Conditions

The SmartCardia 7L Platform provides alarm signals for heart rate (upper and lower threshold violations) and Atrial Fibrillation. In addition, there are information signals for battery charge level and wireless communication status.

Alarm System Delay

The SmartCardia 7L Platform measures the ECG of a patient through a body worn sensor/patch (the source). The ECG waveform and heart rate are communicated via Bluetooth wireless communication to the SmartCardia Phone (the integrator) which acts as a gateway to the SmartCardia cloud-based backend server (the communicator). Alarm signals are communicated when the heart rate exceeds the alarm limit threshold (either upper or lower) or Atrial Fibrillation is detected for more than 30 seconds.

Delays from the 7L Sensor to the SmartCardia Phone to the SmartCardia backend and for presentation on the web browser are shown in Table 1. These were measured using a simulated signal and applying the alarm condition (High or Low HR, or Atrial Fibrillation) to the 7L Sensor and measuring the delay time to see the condition on the SmartCardia Phone, on the SmartCardia Backend server, and resultant display of the alarm signal on the SmartCardia Web Browser.

Table 1. Alarm Signal Delay

7L Sensor to SmartCardia Phone	SmartCardia Phone to SmartCardia Backend	SmartCardia Backend Server to Display on the SmartCardia Web Browser	Total Alarm Signal Delay (seconds)
Up to 100 msec.	Up to 1 sec.	User selectable 0, 4, 8 sec.	Based on user selection up to 9.1 sec.

Alarm signal delay is a user choice to reduce false alarm signals due to artifact or momentary violations of limit settings. Follow clinical practice guidelines for your institution when

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selecting an alarm delay. If no delay is desired, set to "0" and the alarm system delay will be approximately 1.1 seconds. However, this may result in multiple false alarm signals so take caution when making this selection.

Alarm System Presets

The SmartCardia 7L Platform contains one alarm preset for heart rate. This is set by the manufacturer to a lower heart rate value of 40 and an upper heart rate value of 130, either condition lasting longer than the user selectable alarm delay time of 0, 4, 8 seconds. The delay preset is at 0 seconds. . These alarm preset values are configured by the manufacturer and cannot be permanently modified.

These alarm preset values can only be changed by an operator with authorized credentials (username and password login) to ensure proper monitoring for a patient's clinical condition. These settings are automatically selected upon admitting a new patient.

Alarm Settings

In the event of a power failure or loss of power, whether momentarily or for up to 30 seconds, the alarm settings are not affected as these are stored in the SmartCardia cloud-based server. When power is restored to the viewing web browser computer, the alarm settings remain as they were prior to the power loss.

The SmartCardia 7L Platform does not continuously display the alarm limit settings but these are displayed through operation action by selecting "Patient Alarm Settings".
The SmartCardia 7L Platform does not incorporate "Intelligent Alarm System" as defined in the IEC 60601-1-8 standard, nor does it provide automatic setting of alarm limits. Customized alarm limit settings must be done through manual operator action.

To check the alarm system functionality, manually set an alarm limit below or above the current heart rate. The visual and auditory alarm signals should be present after the selected delay time.

Alarm Sounds

The SmartCardia 7L Platform provides alarm signals for heart rate (upper and lower threshold violations) and Atrial Fibrillation. Table 2 shows the alarm condition, alarm priority, alarm signal, and sound presented. The sound level is operator adjusted only, the SmartCardia 7L Platform does not incorporate dynamically algorithm-adjusted sound levels. The SmartCardia 7L Platform does not incorporate reminder signals as defined in the IEC 60601-8 Alarm Standard.

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Table 2. Alarm Signals and Sounds

Alarm Condition	Alarm Priority	Alarm Signal Displayed	Alarm Sound
Heart Rate lower than the low alarm limit setting	High	Patient tile outlined in red, Heart Rate numeric zone backfilled in Red and flashing, Heart Rate numeric in white text	High Priority pointer per IEC 60601-8 standard, Annex G, table G.3
Heart Rate higher than the high alarm limit setting	High	Patient tile outlined in red, Heart Rate numeric zone backfilled in Red and flashing, Heart Rate numeric in white text	High Priority pointer per IEC 60601-8 standard, Annex G, table G.3
Atrial Fibrillation detected for greater than 30 seconds	Medium	AF message displayed below the heart rate when in the single patient data view, below patient name in the multi-patient view. AF message is highlighted in yellow with 'AF' in white text and flashing.	Medium Priority pointer per IEC 60601-8 standard, Annex G, table G.3

The alarm signal auditory sound level is controlled by the speaker volume control on the personal computer that is presenting the SmartCardia *7L Web Browser*. Personal computers have the ability to turn the auditory sound completely OFF (Mute).

	WARNING: Do not try to turn the volume on the personal computer to OFF or Mute. Do not try to adjust the volume to such a low value that auditory alarm signals cannot be heard. The 7L Platform will indicate a waring on the display.

The SmartCardia 7L Platform enables auditory alarm sounds to be turned OFF for an individual patient for five minutes. At the expiration of the five minutes, the audio is turned ON automatically. This inactivation state only impacts the selected patient, other patient's audio remains ON unless they are individually inactivated.

This inactivation state is indicated in the patient tile using the audio off symbol.

Operator Position

For continuous monitoring, the operator should be located from one to four meters from the display of patient data to ensure they can identify alarm signals.

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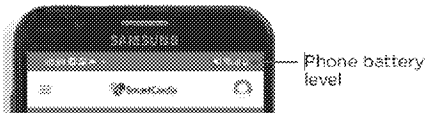
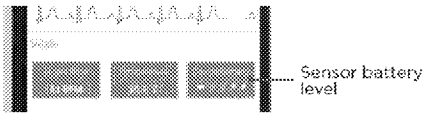
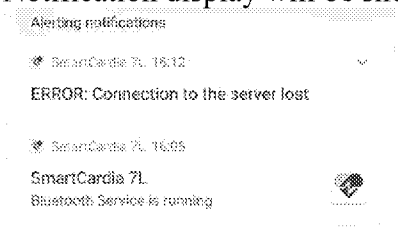
Information Signals

The SmartCardia 7L Platform displays information signals as shown in Table 3.

Table 3. Information Signals

Information Signal	**Meaning**	**Display**	**Sound**
Battery charge level in SmartCardia Phone	Charge level in SmartCardia Phone		Visual indicator
Battery charge level in the SmartCardia 7L Sensor green	Charge level at 100%, 75%, 50% 25%	 100% (4 green dots), 75% (3 green dots), 50% (2 green dots), 25% (1 green dot)	Visual indicator
Battery charge level in the SmartCardia 7L Sensor – red	Charge Level less than 10% remaining		Visual indicator
Bluetooth Connection	Bluetooth not connected between the SmartCardia 7L Sensor and the SmartCardia phone	Bluetooth ON icon located in the upper right of the top bar of the phone disappears, SmartCardia logo appears next to the time. In addition, a red banner "trying to re-connect Please wait" appears on mobile app display	Single notification sound
Cellular Connection	The SmartCardia Phone and the cloud service are not connected	The same SmartCardia logo will appear, and Wi-Fi icon will disappear. If you swipe down from top, the Alerting Notification display will be shown 	Single notification sound

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Alarm System Logging

The SmartCardia 7L Platform logs all alarm related data in a responsible organization log. There is no separate operator alarm system log. The alarm system log can only be accessed by SmartCardia authorized personnel. The alarm log is maintained in the SmartCardia cloud-based backend server. Powering down of the SmartCardia 7L Web Browser instance does not affect the alarm system log. The SmartCardia cloud-based server is maintained by Amazon Web Services and is redundant and automatically backed up. The alarm system will not experience a total loss of power; therefore, the alarm system log is not impacted.

The alarm system log is stored on the SmartCardia cloud-based backend server and has an unlimited capacity. In the event the log reaches maximum capacity, the oldest data stored are deleted and the newest data are saved.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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Attachment B Electromagnetic Compatibility

FCC ID: XOYNINAAB30
Medical electrical equipment can generate or receive electromagnetic energy or interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601-1-2:2020, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2:2015.
Product Essential Performance specified for EMC:

1. The Wireless EEG System shall not change operating modes, settings, or modify stored data during EMC immunity testing.
2. Within 30 s after exposure to transient electromagnetic phenomena, the device shall resume normal operation without operator intervention. The resumption to normal operation shall be without loss of any operator settings or stored data

Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to and when using the product.
Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of electrical medical equipment. If this device does cause harmful interference to other devices, you may need to do one of the following:
• Reorient or relocate the other device,
• Move the devices farther apart,
• Contact the device manufacturer for assistance.
Your service provider for RF communications equipment may have a minimum recommended separation distance between that equipment and the product.
Compliance is only claimed for sensors and accessories that are listed in documentation accompanying the product.

Warnings and Cautions

- The use of accessories, sensors, and cables other than those specified in the technical and user documentation can result in increased electromagnetic emissions or decreased immunity of the product.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Short-range radio communication is subject to interruption that may be caused by interference from other radio sources in the vicinity. This can include microwaves (microwave ovens), other Bluetooth devices, and cellular phones. Outside of the operating frequency and 5% above and below is the exclusion band according to IEC

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60601-1-2. The short-range radio connection is immune up to 10 V/m in the frequency range from 80MHz to 2.7 GHz. If the strength and duration of the radio interference is strong, the interruption may occur for an extended period.

- Always inspect the product before use. If the product appears damaged or out of sorts, do not use.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The SmartCardia 7L Platform is equipped with a wireless communication interface and intentionally receives RF electromagnetic energy for the purpose of its operation. Therefore, other equipment may cause interference, even if that other equipment complies with CISPR emission requirements.
- These guidelines may not apply in all situations. Electromagnetic energy is affected by the type of structures, objects, and people in the vicinity of the product.
- The SmartCardia 7L Platform should not be used in an aircraft.

To Reduce Electromagnetic Interference

The SmartCardia System and associated accessories can be susceptible to interference from other RF energy sources and continuous, repetitive, power line bursts.

Examples of other sources of RF interference are other medical electrical devices, cellular phone products, information technology equipment, microwave ovens, and radio/television transmission. If interference is encountered, as demonstrated by excessive artifact on the ECG or a sudden and dramatic change in measurement values, you should attempt to locate the source.

• Is the interference due to a misplaced or poorly applied SmartCardia 7L Sensor/7L Patch? If this is the case, check the installation to ensure it is properly installed or positioned and located correctly per the user instructions.

• Does the interference come and go or is it always present?

• Does the interference happen only when the SmartCardia 7L Sensor/7L Patch is in a specific place?

• Does the interference occur only when the SmartCardia 7L Sensor/7L Patch are near other medical or electrical equipment?

The first thing to do when the interference source is located is to reduce the interference as much as possible by moving as far from the source as possible. Do this prior to contacting your service representative to ensure you have taken necessary precautions.

Restrictions for Use

Artifact on ECG and other physiological waveforms caused by electromagnetic interference should be evaluated by a physician or physician-authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

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The SmartCardia 7L Platform environment of use is in a physician office, outpatient facility, or in the patient's home.

Electromagnetic Compatibility (EMC) Specifications
Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your equipment according to the EMC information provided in this manual. Portable and mobile radiofrequency (RF) communications equipment can affect medical electrical equipment.
Accessories Compliant with EMC Standards
Only accessories listed as accessories for the SmartCardia system comply, with the requirements of IEC 60601-1-2:2014.

Electromagnetic Emissions
Specification
The SmartCardia 7L Platform uses Bluetooth LE version 5 and includes an RF transmitter for Bluetooth Low Energy that transmits data in the 2.4 GHz frequency band (2.400 to 2.4835GHz)
using data rates of 2 Mbps

Guidance and manufacturers declaration – electromagnetic emissions		
The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Avoiding Electromagnetic Interference**
Radio Frequency (RF) emissions	Group 1	The SmartCardia System uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SmartCardia System is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Not Applicable	Device is powered by disposable battery only
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not Applicable	Device is powered by disposable battery only

Electromagnetic Immunity

Guidance and manufacturers declaration – electromagnetic immunity

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The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Comments**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ±8kV, ±15kV air	± 8 kV contact ± 2kV, ± 4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC61000-4-4 EFT/burst immunity	± 2 kV, 100 kHz burst frequency, coupling duration ≥ 60s, positive and negative polarity	± 2 kV, 100 kHz burst frequency, coupling duration ≥ 60s, positive and negative polarity	
IEC61000-4-5 Surge Immunity	± 0.5 kV, ± 1 kV differential mode source impedance, positive and negative polarity, phase angle at 0°, 90°, 180°, 270°, 60 sec repetition rate, 5 surges at each position	± 0.5 kV, ± 1 kV differential mode source impedance, positive and negative polarity, phase angle at 0°, 90°, 180°, 270°, 60 sec repetition rate, 5 surges at each position	AC Power Line Cable, unshielded, active status, 0.3 m in length
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz 60 s each axis (X, Y, Z)	30 A/m 50 Hz or 60 Hz 60 s each axis (X, Y, Z)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, home, and/or healthcare environment
IEC61000-4-11 Voltage dips	100% dip; 0.5 period, phase angle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 3 interruptions, 15s repetition	100% dip; 0.5 period, phase angle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 3 interruptions, 15s repetition	

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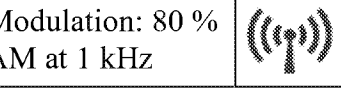
	100% dip; 1 period, phase angle at 180°, 3 interruptions, 15s repetition	100% dip; 1 period, phase angle at 180°, 3 interruptions, 15s repetition	
	30% dip; 30 periods (60 Hz), 180°, 3 interruptions, 15s repetition	30% dip; 30 periods (60 Hz), 180°, 3 interruptions, 15s repetition	
	100% dip; 300 periods (60 Hz), 180°, 3 interruptions, 15s repetition	100% dip; 300 periods (60 Hz), 180°, 3 interruptions, 15s repetition	
IEC61000-4-39 Immunity - Proximity Magnetic Fields	30 kHz, CW Modulation, 5 cm distance, 8 A/m	30 kHz, CW Modulation, 5 cm distance, 8 A/m	
	134.2 kHz, PM Modulation, 5 cm distance, 65 A/m	134.2 kHz, PM Modulation, 5 cm distance, 65 A/m	
	13.56 MHz, PM Modulation, 5 cm distance, 7.5 A/m	13.56 MHz, PM Modulation, 5 cm distance, 7.5 A/m	

Guidance and manufacturers declaration – RF Immunity

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform may use it in such an environment.

Immunity Test	**Immunity Test Levels**	**Compliance Levels**	**Electromagnetic Environment Guidance**
IEC 61000-4-6 Conducted Disturbances, Induced by RF Fields AC Power Line Cable, unshielded, active status, 0.3 m in length	3 Vrms 0.15 MHz – 80 MHz, 6 Vrms in ISM bands between 0.15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	3 Vrms 0.15 MHz – 80 MHz, 6 Vrms in ISM bands between 0.15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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IEC 61000-4-3 Radiated RF	10 V/m, Antenna Separation 2.5 m, 80 MHz – 1000 MHz, 1.0 GHz - 2.7 GHz, 80 % AM modulation at 1 kHz, 1% frequency step @ 3s dwell time	10 V/m, Antenna Separation 2.5 m, 80 MHz – 1000 MHz, 1.0 GHz - 2.7 GHz, 80 % AM modulation at 1 kHz, 1% frequency step @ 3s dwell time	
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartCardia 7L Platform is used exceeds the applicable RF compliance level above, the SmartCardia 7L Platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended Separation Distances

Guidance and manufacturers declaration – recommended separation distances between portable and mobile RF communications equipment and the SmartCardia 7L Platform

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter - W	**Separation distance according to frequency of transmitter m**		

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	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2√P	**d = 1.2√P**	**d = 2.3√P**
	Minimum Separation distance	**Minimum Separation distance**	**Minimum Separation distance**
0.01 W	0.1 m	0.1 m	0.2 m
0.1 W	0.4 m	0.4 m	0.7 m
1 W	1.2 m	1.3 m	2.3 m
10 W	3.8 m	3.8 m	7.3 m
100 W	12.0 m	12.0 m	23.0 m
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).			

Portable and mobile RF communications equipment should be used no closer to any part of the SmartCardia System, than these recommended separation distances that are calculated from the equation appropriate for the frequency of the transmission.

Enclosure Port Immunity

Guidance and manufacturers declaration – Proximity Fields from RF Wireless Communications Equipment

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.

Band (MHz)	Test frequency (Mhz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test level (V/m)
380 – 390	385	Pulse modulation 18 Hz	1.8	0.3	27
430 – 470	450	Pulse modulation 18 Hz	2	0.3	28
704 – 787	710	Pulse modulation 217 Hz	0.2	0.3	9
	745	Pulse modulation 217 Hz	0.2	0.3	9
	780	Pulse modulation 217 Hz	0.2	0.3	9
800 – 960	810	Pulse modulation 18 Hz	2.0	0.3	28

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	870	Pulse modulation 18 Hz	2.0	0.3	28
	930	Pulse modulation 18 Hz	2.0	0.3	28
1700 – 1990	1720	Pulse modulation 217 Hz	2.0	0.3	28
	1845	Pulse modulation 217 Hz	2.0	0.3	28
	1970	Pulse modulation 217 Hz	2.0	0.3	28
2400 – 2570	2450	Pulse modulation 217 Hz	2.0	0.3	28
5100 – 5800	5240	Pulse modulation 217 Hz	0.2	0.3	9
	5500	Pulse modulation 217 Hz	0.2	0.3	9
	5785	Pulse modulation 217 Hz	0.2	0.3	9

Note:

1. For some services, only the uplink frequencies are included.
2. The carrier shall be modulated using a 50% duty cycle square wave signal.
3. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case

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Attachment C: Wireless Communications Specifications

The SmartCardia 7L Platform consists of two wireless links: a Bluetooth link between the 7L Sensor and the SmartCardia smartphone and a cellular link between the SmartCardia smartphone and the internet.

Link	Standard	Frequency	Power output / modulation
BLE link between sensor and phone	IEEE 802.15.4 Bluetooth V 5.0	2.4 Ghz Gaussian	8 dBm Frequency spread spectrum with PSK modulation Gaussian frequency shift
Cellular link between phone and server	Cellular network	746-757 MHz & 776-787 MHz	up to 3 Watts 4G. CDMA-less B2/B3/B4/B5/B7/B12/B13/B20/B66

Operating characteristics:

BLE link

The BLE link is preconfigured by SmartCardia at the time of manufacturing. BLE version 4.0 or greater is implemented. The link is configured such that only SmartCardia sensors will be recognized by the SmartCardia smartphone. No other BL or BLE devices will be recognized. The operating range is within 3 meters. The patient IFU includes a note to keep the 7L Sensor within 10 ft. of the smartphone at all times. Quality of Service and Cybersecurity requirements are managed through the configuration of the sensor and phone by authorized SmartCardia personnel. All data originating in the phone is encrypted at rest and during transport.

Cellular phone link

The cellular phone link is determined by the phone platform, the Samsung Galaxy A12 Smartphone. The phone is configured by SmartCardia authorized personnel and placed in a kiosk mode. The SmartCardia phone hosts no other applications other than the SmartCardia application. The audio telephone operation is disabled. The phone UI includes a cellular signal strength bar. When connectivity is lost the signal strength bar indicated no bars and a notification message is sent to the clinician viewer. When connectivity is restored all data (up to 14 days) stored in the sensor and phone are forwarded to the SmartCardia Server. Quality of Service requirements are managed by SmartCardia when the phone is configured in the kiosk mode. The cellular link is unburdened by all other cellular data allowing only SmartCardia packets to communicate with the SmartCardia server.

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Network Access

Network access is managed only by authorized SmartCardia personnel. All devices are preconfigured during the provisioning process. Users have no access to network administrative functions.

Warnings and Cautions regarding wireless links

Warnings and cautions associated with wireless communications are found in the patient IFU, Clinician IFU and the EMC section of this IFU.

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Attachment D: Cybersecurity Disclosure

SmartCardia is certified to ISO 27001; 2013 Information technology- Security techniques- Information security management systems- Requirements. As continued post-market activities, SmartCardia conducts an annual audit to this standard.

SmartCardia employs a risk-based approach per the ISO 14971 standard to design and develop products with the appropriate cybersecurity protections for the intended use. Hazards are identified early in the project development lifecycle and updated at each phase of development to ensure existing risks are mitigated and any new risk are identified and addressed prior to commercialization. This process ensures the proper maintenance and continuity of device safety and essential performance as well as the continued safety and effectiveness.

The SmartCardia 7L Platform cybersecurity includes:

- **Identification and Protection of Device Assets and Functionality**
    - The SC System is designed to protect assets and functionality to reduce risk of multi-patient harm due to the loss of authenticity, availability, integrity, and confidentiality. Protection mechanisms are established that prevents all unauthorized use (through all interfaces) to ensure code, data, and execution integrity (subversion of system functionality/safety/security features) and protect confidentiality of data (insofar as its release could be leveraged) to effect multi-patient harm.
    - Appropriate protections are in place regarding the SC System that prevents sensitive information from being read by unauthorized parties either in storage or in transmission through the following (Encryption is used)
- **Limit Access to Trusted Users & Devices Only**
    - Access to the SC System is through the authentication of users via:
        - Email and password (for clinicians).
        - Device MAC and patient's date of birth (for patients)
    - Automated time methods will be used to terminate sessions when appropriate.
- **Passwords will be unique for each user and no public access will be given.**
    - During new patient provisioning, a device is assigned to the patient and a monitoring service is configured. The new patient will receive a kit with a device and a phone, with the SmartCardia app already installed. The patient will login using the device MAC and his/her date of birth. This identifies the patient and the specific sensor(s) connected to the mobile App. This authentication is encrypted and stored in an isolated repository with no public access.
    - Administrative access is controlled by a unique Name and Password.

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Cybersecurity Bills of Material (CBOM)

Manufacturer	Manufacturer Reference	Revision	Purpose
Google	Android	10	Mobile Gateway to cloud based server
	com.android.support:support-V4	v4:27.1.1	Support Library
	com.android.support:support-V13	V13:27.1.1	Support Library
	com.android.volley:volley:1.1.0	1.1.0	HTTP request Library
	com.rabbitmq:amqp-client:	4.6.0	AMQP Client for publish/subscribe
	org.greenrobot:eventbus:	3.1	Event bus for inter-module communications
	com.andrognito.flashbar:flashbar:	1.0.3	Customizable alert and notification Library
Google	Chrome Web Browser	93	Web browser Operating system
Ubuntu Server	Linux	18.04 LTS	Server Operating System

Cybersecurity - 7L Sensor:

- The sensor is a sealed unit with no external ports published to an end user.
- There are no software of unknown provenance (SOUP) in the sensor firmware.
- All firmware and software are controlled internally with no access allowed by end users.
- The sensor hardware manufacturer is certified to ISO 13485. The software load is only for a minimum number of functions. Cyclic redundancy checks (CRC) ensure uncorrupted load of data.
- Firmware is loaded after the sensor is completely encapsulated with CRC checks to ensure uncorrupted loading. The sensor is not serviceable.
- Firmware updates are performed over the BLE link using BLE DMU profile. An over-the-air update can only be performed under the control of SmartCardia. Updating sensor software requires acknowledgement of a private key embedded in the sensor firmware. This key is known only to trained authorized SmartCardia personnel.
- The BLE link data is encrypted during transport in normal operation.

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Cybersecurity - Mobile Gateway:

- The Android smartphone mobile gateway is configured and provided by SmartCardia authorized personnel.
- The Android OS is placed in kiosk mode with only necessary functions enabled to support the SmartCardia App. The end user is not allowed to add Apps.
- The USB-C port is disabled of all functionality except battery charging.
- WWAN link is encrypted during transport.
- All data stored by the SmartCardia App is encrypted.
- SW updates are performed only by trained authorized SmartCardia personnel over a secure https link.

Cybersecurity - Backend AWS

- The Amazon Web Service instance is configured and managed by SmartCardia authorized personnel.
- The Amazon Web Service is configured with automatic backup service such that the database can be restored as required by authorized SmartCardia personnel.
- Two factor authentication is required by SmartCardia personnel in order to access administrative functions.
- PHI is separated from physiologic data in the AWS database.
- All data is encrypted at rest and in transport.
- AWS provides routine period scans for the detection of intrusion and malware.

Cybersecurity - Remote Viewing Station

- Access to SmartCardia remote viewing is only through a secured browser.
- All communication between the remote viewing station and backend AWS is encrypted over a https link.

Cybersecurity - Notification to User

In the event of a security breach, users are notified by SmartCardia as soon as the breach becomes noticed. The notification method may be via email or other direct communication.

Forensic Investigation

AWS captures and stores forensic evidence for investigation and resolution.

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Attachment E: Reprocessing

Reprovisioning Process

The patient is instructed to return the SmartCardia *7L Sensor*, SmartCardia *Phone*, medical grade charger, and phone cable using the pre-addressed, pre-paid mailing envelope for reprocessing. They should dispose of all unused *7L Patches*.

NOTE: The *7L Sensor* may be returned inside of the used *7L Patch* if there is difficulty removing the *7L Sensor* after use.

The provider organization reprocesses their own patient returned devices or an approved reprocessing center. Both situations follow the same reprocessing steps.

The reprocessing process shall take place at room temperature and humidity on a clean surface that is separated from all other activities.

Individuals performing this process shall be trained and documented in the appropriate training record.

Service life is not adversely impacted by the number of reprocessing cycles.

Receipt of *7L Sensor*, *Phone*, medical grade charger, and phone cable

- Record the date and time they are received for reprocessing.

NOTE: If any unused *7L Patches* are received, discard.

7L Web Browser

- Verify the *7L Sensor* is listed as an available device on the *7L Web Browser* page assigned to the responsible organization. If not, "Unassign" it from the previous patient.

Clean and Disinfect

1. Using protective gloves, inspect the *7L Sensor*, SmartCardia *Phone*, medical grade charger, and phone cable for physical damage including label integrity.

   NOTE: If the used *7L Patch* is returned with the *7L Sensor* still inside, carefully remove the *7L Sensor* and properly dispose of the *7L Patch*.

   NOTE: Do not immerse the *Phone* in water or other liquid.

2. Remove any debris, damaged labels, adhesive, etc. from surfaces with a damp cloth using a mild detergent.
3. Disinfect the *7L Sensor* with PDI Super Sani-Cloth® Germicidal Disposable Wipe for five minutes following the instructions on the package.
4. Wipe Phone with disinfectant wipes per instructions on the disinfectant package.
5. Wipe devices with clean cloth to remove any residual disinfectant.
6. Set devices aside and covered for two minutes with a clean disposable towel to maximize drying time.

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Testing of Components

1. Check if there is any damage on the *7L Sensor* or labels. If you find any damage, stop using it, and contact SmartCardia Customer Support.
2. Insert *7L Sensor* into a test *7L Patch* to verify it works (LED lights turn on)
3. Turn Phone on and test for wireless link. (Verify BLE link between *Phone* and *7L Sensor* is connected)
4. Using the *7L Mobile Application*, scan for the *7L Sensor*
5. Verify the MAC address of the *7L Sensor* is recognized
6. Record testing of *7L Sensor*, MAC address, and *Phone*
7. Store cleaned and disinfected *7L Sensor*, *Phone*, medical grade charger, and phone cable (keep the *7L Sensor* and SmartCardia *Phone* together as they are paired)

Provision 7L Sensor and Phone for new patient admission

1. "Add Patient" on the *7L Web Browser*
2. Enter patient information
3. Select the *7L Sensor* device and *Phone* that are going to be used by the new patient
4. Insert the selected *7L Sensor* into an unused *7L Patch* (confirm LED lights turn on)
5. Turn on the Phone (confirm that it is fully charged)

NOTE: If "Error occurred while logging you in"

- Select CANCEL at the bottom of the screen
- For password, enter 0111, select "OK".
- Scan
- Select S7L with the MAC address of the *7L Sensor* in use
- Once connection successful, select OK to pair *7L Sensor* and *Phone*

Verification *Sensor* and *Phone* are ready to send patient

1. Verify that the *Phone* screen shows Welcome with the new patient's name asking them to enter their date of birth
2. Turn off *Phone* and remove *7L Sensor* from *7L Patch* used for testing

Preparation of SmartCardia Kit for shipping

Insert the following components into the kit box insert

- *7L Sensor placed in sensor box*
- *Phone*, phone cable, and *Phone* instructions placed in phone box
- Medical grade charger

Place on top of the assembled components listed above

- Small envelope for phone return to put into larger pre-addressed, pre-paid mailing envelope for return following monitoring service

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- *7L Patch* (two packages)
- Guide card, “let’s get started assembling and positioning patch”
- Patient User Guide

Reference: ISO 17664-1:2021(E) Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

Software License Agreement and Warranty

Contact SmartCardia Customer Support for information about the software license agreement and warranty.

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UDI	Unique Device Identifier(s) 7L Sensor 7640375610058 7L Patch 7640375610041
	SmartCardia Inc. EPFL Innovation Park, Building C 1015 Lausanne, Switzerland Customer Support: 800-363-8151
REF	PL-08 SmartCardia 7L™ Platform – Patient Guide
	July 15, 2023
Rx ONLY	Prescription Only
	Consult Instructions for Use or User Manual
	Type BF
	See Warnings and Cautions
EC REP	SmartCardia Inc. EPFL Innovation Park, Building C 1015 Lausanne, Switzerland
FCC	This device complies with Part 15 of the FCC Rules. Operation and is subject to the following two conditions. 1. These devices may not cause harmful interference, and 2. These devices must accept any interference received, including interference that may cause undesired operation.
FCC ID:	XPYNINAAB30
	Non-ionizing electromagnetic radiation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118
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· PL-10 SmartCardia 7L Clinician QRG

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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We are here to help 800-363-8151

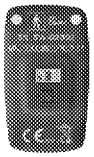
System Description

The SmartCardia 7L™ Platform is a system comprising of a wireless sensor component (the *7L Sensor*), an adhesive patch (the *7L Patch*) that the *7L Sensor* connects to, a mobile component (the SmartCardia *Phone*), and a backend server cloud platform (SmartCardia *7L Web Browser*) used to access the patient data.

SmartCardia *7L Sensor*

A reusable Sensor (NOT Disposable)

- Inserts into *7L Patch*
- Sends patient ECG data to SmartCardia Phone
- Waterproof (IPX7) in *7L Patch*



SmartCardia *7L Patch*

A single-use Patch (Disposable)

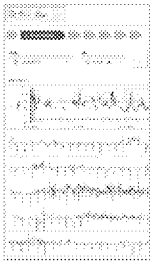
- Includes batteries
- Holds reusable *7L Sensor*
- Medical adhesive to skin on chest

SmartCardia *Phone*

- Mobile gateway for SmartCardia data
- Must always be kept close to SmartCardia *7L Sensor*
- Charge daily (or more often)

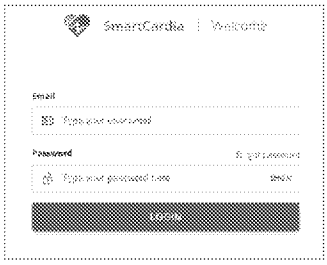
SmartCardia *7L Web Browser*

- Service mode choices (Holter, Extended Holter, Event, Mobile Cardiac Telemetry)
- View patient data, manage alarms, perform Holter analysis, create reports



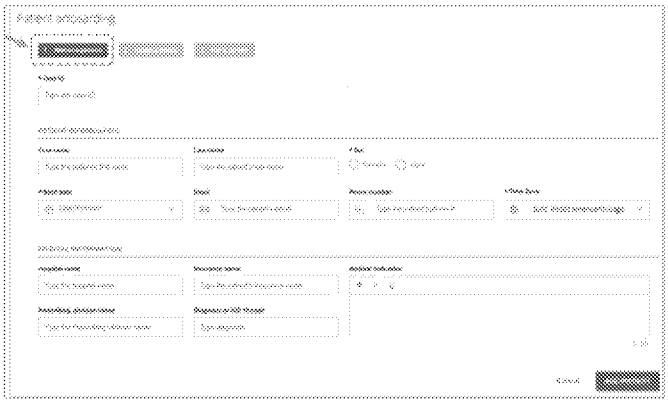
Clinician LOGIN

- Enter your user email and password
- Click LOGIN to show list of patients



Admit a Patient

- On “List of patients” screen in upper right corner select “ADD PATIENT”
- The “Patient onboarding” screen opens with the “Add new patient” screen
- Enter all patient information
- Select “ADD PATIENT” at the bottom right of screen to advance to next step in onboarding process to assign a device



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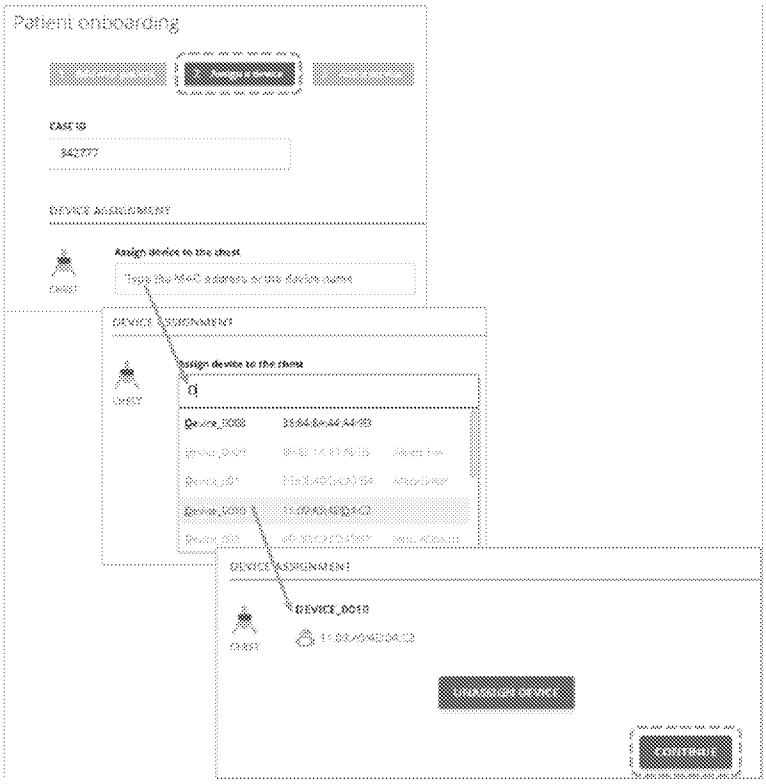
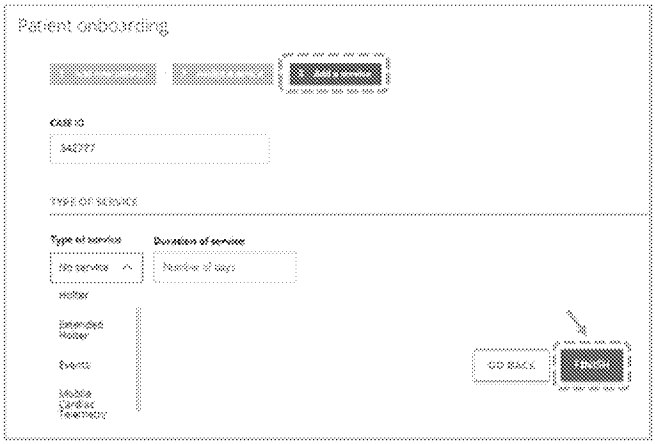
- On the next screen "Assign a device"
- Type MAC address or device name. As information is typed, a box below begins to populate with device, then select it from list of options, next select "CONTINUE" to associate *7L Sensor* to the patient (MAC address is found on surface of *7L Sensor* that is inserted into *7L Patch*)
- This advances you to the next step in onboarding process to "ADD A SERVICE"



- From drop-down menu, select type of service
- Enter number of days duration of service
- Select "FINISH"
- This new patient is now added to the patient list and displayed on Multi-Patient View



NOTE: Service begins once *7L Sensor* is on patient's body and connected to *7L Mobile Application*.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display. Consult Technical Manual.

Service type options and features

		Features				
		Measurements	**Event Capture**	**Real Time View**	**Duration**	**Report Editing and Creation**
Service Type	**Holter**	7 leads ECG, Atrial Fibrillation	Yes	Optional	<48 hrs.	Yes
	Extended Holter	7 leads ECG, Atrial Fibrillation	Yes	Optional	>48 hrs.	Yes
	Event	7 leads ECG, Atrial Fibrillation	Yes	Optional	Ordered	Yes
	Mobile Cardiac Telemetry	7 leads ECG, Atrial Fibrillation	Yes	Yes, 24/7 monitor watchers	Ordered	Yes

Type of service for monitoring is listed as ordered by the physician. Status is “Running”, “Not Started”, or “Finished”. Service can be changed or stopped at any time as ordered by the physician.

Select “Stop” to change the type of monitoring service and/or number of days.

Select “Stop” at the completion of monitoring and continue to “Unassign” *7L Sensor* device.

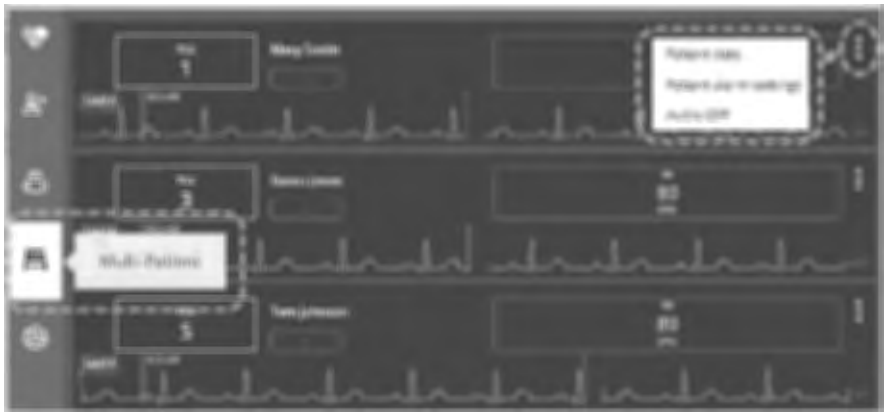
Customizing Heart Rate Alarm and Event Notification Settings for Individual Patients

Alarms and event notifications are pre-set by manufacturer, can be modified to meet practice requirements, customized for patient clinical condition, and provider orders.

- Select patient by clicking on the “Patients” icon on left menu to see list of patients
- Click on patient’s name to adjust their heart rate alarm and arrhythmia event notification settings
- On right navigation menu, select “Alarm Settings” to review and edit heart rate alarm and arrhythmia event notification settings

Access alarm and arrhythmia event notification settings when in “Multi-Patient” view

- Click on ‘Three Dots’ on upper right side of patient tile of your selected patient
- In pop-up window menu, select “Patient alarm settings” to review heart rate alarm and arrhythmia event notification settings and edit settings



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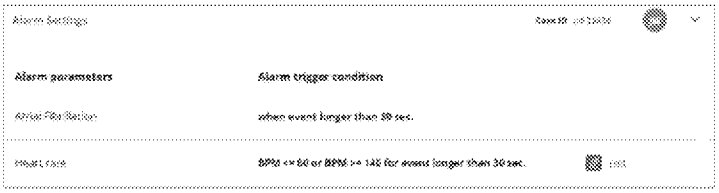
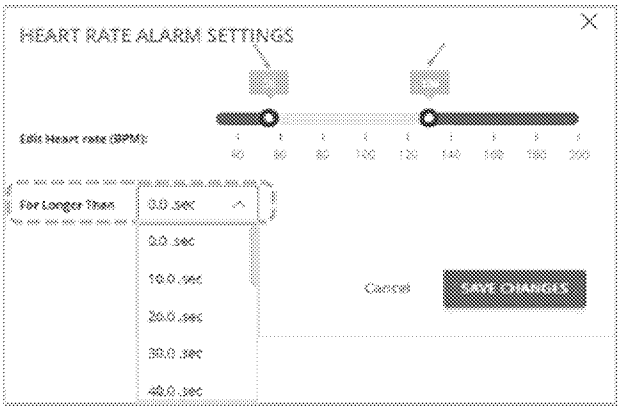
Alarm Settings screen:

Heart Rate Alarm parameters: Customize the alarm trigger condition for heart rate

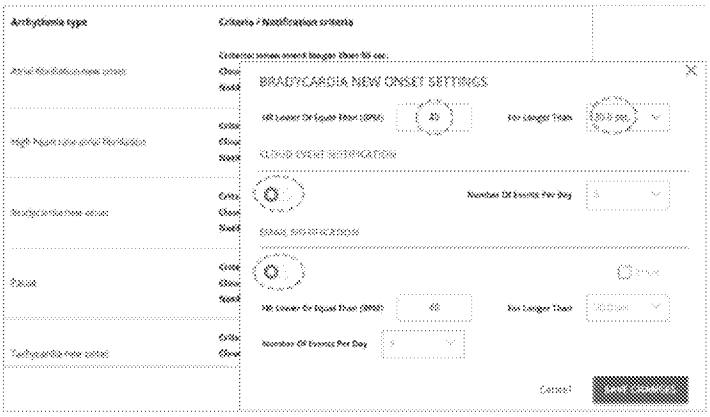
- Select "Edit" to change heart rate alarm setting values
- Slide each circle above scale to the left or right to adjust alarm settings (options in increments of 5 BPM)
- Using drop-down menu you can change length of time (0 – 120 seconds) for this alarm setting (i.e. when heart rate setting is less than 60 or greater than 140 BPM for longer than 30 seconds means an alarm will be triggered when the heart rate is outside of those limits for more than 30 seconds)
- Select "SAVE CHANGES" or "Cancel" if you choose to not make any changes





Arrhythmia Event Notification: Notification criteria and settings can be customized for arrhythmia type

- Select "Edit" to customize arrhythmia event notifications
- Enter numerical value for heart rate limit and select number of seconds duration for length before notification
- Cloud (*7L Web Browser*) Event Notification- use radio button to turn Off/On this arrhythmia event notification to be sent to the *7L Web Browser* and you can set how many of these arrhythmia events per day are sent when this function is enabled
- Email Notification- use radio button to turn Off/On for email to be sent to the patient's clinician listed in their profile and enter numerical value, select number of seconds duration of delay, and number of events per day are emailed when enabled
- Select "SAVE CHANGES" or "Cancel" if you choose to not make any changes



WARNING: Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a skilled clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.

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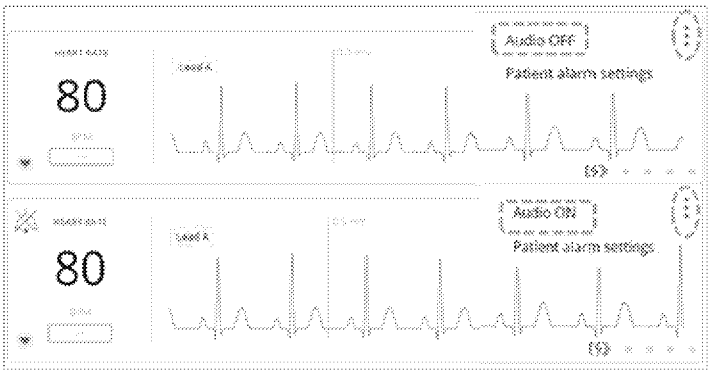
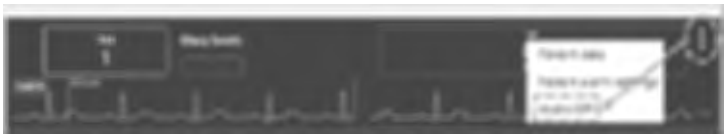
Turning Alarm Audio OFF and Audio ON

- Click on 'Three Dots' on upper right side of patient tile of your selected patient
- When you select "Audio OFF" for the selected patient, all auditory alarm sounds for that patient are turned off for five minutes (indicated by a red "crossed bell" in the upper left corner of patient tile)
- After five minutes of audio OFF, alarm audio turns ON automatically
- When Audio OFF is selected, the next time that menu is opened within the five-minute time period, Audio ON is displayed as option to turn on auditory sound for alarms
- Turning alarm Audio OFF and Audio ON can also be done when using Multi-Patient view in the same way

Individual Patient View



Multi-Patient View



WARNING: Do not try to turn the volume on the personal computer to OFF or Mute. Do not try to adjust the volume to such a low value that auditory alarm signals cannot be heard. The 7L Platform will indicate a warning on the display.

Multi-Patient View

- Select "Multi-Patient" icon on left navigation menu to display all monitored patients
- When a new patient is added they are automatically placed in a patient tile.
- When monitoring more than 12 patients, ensure all patients are viewed at all times by opening another instance of the 7L Web Browser on additional displays.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display.

WARNING: When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.

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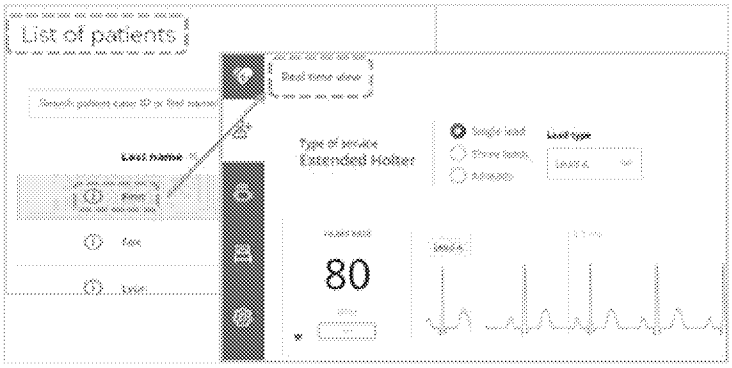
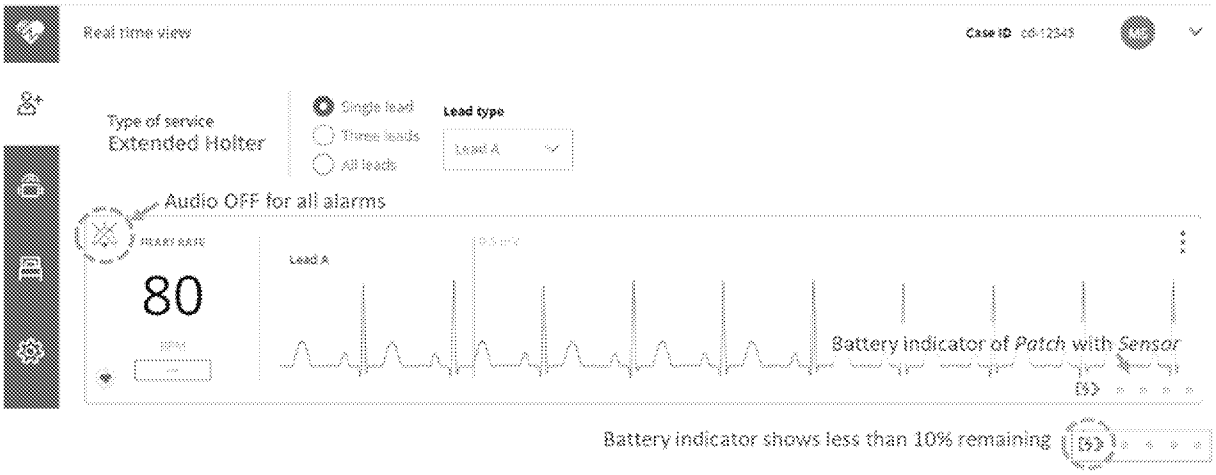
Viewing Patient Data

- Select patient by clicking on "Patients" icon on left navigation menu to see list of patients
- Click on patient's name to view their real time ECG and heart rate.

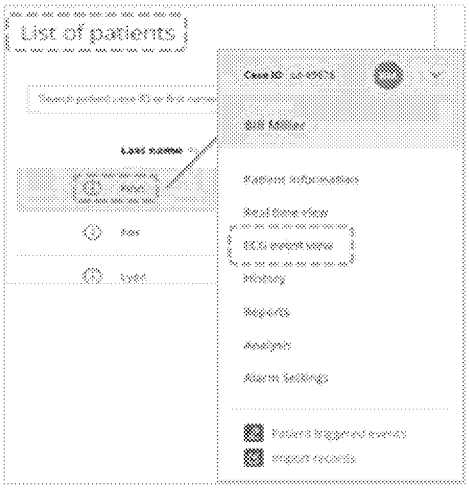


Real Time View screen



Review of Alarm Condition- "ECG event view"

- Select patient by clicking on "Patients" icon on left navigation menu to see list of patients
- Click on patient's name to view their real time ECG and heart rate
- On top right navigation menu select "ECG event view"
- Select date to review



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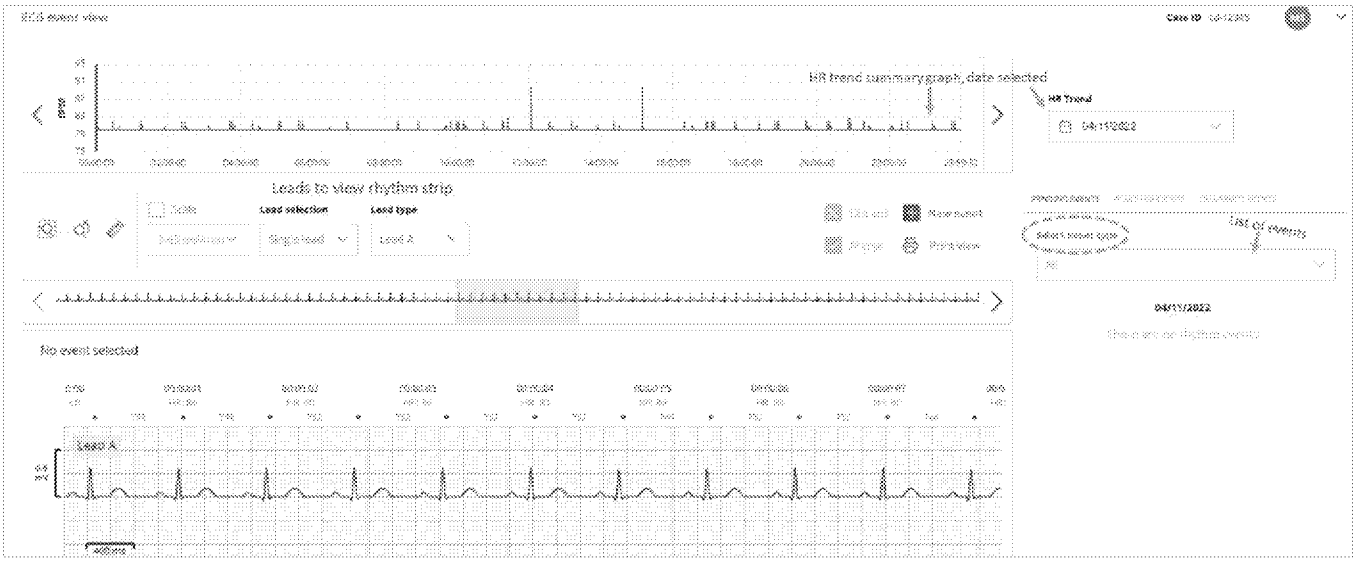
ECG event view



- Use arrows to move through summary graph for data you want to review in detail. Each click shifts ECG by one hour
- ECG shown represents highlighted section on compressed ECG, slide highlighted section left or right to view other ECG segments
- When events are listed, review can be done looking at pending, accepted, and discarded events
- Sorting can be done by event type
- A “New event” can be added, you can Accept, or Discard captured events

WARNING: The 7L Platform™ is not an emergency response system. If the patient has alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

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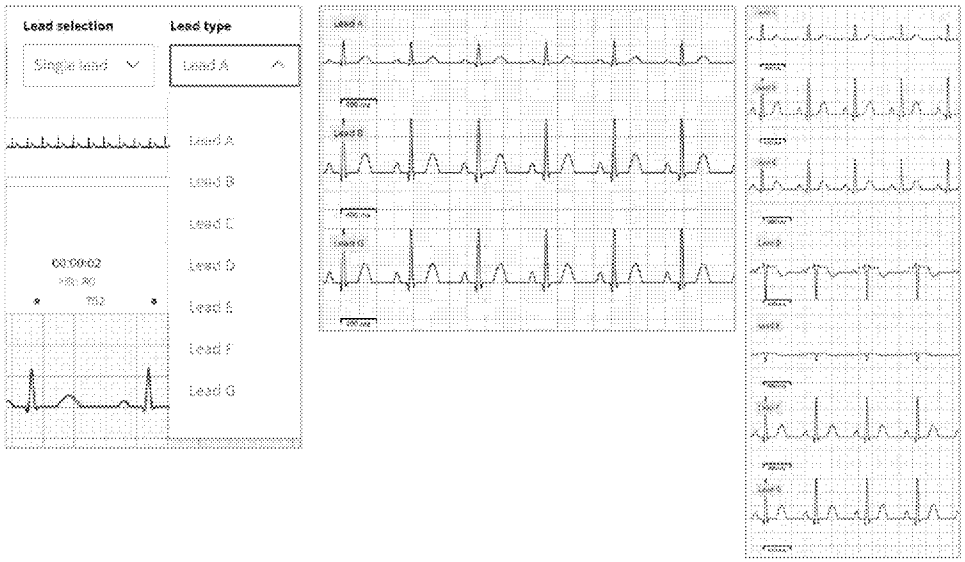
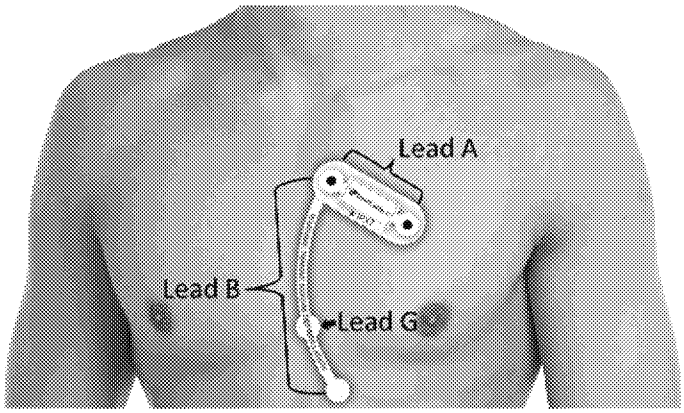
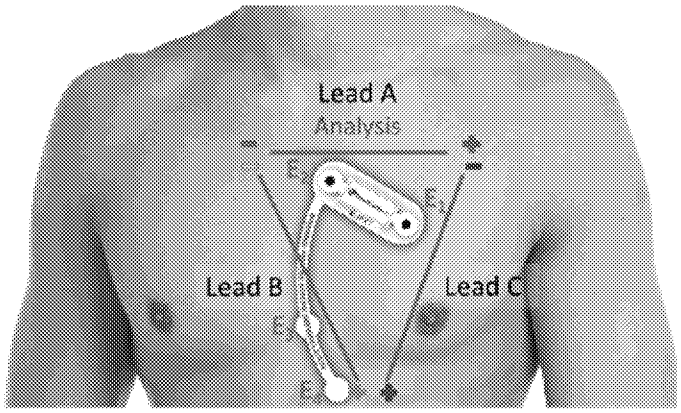
- Rhythm strip can be viewed in one lead, three leads, or seven leads (Leads A, B, C, D, E, F, G)





ECG Channels Transmitted



ECG Electrode Identification (E_x) and Polarity Measurements

NOTE: Analysis is done on Lead A only

WARNING: The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia 7L Patch and 7L Sensor before external defibrillation.

Editing and analyzing patient historical data (Refer to Clinician User Guide for details)

What the patient needs to do (Refer to the Patient User Guide and Kit)

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Specifications

Physical and Environmental	
Size	7L Sensor: 1.97 x 1.18 x .39 inch; (50 x 30 x 10mm) 7L Patch (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14mm)
Weight	7L Sensor: Less than 3.52oz. (100 g) 7L Patch: <1.0 oz. (28.4 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C) Operating: +41 to +104°F (+5 to + 45°C)
Humidity	Storage and transport: relative humidity up to 90%, non-condensing Operating: 10 to 95% at +41 to 95°F (+5 to +35°C) (non-condensing) / 700 – 1060 hPa
Safety	Type BF
Water Ingress	IPX7 (waterproof)
Battery Life	Up to 14 days, depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993-5, ISO 10993-10, ISO 10993-12 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30 - 200	Beats per Minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Manufacturer Default Alarm Settings			
Parameter	Low Limit	High Limit	Alarm Delay
Heart Rate	40	130	9.1 sec. max
Atrial Fibrillation	When event is longer than 30 sec.		NA

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Warnings

- **The 7L Platform™ is not an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.**
- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia 7L Patch and 7L Sensor before external defibrillation.**
- **Alarm conditions must be set to ON for a notification to be presented at the remote viewing station.**
- **When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.**
- **Make sure that parameter limit settings are appropriate for the clinical condition of the patient being monitored - do not set parameter limit settings outside the physiological range for the patient.**
- **Alarm limits are patient or facility specific. The clinician must set and verify alarm limits appropriate for each patient. Failure to set alarm limits properly can lead to false alarms or failure to alarm.**
- **If a patient has severe skin irritation or burning feeling, they should remove 7L Patch right away and contact their doctor.**
- **Do not use this device in an MRI.**
- No computerized interpretation of patient data can correctly detect and classify a medical condition 100% of the time. Use sound clinical judgment when monitoring your patients.
- Audio on the PC used to view the *7L Web Browser* must be ON and sufficiently loud enough.
- When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.
- Do not turn OFF the audible notifications without providing continuous observation of the patient.
- Check notification volume periodically! If the volume is too low, it could result in the inability to hear a notification.
- In certain circumstances the pacemaker pulse may be detected as a heartbeat. Verify heartbeat with an alternative method such as auscultation, radial artery palpation, or viewing ECG.
- Make sure that proper patient preparation and settings are in place to avoid sensitivity to excessive artifact which can result in inaccurate notifications.
- Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.
- The alarms provided on the SmartCardia 7L Platform should be properly assessed by medically trained or relevant qualified and accredited personnel.
- It is the responsibility of the clinician or care provider to respond to alarms consistent with their practice license.
- The SmartCardia 7L Platform should not be used in an aircraft.

Cautions

- The 7L Platform is used for adults over the age of 18 years.
- Install the 7L Platform and use as instructed. Do not attempt to connect it to another piece of equipment.
- Do not try to service the 7L Platform. It is not field repairable and there are no replaceable components.
- The 7L Platform is to be used by adequately trained personnel.
- Do not use with other devices, which have high-level electromagnetic radiation.
- The 7L Platform is not designated for use in the operating room or operating theater.
- Make sure to have a good internet connection and sufficient bandwidth.

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Cautions (continued)

- The 7L Platform is designed to operate in the presence of pacemaker pulses. Caution should be used to not locate the *7L Patch* with the *7L Sensor* on top of a pacemaker.
- The *7L Patch* is single use for a single patient. Do not reuse.
- Follow the instructions to use correctly.
- Make sure the *7L Sensor* is installed correctly and is firmly sealed in the *7L Patch*.
- Care should be taken by the patient if showering. Caution should always be taken when wearing in a wet location.
- Follow the instructions for the correct cleaning solution and process.
- Do not place the *7L Patch* on open wounds.
- The patient must keep the SmartCardia *Phone* within 10 ft of the *7L Sensor* at all times.
- Make sure the SmartCardia *Phone* is fully charged. It is best to charge the phone at night.
- If the Bluetooth on the SmartCardia *Phone* Is OFF, contact SmartCardia customer support.
- Only use the charger provided with the SmartCardia *Phone*.
- It is very important to have a good internet connection.
- For best results, the patient's skin where the *7L Patch* is applied should be cleaned and hair clipped or shaved to reduce artifact and prevent a noisy signal.
- Do not use the *7L Patch* if date of manufacture is more than two years. Refer to the *7L Patch* labeling.
- Keep username and login in a safe place and do not share them with anyone.
- Do not access the cloud platform from a shared computer.
- Make sure to set the correct mode of monitoring operation for the patient (Holter, Extended Holter, Event, or Mobile Cardiac Telemetry).
- Measured vital sign values should be reviewed and verified by alternate means if measurements are suspected to be inaccurate.
- When remote monitoring a patient, remember they may not have a caregiver or helper nearby and they may not be able to respond to communications. Always know how to provide aid for each patient.
- Receipt of alarms is not confirmed.
- Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.
- If the wireless connection from the *7L Sensor* and *7L Patch* to the *Phone* or the *Phone* to the internet/cloud application is broken, a notification will show on the display. Periodically check to make sure the connection is intact.

Please refer to Clinician User Guide for the complete list of warnings and cautions.

Customer Support
(800) 363-8151

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SmartCardia 7L™

monitoring the fabric of life™

SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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· PL-17 SmartCardia 7L Platform Technical Manual

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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022_Performance Testing - Bench

- IEC 60601-1 (b)(4)

(b)(4)

(b)(4)

(b)(4) Test Reports

- IEC 60601-2-47

(b)(4) Supplemental Test Reports

- IEC 60601-1
- IEC 60601-1-11
- IEC 60601-2-47
- Essential Performance - Defibrillation Performance - Test Plan and Report
- (b)(4) Performance Testing

SmartCardia Performance Testing

(b)(4) Sensor Positioning Effects on ECG Performance

(b)(4) ECG Waveform Quality and Wearability Report

(b)(4) Shock and Vibration Summary Test Report

(b)(4) SCDV ECG Test Results - Arrhythmia Performance

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(b)(4)

(b)(4)

IEC/EN Safety Report

Model:	SC-100-07
Device Description:	Electrocardiographs Patch
Applicant:	SmartCardia EPFL Innovation Park, Building C 1015 Lausanne Switzerland
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	Same as Applicant

(b)(4)

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(b)(4) Testing IEC 60601-2-47

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IEC 60601-2-47
Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

Report Reference No. ..... :	(b)(4)
Date of issue ..... :	August 30, 2022, **M1: September 23, 2022**
Total number of pages ..... :	43
CB Testing Laboratory ..... :	(b)(4)
Address ..... :	
Applicant's name ..... :	SmartCardia SA
Address ..... :	EPFL Innovation Park Building C 1015 Lausanne Switzerland
Test specification:	
Standard ..... :	IEC 60601-2-47: 2012 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition)
Test procedure ..... :	CER
Non-standard test method ..... :	Limit evaluation, See engineering considerations
Test Report Form No. ..... :	IEC60601_2_47D
Test Report Form Originator ..... :	(b)(4)
Master TRF ..... :	Dated 2014-01

General disclaimer:

(b)(4)

Test item description ..... :	Halter Monitor
Trade Mark ..... :	N/A
Manufacturer ..... :	SmartCardia SA
Model/Type reference ..... :	SC-100-07

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(b)(4) Supplemental Test Reports

- **IEC 60601-1**
- **IEC 60601-1-11**
- **IEC 60601-2-47**
- **Essential Performance - Defibrillation Performance**
- **(b)(4) Performance Testing**

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(b)(4)

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number. .....:	(b)(4)
Date of issue .....:	2023-04-12
Total number of pages.....:	12
Name of Testing Laboratory preparing the Report.....:	(b)(4)
Applicant's name.....:	SmartCardia
Address .....:	EPFL Innovation Park, Building C CH 1015 Lausanne, Switzerland
Test specification:	
Standard.....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....:	(b)(4)
Non-standard test method .....:	
TRF template used .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	(b)(4)
Test Report Form(s) Originator ....:	(b)(4)
Master TRF .....:	2022-05-13

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Test Report issued under the responsibility of:

meca
Experts in Product Safety

TEST REPORT
IEC 60601-1-11
Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Report Number.	(b)(4)
Date of issue	2023-04-12
Total number of pages	9
Name of Testing Laboratory preparing the Report	(b)(4)
Applicant's name	SmartCardia
Address	EPFL Innovation Park, Building C CH 1015 Lausanne, Switzerland
Test specification:	
Standard	IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020 for use in conjunction with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure	(b)(4)
Non-standard test method	N/A
TRF template used	(b)(4)
Test Report Form No.	
Test Report Form(s) Originator	UL(US)
Master TRF	2021-09-16

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SmartCardia Performance Testing

(b)(4) Sensor Positioning Effects on ECG Performance

(b)(4) ECG Waveform Quality and Wearability Report

(b)(4) Device Specifications Test Report - Shock and Vibration Summary Test Report

(b)(4) SCDV ECG Test Results - Arrhythmia Performance

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(b)(4) Sensor positioning effects on ECG Performance - Results

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(b)(4) ECG Waveform Quality and Wearability Report

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(b)(4) Device Specifications Test Report - Shock and Vibration Summary Test Report

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(b)(4) SCDV ECG Test Results - Arrhythmia Performance

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Device Hazard Analysis

(b)(4)

Risk Management Plan

Risk Analysis Summary

Risk Management Report

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: Vincent Do
CDRH/OPEQ/OHT2/DHT2A

CC: Hong (Laura) Lu, Assistant Director, CDRH | OPEQ | OCEA | DCEA2
Lan Huang, Team Leader, CDRH | OPEQ | OCEA | DCEA2

From: Feiming Chen, Ph.D.
Mathematical Statistician, Biostatistics Team 3 (All Diagnostic Products)
DCEA2: Division of Biostatistics | OCEA: Office of Clinical Evidence and Analysis | OPEQ: Office of Product Evaluation and Quality | CDRH

Due Date: 6/21/2023

Subject: Statistical Review of 510(k) submission K231276 (SmartCardia 7L Platform by SmartCardia SA)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

If you have any questions about this review or the submission in general, please contact me at (301)796-4394 or at Feiming.Chen@fda.hhs.gov.

Feiming Chen -S

Digitally signed by Feiming Chen -S
Date: 2023.06.20 17:10:59 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: steurerbob@gmail.com <steurerbob@gmail.com>

Sent: Tuesday, August 1, 2023 12:42 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov>

Subject: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Thank for your quick review. I am attaching the updated cover letter and response to the AINN as you requested. Sorry for the mis-understanding.

Best Regards,

Bob Steurer

[cid:image007.png@01D9C46D.39D351D0]Steurer Consulting Group

http://www.scgconsulting.net<http://secure-web.cisco.com/1pzGa9tFRbwZTKRaJ4aCh27XPI7bR6Q8S_PhxbYgyJNhc_DCZg5shoIXRcWa7t2Z2X-Ni0Nad3vssBNlXOvTsVD5Si03y9yKppCu0jkze35unrWIJbbdZuB8yCDjuTl_atMaaf1UaDFOlVHqTWp9V8EaoeZz-vdoNnpDdpNhc6Ofv8-nRvn_VH-6ZoMDo7iH-DwQ_0p4cJcW81fqY8T4URq3cnRP0src_WdPF6Z3Hbb0/http%3A%2F%2Fwww.scgconsulting.net%2F>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Tuesday, August 1, 2023 9:53 AM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Subject: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request

Good morning Bob,

I hope you and your team are doing well.

(b)(4)

Please let me know if you have any questions.

Best Regards,

Vincent

Vincent Do

Lead Reviewer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Cardiac Ablation, Mapping and Imaging Devices Team

Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: (240) 402-4584

Email Address: Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>

[cid:image008.png@01D9C46D.39D351D0]<http://www.fda.gov/>

[cid:image009.jpg@01D9C46D.39D351D0]<https://www.facebook.com/FDA>
[cid:image010.jpg@01D9C46D.39D351D0] <https://twitter.com/US_FDA>
[cid:image011.jpg@01D9C46D.39D351D0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image012.jpg@01D9C46D.39D351D0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image013.jpg@01D9C46D.39D351D0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 7/28/2023 8:05:27 PM
To: steurerbob@gmail.com
CC: DCCLetters@fda.hhs.gov
Subject: K231276/S001 Acknowledgement Letter
Attachments: K231276-S001-Acknowledgement Letter.pdf

July 28, 2023

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

The CDRH Portal is now available:
Instead of shipping your submissions to us, you can now upload them at our CDRH Portal.

*** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgement Letter

07/28/2023

Robert Steurer, Consultant
Steurer Consulting Group LLC
800 Blue Quail Rd
Keller, TX 76248
UNITED STATES

Dear Robert Steurer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov.

Submission Number: K231276/S001
Received: 07/28/2023
Applicant: SmartCardia SA
Device: SmartCardia 7L Platform

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Wednesday, August 30, 2023 2:42 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Cc: 'Francisco Rincon' <francisco.rincon@smartcardia.com>; 'Srini Murali' <srinivasan.murali@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; 'James Welch' <jwelch@arcbiomed.com>
Subject: RE: [EXTERNAL] 2nd Hold Confirmation

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

(b)(4)

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Wednesday, August 30, 2023 1:28 PM
To: steurerbob@gmail.com
Cc: Francisco Rincon <francisco.rincon@smartcardia.com>; Srini Murali <srinivasan.murali@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; James Welch <jwelch@arcbiomed.com>
Subject: RE: [EXTERNAL] 2nd Hold Confirmation

Hi Bob,

Thank you so much for all of your help with this.

As mentioned in our meeting yesterday, we reached out to the 510(k) Staff regarding the option of putting this submission on the 2nd hold. We just heard back from them that we can move forward with a 2nd hold for this submission. Please help confirm whether you prefer to put this submission on the 2nd hold or proceed with where we are right now (b)(4)

Please let me know if you have any questions.

Thank you,

Vincent

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Wednesday, August 30, 2023 12:16 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Cc: Francisco Rincon <francisco.rincon@smartcardia.com>; Srini Murali <srinivasan.murali@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; James Welch <jwelch@arcbiomed.com>
Subject: [EXTERNAL] Revision History, Regression Testing, IFU with note added

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

(b)(4)

Thank you,
Bob
Best Regards,
Bob Steurer

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Form Approved: OMB No. 0910-0511 Expiration Date: October 31, 2024. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

SmartCardia SA
Building C
EPFL Innovation Park
Lausanne
CH
1015
CH

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Srinivasan Murali
2.1 E-MAIL ADDRESS
srinivasan.murali@smartcardia.com
2.2 TELEPHONE NUMBER (include Area code)
7887-50864
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: (b)(4)

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 01-May-2023

Form FDA 3601 (07/22)

"Close Window" Print Cover sheet

Redacted per FOIA Request 2023-2122 Released by CDRH on 04-07-2023

electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 2.1 (2022-10-07)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. We tested eSTAR submissions up to 1GB in size. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

Q: If an eSTAR is signed, a message is displayed at the top saying changes were made after signing. Why?

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.1 (2022-10-07): Grey text in FDA standards selection no longer disappears when an SDO is selected. Warning

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA
Show Application Introduction	
Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special
Show Application Type Introduction	
Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	( ) New Application/Submission (•) Additional Information
Please enter the parent application/submission number.	K231276

Records processed under FOIA Request 2021-2182 Released Date: April 19, 2021

Cover Letter / Letters of Reference

Add Attachment | Attach your Cover Letter

Open Attachment | Cover Letter Signed.pdf | Delete Attachment

Add Attachment | Attach any Letters of Reference

Applicant Information

Contact

Title: Mr. | Last Name: Murali | First Name: Srinivasan

Email: srinivasan.murali@smartcardia.com | Phone Number: +41 7887 50864

Occupation Title: Chief Executive Officer

Company

Company Name: SmartCardia SA

Address - Line 1: EPFL Innovation Park Building C

Address - Line 2:

City: Lausanne | State: | Zip: 1015 | Country/Region: Switzerland

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title: | Last Name: Steurer | First Name: Robert

Email: steurerbob@gmail.com | Phone Number: 425-358-1072

Occupation Title: Consultant

Company

Company Name: Steurer Consulting Group LLC

Address - Line 1: 800 Blue Quail Rd

Address - Line 2:

City: Keller | State: TX | Zip: 76248 | Country/Region: United States

Add Correspondent/Consultant | Delete Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Are there prior related submissions or regulator interaction for the subject device(s)? Yes

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

(b)(4)

Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment | 002_Prior Coorespondence and Regulator Interaction QSUB | Delete Attachment

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A	19-46	Delete Standard

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | K231276_S001_60601-1 Extent of Standard Conformance Checklist | Delete Attachment

Add Standard

IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36	Delete Standard

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collater

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | K231276_S001_60601-2 EMC Extent of Standard Conformance Checklist | Delete Attachment

Add Standard

IEC	60601-1-11 Edition 2.0 2015-01	19-14	Delete Standard

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collate

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | K231276_S001_60601-1-11 Home Healthcare_Redline.pdf | Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Add Standard

IEC	60601-2-47 Edition 2.0 2012-02	3-155	Delete Standard

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	K231276_60601-2-47 Ambulatory ECG Extend to Standard Conformance	Delete Attachment

Add Standard

IEC	60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131	Delete Standard

Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance ¿ Collater

Are you using this standard for general use, or are you declaring conformity to it?	General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	K231276_S001_ISO 60601-1-8 Alarm Standard Checklist Redline.pdf	Delete Attachment

Add Standard

ISO	10993-5 Third edition 2009-06-01	2-245	Delete Standard

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?

Add Standard

ISO	10993-10 Third Edition 2010-08-01	2-174	Delete Standard

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?

Add Standard

ISO	10993-23 First edition 2021-01	2-291	Delete Standard

Biological evaluation of medical devices - Part 23: Tests for irritation

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request released by CDRH on 10-02-2024

Add Standard

ANSI AAMI	EC12:2000/(R)2015	3-52	Delete Standard
Disposable ECG electrodes			

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	K231276_S001_EC12 Disposable ECG Electrodes Checklist RedLine.pdf	Delete Attachment

Add Standard

Records processed under FOIA Request 2024-8126 Released by CDRH on 10-02-2024

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

SmartCardia 7L Platform	Model Number/Name	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	No
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	Yes
• Please check the attributes that are applicable to your device.	☒ Cloud Communication ☒ Network connection (active or not) ☒ Wireless communication in any form ☐ USB/serial ports/removable media ☒ Software upgrades (this includes patches) ☐ None of the above
Is the device or a component packaged as sterile?	No
The device/system uses or is... (choose all that apply)	☒ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use device(s) ☒ a reusable multi-patient use device(s)
The environment of use of the device/system includes... (choose all that apply)	☒ Professional Healthcare Facility ☒ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the device a combination product?	No
Is the device electrical (battery or wall powered)?	Yes, it is battery and mains powered
• Does the device/system include wireless technology?	Yes
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

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If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

(b)(4)

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	007_Comprehensive Device Description and Principles of	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	008_Device Description Sensor mechanical dwgs.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	010_Description of Device Packaging.pdf	Delete Attachment

Accessories

Redacted per Freedom of Information Act, 5 U.S.C. 552(b)(4); Released by CDRH on 10-02-2024

Is the device intended to be marketed with accessories? Yes

Add Accessory | List all the accessories to be marketed with the submission.

7L Patch | Delete Accessory

Please include a description of each accessory (see help text for the information we request be included). Please also provide the submission number if the accessory was previously marketed (or a statement that it was not).

The SmartCardia 7L Patch is a single use component that is disposable. If extended use of the SmartCardia 7L Platform is required, the 7L Patch is replaced. The SmartCardia 7L Patch has not been previously marketed.

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request? No

Add Attachment | Please attach Accessory Pictures, Illustrations, Schematics, and/or Diagrams

Open Attachment | 009_SmartCardia 7L Patch Accessory Photo.pdf | Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231276

Device Name

SmartCardia 7L Platform

Indications for Use *(Describe)*

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:
1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening
conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Records processed under FOIA Request 2024-6114 Released by CDRH on 10-02-2024

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	
Regulation	
Product Code	DSI

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-arrhythmia-detector-and-alarm-guidance-industry-and-fda

Associated Product Code(s) DRG ?

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K192757
Predicate Device Trade Name	VitalPatch
Predicate Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DRG

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K160064
Predicate/Reference Device Trade Name	MoMe Kardia Wireless Ambulatory ECG Monitoring And Dete
Predicate/Reference Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DSI

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Predicates and Substantial Equivalence Summary
Primary Predicate
VitalConnect VitalPatch K192757
Product Code: DRG
Intended Use:
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.
The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

Predicate/Reference Device
InfoBionics MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System K160064
Product Code: DSI
Intended Use:
MoMe® Kardia is intended to be used for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.
MoMe® Kardia is contraindicated for:
1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life

Contains Nonbinding Recommendations

threatening arrhythmias.

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Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Substantial Equivalence Comparison Statement
The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

Substantial Equivalence Comparison Technological Characteristics Statement
The SmartCardia 7L Platform has the same technological characteristics as the predicate device and the predicate/reference device.
1) They are body worn sensors that communicate wirelessly to a gateway device that transmits the data to a cloud bases server for storage and further analysis.
2) The material used in the predicate device and the SmartCardia 7L body worn device is the same.
a. The ECG electrodes are a hydrogel component
b. The adhesive body is a hydrocolloid material.
c. The predicate/reference device uses individual ECG electrodes connected to the transmitter device via wire leads.
d. The devices use integrated batteries to power the body worn sensor.
i. The predicate device uses zinc air and the SmartCardia 7L body worn device uses manganese oxide-lithium.
ii. Both are disposable and do not require charging.
e. The predicate device and SmartCardia 7L body worn device both use Bluetooth BLE communication to a gateway.
i. The predicate device communicates to a tablet,
ii. The SmartCardia 7L body worn device communicates to a smartphone.
iii. The predicate/reference device incorporates a cellular transmitter directly into the sensor and transmits via cellular technology to the cloud server.
iv. These gateways then transmit the data to a cloud server.
3) The VitalConnect predicate device measures more physiological parameters than the SmartCardia 7L Platform.
4) The InfoBionics predicate/reference device measures just ECG and heart rate which is the same as the SmartCardia 7L Platform.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	011_Substantial Equivalence Comparison Table Attachment.pdf	Delete Attachment

Records processed under FOIA Request 2024 Released by CDRH on 10-02-2024

Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	PL-09 Clinician User Guide IFU, Icon and Symbol Table, pages 40, 41, 42, and 43 of 235 (IFU pages 15, 16, 17, 18); PL-17 (b)(4) Manual, pages 186 and 187 of 235
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	MR Unsafe

Package Labeling

Add Attachment	Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.	
Open Attachment	012 Package Labeling.pdf	Delete Attachment

Package Insert / Instructions for Use

Add Attachment	Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.	
Open Attachment	Redline IFUs (b)(4) Proposed Labeling SmartCardia Update (b)(4).pdf	Delete Attachment
Open Attachment	Redline Tech Manual (b)(4) Proposed Labeling SmartCardia	Delete Attachment
Open Attachment	013_Instructions for Use from eSTAR redlined after AINN.pdf	Delete Attachment
Open Attachment	013_Instructions for Use K231276_S001.pdf	Delete Attachment

Other Labeling

Add Attachment	Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	013_Instructions for Use K231276; PL-08 Patient Guide, page 23 of
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	File 013_Instructions for Use K231276, PL-08 Patient Guide, page
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	File 013_Instructions for Use K231276, PL-08 Patient Guide, page 23 of 235, and 24 of 235;

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Based on the answers provided in the Device Description section, reprocessing information, but no sterility information, is needed.

Reprocessing

Are cleaning or disinfection or sterilization instructions included in the labeling?	Yes
How many different sets of reprocessing instructions are included (maximum of 4):	(b)(4)

Reprocessing Instructions 1

Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

SmartCardia 7L Sensor, SmartCardia Phone, Charger and charger cable

Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.	013_Instructions for Use, Page 161 of

Cleaning Instructions

Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?	No
Is a Point-of-Use care instruction included (e.g., to prevent drying)?	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable. (Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161
If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.	N/A
Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235

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Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., "no visual contamination"), and 3) steps the user should repeat if the endpoint is not met.	013_Instructions for Use K231276, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.	013_Instructions for Use K231276, page 18 of 235; page 161
If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.	7L Patch is single use, stated in 013_Instructions for

Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

Which types of microbicidal process instructions are present in these instructions?	None (cleaning alone)

Technically Feasible, Understandable, and Comprehensive

Be sure the reprocessing instructions can be understood and reasonably implemented by the end user in the intended reprocessing location. If a device is intended to be reprocessed in the home, then reprocessing steps should include products that are available for use in the home (not sterilizers or high-level disinfectants) and are appropriate for the reprocessing procedure (e.g., baby bottle sanitizers are not recommended for reprocessing most medical devices).

If the device is initially supplied non-sterile to the user and specifies to sterilize the device before use, the device should be prominently labeled "Non-sterile" directly on the individual device label (e.g., as opposed to only on the shipper carton).

When warranted, the labeling should include special warnings or precautions about potential damage to the device from improper reprocessing procedures. These may be related to user safety or emphasize

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conditions that could significantly alter the safety or effectiveness of reprocessing or performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. Not all devices may need this type of warning in the labeling. If you are unsure, check if similar devices have labeling with this type of warning.

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A, no special controls for reprocessing or sterility.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf-life?	2	Years

Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

Device is not a sterile device. Device tested per IEC 60601-1-11 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.	?

Other

Open Attachment	014_Reprocessing_Sterility_Shelf-Life_Documents.pdf	Delete Attachment

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Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? *(See Help Text if multiple materials share the same justification for no testing.)*	(b)(4)

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrogel electrode component

Please state the exact name and any identifiable information for the particular material used.

Hydrogel, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PCSTATUS@fda.hhs.gov or 301-796-5115

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tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Records processed under FOIA Request 2023-8108, Released by CDRH, on 10-02-2024

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

documentation error did not impact assessment of the study endpoints.

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Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 2

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrocolloid adhesive component

Please state the exact name and any identifiable information for the particular material used.

Hydrocolloid, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

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Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No Hydrogel, No Hydrocolloid)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DAD at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 3

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, adhesive component

Please state the exact name and any identifiable information for the particular material used.

Adhesive, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, No hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 4

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, sensor window lens

Please state the exact name and any identifiable information for the particular material used.

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.
Open Attachment	015_ISO 10993 Biocompatibility Test Reports.pdf Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, software, cybersecurity, and interoperability information is needed.

Software

Software Level of Concern (LOC) Determination

Does the Software qualify as Blood Establishment Computer Software?	(b)(4)
Is the Software intended to be used in combination with a drug or biologic?	
Is the Software an accessory to a medical device that has a Major LOC?	
Prior to mitigation of hazards, could a failure of the Software result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a) Does the Software control a life supporting or life sustaining function? b) Does the Software control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c) Does the Software control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d) Does the Software provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e) Does the Software provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	
Is the Software an accessory to a medical device that has a Moderate LOC?	(b)(4)
Prior to mitigation of hazards, could a failure of the Software result in Minor Injury, either to a patient or to a user of the device?	
Could malfunction of, or a latent design flaw in, the software lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	

Based on the questions answered above, your LOC is determined to be: (b)(4)

The software documentation below is recommended for the level of concern specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Software Description

Add Attachment

Please attach a description of the software / firmware that includes: a textual description of the software / firmware, the version number of the software / firmware, the input parameters (user inputs), and the output parameters (device actions).

Open Attachment 016_Software Description.pdf Delete Attachment

Records processed under FOIA Request 2024-4118 | Released by CDRH on 10-02-2024

Software Documentation

Add Attachment	Device Hazard Analysis	?
Open Attachment	016_K231276_S001 (b)(4)	Delete Attachment
Add Attachment	Software Requirements Specifications (SRS)	?
Open Attachment	SW Requirements Specification (b)(4) Design Inputs.pdf	Delete Attachment
Add Attachment	Architecture Design Chart	?
Open Attachment	(b)(4) SmartCardia 7L Platform Software Architecture.pdf	Delete Attachment
Add Attachment	Software Design Specifications (SDS)	?
Open Attachment	Software Design Specification (SDS).pdf	Delete Attachment
Add Attachment	Traceability Analysis/Matrix	?
Open Attachment	Tracability Analysis-Matrix (b)(4) Design Inputs Trace Matrix.pdf	Delete Attachment
Add Attachment	Software Development Environment/Life Cycle Process Description	?
Open Attachment	SW Development EnvironmentLifeCycle ProcessDescription.pdf	Delete Attachment
Add Attachment	Verification & Validation Testing	?
Open Attachment	016_K231276_S001 (b)(4)	Delete Attachment
Add Attachment	Revision Level History	?
Open Attachment	Software Information SmartCardia Revision History.pdf	Delete Attachment
Add Attachment	Unresolved Anomalies	?
Open Attachment	Unresolved Anomalies.pdf	Delete Attachment

Cybersecurity

Add Attachment	Risk Management	?
Open Attachment	017_Cybersecurity Risk Management.pdf	Delete Attachment
Add Attachment	Cybersecurity Management Plan / Plan for Continuing Support	?
Open Attachment	017_Cybersecurity Plan and Design.pdf	Delete Attachment

Please specifically cite the attachment(s) and page number(s) where the cybersecurity labeling is located. (Note: If there is separate cybersecurity labeling for the device, please attach this in the Labeling section above.)	013_Instructions for Use K231276, PL-09 Clinician User Guide	?

Interoperability

How many Electronic Interfaces are there?	3	?

Electronic Interface 1

Name the Electronic Interface	7L Sensor to SmartCardia Phone, Bluetooth BLE

Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 2	
Name the Electronic Interface	SmartCardia Phone to SmartCardia back end, cellular
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 3	
Name the Electronic Interface	SmartCardia back end to SmartCardia 7L Web Browser, wifi
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Records may contain Confidential Commercial Information (CCI) or Trade Secret

Based on the answers provided in the Device Description section, EMC and wireless technology information is needed.

Electromagnetic Compatibility (EMC)

How many devices/accessories/components were subjected to EMC testing (maximum of 4)? (b)(4)

EMC Test 1

Device Specific EMC Considerations

Please select the highest possible risk associated with this device(s) resulting from potential malfunction, disruption, or degradation due to electromagnetic interference (EMI) that could cause harm to the patient, user, or operator.

Deaths or Serious Injuries: Medical device-related deaths or **serious injuries** include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to a death or injury or illness that is life-threatening, results in permanent impairment or damage to the body, or requires medical or surgical intervention to prevent permanent harm to the body.

Non-Serious Adverse Events: Medical device-related non-serious adverse events include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to minor, temporary or medically reversible injuries that do not meet the criteria for classification as a medical device-related serious injury.

No Reported Or Potential Harm: Medical device-related events without reported or potential harm include medical device nonconformities that have no related harm, medical device malfunctions that have no related harm, and procedure-related complications with no related harm.

(b)(4)

Was testing performed according to a recognized edition of IEC 60601-1-2 and, if so, was an ASCA test summary report provided? Please attach any summaries/reports in the "EMC, Wireless & EMT Documentation" section below.	(b)(4)
Please list the Essential Performance that is specific to the device, or provide a rationale why the device has no Essential Performance, in the space below.	

1. The SmartCardia 7L Platform shall provide correct data output for the vital sign parameters that it measures.

Please provide the page number(s) in the summary/report that include pass/fail criteria specific to the device that are based on the device functions, intended use, and Essential Performance. It is recommended that all device functions that are associated with basic safety or Essential performance be tested and include device-specific pass/fail criteria.	021_Pages 10 and 11 of 305 (Pages 8, 9 of test report)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8218, Released by CDRH on 10-02-2024

If the device under test is not the final finished version, please provide a justification for why the differences don't affect EMC. If the device under test is the final finished version, please state this.	
The device tested is a pre-production unit that represents the final finished version of the product. There were no changes to hardware from the pre-production device tested to the production unit.	
Please provide the page number(s) in the summary/report that include a description of the device/system configuration that adequately addresses and monitors the specific functions of the device that were tested.	021_Pages 8 and 9 of 305 (pages 6 and 7 of test report)
If the wireless technology is used in the medical device to achieve its intended use, was it "On" and communicating with other medical device subsystems or ancillary equipment during EMC testing?	Yes

EMC Emissions and Immunity Test Information

Please provide the page number(s) in the summary/report where the CISPR 11 emission limits are located.	021_Pages 16, 17 of 305; Pages, 23 and
If the device includes any smart batteries that can be removed from the device for recharging, were the batteries tested as a standalone component during ESD testing?	Inapplicable
Please provide the page number(s) in the summary/report where the IEC 61000-4-2 electrostatic discharge (ESD) immunity test levels and test results (or observations) are located.	021_Page 30 of 305 (test report page 28)
Please provide the page number(s) in the summary/report where the IEC 61000-4-3 radiated RF electromagnetic field immunity test levels and test results (or observations) are located.	021_Pages 33 and 35 of 305 (test report pages 31,33)
Please provide the page number(s) in the summary/report where the proximity field immunity test levels and test results (or observations) from IEC 60601-1-2 Sec 8.10 and Table 9 are located.	021_Pages 33, 35, and 37 of 305 (test report pages 31, 33,
Please provide the page number(s) in the summary/report where the IEC 61000-4-8 power frequency magnetic field immunity test levels and test results (or observations) are located.	021_Page 45 of 305 (test report page 43)
Please provide the page number(s) in the summary/report where the IEC 61000-4-6 conducted disturbances induced by RF fields immunity test levels and test results (or observations) are located.	021_Page 43 of 305 (test report page 41)
Please provide the page number(s) in the summary/report where the IEC 61000-4-4 electrical fast transient/burst immunity test levels and test results (or observations) are located.	021_Page 39 of 305 (test report page 37)
Please provide the page number(s) in the summary/report where the IEC 61000-4-5 surge immunity test levels and test results (or observations) are located.	021_Page 41 of 305 (test report page 39)
Please provide the page number(s) in the summary/report where the IEC 61000-4-11 voltage dips, short interruptions, and voltage variations immunity test levels and test results (or observations) are located.	021_Page 47 of 305 (test report page 45)

Questions? Contact CDRH/OCE/DPH at CARLETOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-6128, Released by CDRH on 10-02-2024

Please provide the page number(s) in the summary/report where test data for the specifications in Section 20 (RF immunity, category R) of RTCA DO-160 are located. Alternatively, please specifically cite the attachment and page number where the labeling mitigation that cautions against the use of the device in an aircraft is located.	013_Instructions for Use K231276, PL-09, page 126 (page 151 of 235); PL-17 Technical

If there were any degradations or observations noted during the testing, describe how the device(s) continued to meet the essential performance during these degradations or observations.

Add Attachment	Please add an attachment (e.g., Summary Report) that demonstrates that the device passed testing according to IEC 60601-4-2. If a Declaration of Conformity was used, choose TR 60601-4-2 in the Standards section above, and indicate you are declaring conformity to it (i.e., it is not for general use). Then attach a statement here indicating this standard is included in the eSTAR generated Declaration of Conformity in the Administrative Documentation section below.
Open Attachment	018_EMC Summary Report for (b)(4) Delete Attachment

Emitters, Allowances, Deviations & Modifications

If any of the referenced standard's allowances were used during the testing (e.g., lowered ESD immunity), please provide these below.

If there were any deviations from the referenced standard, please describe these below.

Add Attachment	Please add an attachment that includes descriptions of all modifications, as well as a statement indicating that all changes or modifications will be incorporated in the device intended for marketing. Not providing an attachment indicates no modifications were made in order to pass any of the EMC tests. In addition, be sure you include an adequate assessment of whether these modifications might impact other aspects of the device (e.g., performance, biocompatibility). It is recommended that the attachment contain information to demonstrate that the modifications would have no impact on the other aspects or that the modified device was used for the other performance tests.

Records processed under FOIA Request 2023-8128, Released by CDRH on 10-02-2024

Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to common EM emitters including but not limited to: radio-frequency identification (RFID) readers, security systems (e.g., metal detectors or electronic article surveillance (EAS)), wireless power transfer (WPT), and 5G cellular signals. Security systems may be excluded if the device is only intended for use in a Professional Healthcare Facility environment.	018_Page 1 and 2 "Results Summary"
Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to unique medical emitters, such as electrocautery, MRI, electrosurgical units, and diathermy devices. Alternatively, if the intent is to caution against exposure to these or other specific potential electromagnetic disturbance sources, please specifically cite the attachment(s) and page number(s) where the instructions describe avoiding the source or other mitigations.	013_Instructions for Use K231276; Warnings and Cautions are included in PL-09 IFU against exposure to other specific potential

Device Labeling

Please specifically cite the attachment(s) and page number(s) where the recommended separation distances and appropriate environment(s) of use are located in the labeling. This information is analogous to the Guidance Tables 1 through 8 from the 3rd edition of IEC 60601-1-2.	013_Instructions for Use K231276; PL-09, Instructions for Use, pages 148 to 155 of 235
Please specifically cite the attachment(s) and page number(s) where the performance of the device that was determined to be Essential Performance and a description of what the operator can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances are located in the labeling.	013_Instructions for Use K231276; Page 148 of 235 (IFU page 123); Page 210 of 235 (TM page 31)
Please specifically cite the attachment(s) and page number(s) where the compliance for each emissions and immunity standard or test specified by the collateral standard (e.g., emissions class and group and immunity test level) are located in the labeling.	013_Instructions for Use K231276; PL-09, Instructions for Use, pages 148 to 155 of 235
Please specifically cite the attachment(s) and page number(s) where any deviations from the collateral standard and allowances used are described in the labeling. Type "N/A" if not applicable.	N/A

Wireless Technology

How many separate wireless functions are there (maximum of 5)?	(b)(4)

Wireless Function 1

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request (b)(4); Released by CDRH on 10-02-2024

Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The BLE link shall pass all digitized data from the sensor to the SmartCardia phone which is in the RF chamber.

Please select all the technologies that apply to this wireless function:

☒ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☐ Cellular ☐ Other

Bluetooth

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 019_Wireless Coexistence and RFID Testing_BlueTooth.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DIDSI at CDRH-EDISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	(b)(4)
Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use K231276, pages
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use K231276, pages 013_148 of 235 through
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Wireless Function 2

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

(b)(4)

Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The Cellular link is expected to disconnect while in the RF Chamber Data corrupted or lost packets due to RF interference shall be retransmitted when the interference is removed. Pass criteria is a continuous ECG waveform file reviewed in the SmartCardia backend at the conclusion of the test.

Please select all the technologies that apply to this wireless function:

☐ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☒ Cellular ☐ Other

Cellular

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 020_Wireless Coexistence and RFID Testing_Cellular.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

The Functional Wireless Performance (FWP) of the SmartCardia 7L Platform was monitored using the Key Performance Indicators listed in the attached test report, pages 020_Page 16 of 36 and 020_Page 17 of 36.

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	

(b)(4)

Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	(b)(4)
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use K231276, pages
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use K231276, pages 013_148 of 235 through
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The SmartCardia 7L Platform was tested for compliance with the following standards to verify the electrical, mechanical, and thermal safety considerations:

- IEC 60601-1 General Requirements for Basic Safety and Essential Performance
  - o Essential Performance – Defibrillation Performance (b)(4)
- IEC 60601-1-2 Collateral Standard, Electromagnetic Disturbances – Requirements and Tests
  - o Wireless Coexistence (ANSI C63.27) and Exposure to RFID (AIM 7351731)
- IEC 60601-1-11 Collateral Standard, Medical Equipment used in the Home Healthcare Environment
- IEC 60601-2-47 Requirements for Ambulatory ECG Systems
- IEC 60601-1-8 General requirements, tests and guidance for Alarm Systems in Medical Equipment
- EC12 Requirements for Disposable ECG Electrodes
- ISO 10993-5 Biological Evaluation for Cytotoxicity
- ISO 10993-10 Biological Evaluation for Sensitivity

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

The SmartCardia 7L Platform was tested for energy reduction to verify defibrillation safety required by IEC 60601-1 ed3, second amendment clause 8.5.5.2.
The energy reduction test was performed as directed in the standard and the results of the test are provided in IEC 60601-1 report from (b)(4) This is included in the file 022_Performance Testing – Bench.

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.	
Open Attachment	021_EMC, Wireless, & EMT Test Reports.pdf	Delete Attachment

Records processed under FDA Premarket CAM Pilot Program for CDRH on 10-02-2024

Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.	K192757

Records processed under FOIA Request 2023-8118, Released by CDRH on 10-02-2024

Add Attachment	Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.	?

Other Non-Clinical Evidence

Open Attachment (b)(4) K231276_S001.pdf Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

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If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request 2022-8116 Released by CDRH on 10-02-2024

References

Is literature referenced in the submission? Yes

Add Attachment | Please add legible reprints or a summary of each article in English.

Open Attachment | 023_Reference Literature.pdf | Delete Attachment

Please include a discussion of how each article is applicable to support the submission.

Summary of Literature Supporting the SmartCardia 7L Platform
Published scientific papers or documents are referenced to support the SmartCardia 7L Platform.

1. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part IV: The ST Segment, T and U Waves, and the QT Interval. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society

Pentti M. Rautaharju, MD, PhD; Borys Surawicz, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC

(b)(4)

2. Cleveland Clinic: Center for Continuing Education, Atrial Fibrillation; Cantillon, Daniel J, Amuthan, Ram. August 2018 www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/atrial-fibrillation/

(b)(4)

3. Hannun, A.Y., Rajpurkar, P., Haghpanahi, M. et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nature Medicine 25, 65–69 (2019).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

4. Steven Walfish, November 30, 2016, FOI Services Teleconference TC161130 Presentation, Slide 'Sample Size for Proportions'. https://www.foiservices.com/tc-docs/tc161130/TC161130A.pdf

(b)(4)

Administrative Documentation

Add Attachment	General Summary of Submission/Executive Summary	?
Open Attachment	023_General Summary of Submission-Executive Summary.pdf	Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.	Yes
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	No

Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.	?
Open Attachment	User Fee Cover Sheet.pdf	Delete Attachment

Please enter in the User Fee Payment Identification Number.	(b)(4)	?

Show User Fee Introduction

Records Processed Under FOIA Request Number: 2024

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of SmartCardia SA, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Srinivasan Murali

Digitally signed by Srinivasan Murali
Date: 2023.07.28 21:59:08 +05'30'

Date Signed: 2023-07-28

510(k)#: K231276 For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Declaration of Conformity

Application # K231276

Company Name	SmartCardia SA
Company Address	EPFL Innovation Park Building C Lausanne 1015 Switzerland
Device Trade Name	SmartCardia 7L Platform

The object of the declaration described above is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:201	19-46
IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
IEC	60601-1-11 Edition 2.0 2015-01	19-14
IEC	60601-2-47 Edition 2.0 2012-02	3-155
ISO	10993-5 Third edition 2009-06-01	2-245
ISO	10993-10 Third Edition 2010-08-01	2-174
ISO	10993-23 First edition 2021-01	2-291
ANSI AAMI	EC12:2000/(R)2015	3-52

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of:	Lausanne	2023.07.28
Full Name and Function:	Srinivasan Murali, CEO	
Signature	Srinivasan Murali Digitally signed by Srinivasan Murali Date: 2023.07.28 22:00:41 +05'30'	

510(k) Summary

Prepared on: 2023-07-28

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Additional Information Response

Is this a response to an Additional Information request?	Yes

Additional Information

Changes that are necessary to resolve deficiencies should be made in the respective section. For example, if additional Sterilization information will be provided to resolve a deficiency, this documentation should be added to the Sterilization documentation that is already present. If attachments need to be updated, remove the old attachments and replace them with the new attachments (be sure to give new attachments a different name in comparison to the old attachments to ensure they are distinguished). Data that are typed in can also be modified. If you need to respond to subsequent Additional Information requests, you should replace the deficiencies below with those from the latest Additional Information request when responding. Although previously submitted data and attachments will remain in the FDA database, old data superseded by new data will not be considered the final data in our final review.

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response		Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2023-8118 Released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See response to 3a, and 3b below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See Responses to 4a, 4b, 4b i, 4b ii below

Add Response Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2018-8118, Released by CDRH on 10-02-2021

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See Response to 4b i and 4b ii below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2018-8118, Released by CDRH on 10-02-2021

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

SmartCardia Response:

See Response to 5a, 5b, 5c, 5d, 5e below

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Electronically processed under FOIA Request 2023-8113, Released by CDRH on 10-02-2024

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Records processed under FOIA Request 2023-6213; Released by CDRH on 10-02-2024

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Records processed under FOIA Request 2018-8118, Released by CDRH on 10-02-2018

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

(b)(4)

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

(b)(4)

Add Response | Delete Response

Records processed under FOIA Request F-2024-4611 released by CDRH on 10-02-2024

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation
Additional Information Response

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review to the Center for Devices and Radiological Health (CDRH) using

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

510(k) Summary

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: steurerbob@gmail.com <steurerbob@gmail.com>

Sent: Wednesday, August 30, 2023 2:42 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov>

Cc: 'Francisco Rincon' <francisco.rincon@smartcardia.com>; 'Srini Murali' <srinivasan.murali@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; 'James Welch' <jwelch@arcbiomed.com>

Subject: RE: [EXTERNAL] 2nd Hold Confirmation

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

I believe we want to proceed with what we have now, (b)(4)

(b)(4)

Best Regards,

Bob Steurer

[cid:image001.png@01D9DB47.31ADB950]Steurer Consulting Group

http://www.scgconsulting.net<http://secure-web.cisco.com/1-eWoFDmRE-Z_xZiwl80w0zGdLXGEMbk-nDApXVSH5-PXIfsLfgMy5RgpyV8VhoGuIhU0Y9g20gvlQR2PV9w1-WDFiMBbpzTA21Pn1dWQEZsgJzFkbT7iZFfSgYB41ALUxBNNgoNeR8qI0luthaO0Dz-8lfoy8u4j5d_w8QLtCA6qRueKNZzOappcqq7_n9O-H9OTugEFjOGjmrL0A1B9Jzsi3qL8eX-r-P5FGBZrTm4/http%3A%2F%2Fwww.scgconsulting.net%2F>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Wednesday, August 30, 2023 1:28 PM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Cc: Francisco Rincon <francisco.rincon@smartcardia.com<mailto:francisco.rincon@smartcardia.com>>; Srini Murali <srinivasan.murali@smartcardia.com<mailto:srinivasan.murali@smartcardia.com>>; 'Brodie Pedersen' <brodiecp@borderlessmd.com<mailto:brodiecp@borderlessmd.com>>; James Welch <jwelch@arcbiomed.com<mailto:jwelch@arcbiomed.com>>

Subject: RE: [EXTERNAL] 2nd Hold Confirmation

Hi Bob,

Thank you so much for all of your help with this.

As mentioned in our meeting yesterday, we reached out to the 510(k) Staff regarding the option of putting this submission on the 2nd hold. We just heard back from them that we can move forward with a 2nd hold for this submission. Please help confirm whether you prefer to put this submission on the 2nd hold or proceed with where we are right now (b)(4)

Please let me know if you have any questions.

Thank you,

Vincent

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: steurerbob@gmail.com<mailto:steurerbob@gmail.com>
<steurerbob@gmail.com<mailto:steurerbob@gmail.com>>

Sent: Wednesday, August 30, 2023 12:16 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Cc: Francisco Rincon
<francisco.rincon@smartcardia.com<mailto:francisco.rincon@smartcardia.com>>; Srini
Murali <srinivasan.murali@smartcardia.com<mailto:srinivasan.murali@smartcardia.com>>;
'Brodie Pedersen' <brodiecp@borderlessmd.com<mailto:brodiecp@borderlessmd.com>>; James
Welch <jwelch@arcbiomed.com<mailto:jwelch@arcbiomed.com>>

Subject: [EXTERNAL] Revision History, Regression Testing, IFU with note added

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

(b)(4)

Thank you,

Bob

Best Regards,

Bob Steurer

[cid:image001.png@01D9DB47.31ADB950]Steurer Consulting Group

http://www.scgconsulting.net<http://secure-
web.cisco.com/1uUweTdBzrTkvEvNfoBtNDHuyMhRbvGxBSZq0nwUFa_EIeglEZNNGkGVb2q2l2GNppg1fypDs
5iP0l1P1m775HaEdbO4e-
wwoklRvhmsHxoH6GfegmTiWj2hG7IeM9kjdrK_udrmGYy3gtZYBvCsUZRawkxfTlzjFBcWdJN7EtB-
JZy_hfRFR63lW_lc2hQSq2Lm0uGDSYbd7bvjaPHdrHA/http%3A%2F%2Fwww.scgconsulting.net%2F>

m: +1 425-358-1072

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

August 30, 2023

SmartCardia SA
% Robert Steurer
Consultant
Steurer Consulting Group LLC
800 Blue Quail Rd
Keller, Texas 76248

Re: K231276
Trade/Device Name: SmartCardia 7L Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DSI
Dated: July 28, 2023
Received: July 28, 2023

Dear Robert Steurer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Shruti N. Mistry -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231276

Device Name
SmartCardia 7L Platform

Indications for Use *(Describe)*
The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

510(k) Summary

Date Prepared:	July 21, 2023
Submitter:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland Srinivasan Murali SmartCardia SA Phone: +41 7887 50864 Fax: N/A Email: srinivasan.murali@smartcardia.com
Application Correspondent:	Robert Steurer Principal Consultant Steurer Consulting Group 800 Blue Quail Rd. Keller, TX 76248 steurerbob@gmail.com +1 (425) 358-1072
Manufacturing Site:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland
Common Name:	SmartCardia 7L Platform
Classification Name:	Radiofrequency Physiological Signal Transmitter And Receiver
Device Class:	Class II
Primary Classification Regulation:	21 CFR 870.2910
Primary Product Code:	DRG
Secondary Codes:	DSI
Primary Predicate Device:	VitalConnect, Inc.; VitalConnect Biosensor; K192757

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Secondary Predicate / Reference Device:	InfoBionics; MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System; K160064
Device Description:	The SmartCardia 7L Platform is a body worn Holter monitoring product that is designed with a disposable adhesive 7L Patch and reusable 7L Sensor. It is designed to be worn by the patient for up to 14 days. If longer monitoring is necessary, the 7L Patch is removed from the body, the 7L Sensor is removed from the worn 7L Patch which is discarded. The 7L Sensor is inserted into a new 7L Patch and the new assembly is placed on the patient for monitoring to continue. The 7L Sensor/7L Patch assembly communicates to the SmartCardia Phone via Bluetooth technology and shows the patient's heart rate and ECG on its display and allows the patient to input symptoms (Mark Event) which are shown in the patient record. The SmartCardia Phone has a medical grade mains powered charger and uses its cellular technology to act as a gateway to the SmartCardia Cloud Service provided by Amazon Web Services. The SmartCardia Phone is pre-configured by SmartCardia and placed in a kiosk mode. Data stored in the SmartCardia cloud can be viewed in the SmartCardia Web Browser application by a clinician or healthcare provider. The SmartCardia 7L Platform incorporates two modes of Holter monitoring: 1. Holter Monitoring (up to 48 hours) and Extended Holter Monitoring (>48 hours and up to 14 days), 2. Event Monitoring (up to 48 hours, and >48 hours up to 14 days) During any of the selected modes of Holter monitoring, a clinician or healthcare provider can use the SmartCardia Web Browser and continuously monitor the patient. The SmartCardia 7L Platform provides alarm notifications for heart rate and atrial fibrillation. As stated in the Intended Use statement, the system is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required. There are no alarm signals presented to the clinician for conditions other than heart rate and atrial fibrillation. The SmartCardia 7L Platform, like most Holter monitoring systems performs retrospective analysis and identifies events which it shows the clinician when they are reviewing historical data. The clinician must then review these events and determine if they are indeed valid and should be included in a physician's report. These events are things like "Ventricular Bigeminy', 'Supraventricular Couplet', etc. A full list is included in the Clinician Instructions for Use.
Intended Use / Indications for Use:	The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for: 1. Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 3. Patients with symptoms that may be due to cardiac arrhythmias. These

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may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.

5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.

2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Summary of Substantial Equivalence:

Substantial Equivalence – Intended Use:

The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

MoMe® Kardia is intended to be used for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac

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arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)

4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. MoMe® Kardia is contraindicated for:

1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Substantial Equivalence – Intended Use Comparison Statement:
The indications for use of the primary predicate and the predicate / reference device are substantially equivalent to the SmartCardia SA 7L Platform.

Substantial Equivalence – Technological Characteristics:
The SmartCardia 7L Platform and the predicate/reference devices technological characteristics:

1) They are body worn sensors that communicate wirelessly to a gateway device that transmits the data to a cloud bases server for storage and further analysis.
2) The material used in the predicate device and the SmartCardia 7L body worn device is the same.
   a. The ECG electrodes are a hydrogel component
   b. The adhesive body is a hydrocolloid material.
   c. The predicate/reference device uses individual ECG electrodes connected to the transmitter device via wire leads.
   d. The devices use integrated batteries to power the body worn sensor.
      i. The predicate device uses zinc air and the SmartCardia 7L body worn device uses manganese oxide-lithium.
      ii. Both are disposable and do not require charging.
   e. The predicate device and SmartCardia 7L body worn device both use Bluetooth BLE communication to a gateway.
      i. The predicate device communicates to a tablet,
      ii. The SmartCardia 7L body worn device communicates to a smartphone.
      iii. The predicate/reference device incorporates a cellular transmitter directly into the sensor and transmits via cellular technology to the cloud server.
      iv. These gateways then transmit the data to a cloud server.
3) The VitalConnect predicate device measures more physiological parameters than the SmartCardia 7L Platform.
4) The InfoBionics predicate/reference device measures just ECG and heart rate which is the same as the SmartCardia 7L Platform.

Substantial Equivalence – Technological Characteristics Comparison

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Statement:
The SmartCardia 7L Platform has the same technological characteristics as the predicate and predicate/reference device.

Non-Clinical Bench Performance Testing Summary:

The SmartCardia 7L Platform was tested for compliance with FDA Guidance "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" released October 28, 2003.

Additional non- clinical bench performance testing was done per the following:

- Basic Safety and Essential Performance per IEC 60601-1
- Electromagnetic Compatibility per IEC 60601-2
- Wireless Coexistence testing per FDA Guidance document "Radio Frequency Wireless Technology in Medical Devices, August 14, 2013", and exposure to RFID devices per AIM 7351731.
- Wireless Coexisting testing per ANSI C63.27: 2017
- ECG Monitoring for Ambulatory ECG devices per IEC 60601-2-47
- Life Cycle testing per IEC 60601-11 Home Healthcare
- ECG electrode testing per ANSI/AAMI EC12
- Cleaning and disinfection methods as defined by SmartCardia SA
- ECG Waveform Quality and Wearability
- Effects of Sensor Positioning on ECG Performance
- DVR-66 SCDB ECG Test Results (algorithm testing and reporting) per EC57

Objective(s) of the Test(s):
To test the claimed ranges of measurement provided in the specification and labeling that support the intended use and three monitoring modes of operation: Holter and Extended Holter (Ambulatory electrocardiographic monitoring, Event Monitoring.

Test Methods
Bench testing was performed on an end-to-end system using electronic patient simulators and/or electronic test equipment (signal generators, etc.). This was performed per the applicable standards using production equivalent units.

Pass/Fail Criteria
Pass criteria is compliance with the claimed range and precision provided in the labeling for the SmartCardia 7L Platform. Deviations from the recognized standard criteria are identified in the applicable test report.

Results Summary
Testing showed that the SmartCardia 7L Platform met the pass/fail criteria established by the appropriate standards.
The SmartCardia 7L Platform is contraindicated for use during defibrillation and is visibly labeled to indicate removal during defibrillation. Defibrillator protection testing was performed to ensure there was not excessive energy shunted away from the patient during defibrillation.

To verify the reproduction of the ECG and ensure that there are not significant morphological changes that could impact the

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measurements and/or classifications, SmartCardia SA performed verification testing using a standard 12 lead ECG machine and comparing the morphology and ECG characteristics. The result of this testing is included in the document, DVR-67-01 ECG Waveform Quality and Wearability Report is included in this section.

The ECG detection algorithm was tested per ANSI/AAMI EC57 standard for testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms. The SmartCardia 7L Platform does not claim ST analysis or measurements. Therefore, the sections of the EC57 standard relating to ST measurement is not applicable. Because of the nature of the SmartCardia 7L Platform as a body worn sensor and patch device with the electrodes in close proximity to each other, and not utilizing ECG lead wires such as a traditional ECG device, SmartCardia developed a protocol and database for evaluating the analysis algorithm. The results show that the SmartCardia 7L Platform algorithm detection and reported results for the stated output arrhythmia were satisfactory and met industry norms.

Discussion/Conclusion: Based on a review of the test results and a comparison to the predicate devices characteristics and known specifications, the results show that the SmartCardia 7L Platform is substantially equivalent to the predicate and reference devices.

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2564
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4584

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: June 29, 2023

Reviewer: Vincent Do

510(k)# K231276 Subject: Traditional

Applicant: SmartCardia SA	**Device Trade Name:** SmartCardia 7L Platform
Contact Name: Robert Steurer	**Contact Title:** Consultant
Correspondent Firm: Steurer Consulting Group LLC	**Phone:** (425) 358-1072 **Email:** steurerbob@gmail.com
Received Date: May 2, 2023	**Due Date:** August 1, 2023
Pro Code(s): DRG **Class:** II **Reg #:** 870.2910	**Reg Name:** Radiofrequency Physiological Signal Transmitter And Receiver
Pro Code(s): DSI Class: II Reg #: 870.1025	Reg Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192757	DRG, DSI, MHX	VitalPatch 5D Biosensor - single, VitalPatch 7D Biosensor - single, VitalPatch 5D Biosensor – bag of 20, VitalPatch 7D Biosensor – bag of 20	VitalConnect, Inc.
K160064	DSI	MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System	Infobionic, Inc.

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K231276
SmartCardia SA
Trade/Device Name: SmartCardia 7L Platform
Contact Name: Robert Steurer

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K231276 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K231276 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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MAJOR DEFICIENCY LIST

(b)(4)

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(b)(4)

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(b)(4)

MINOR DEFICIENCY LIST

(b)(4)

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(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two

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business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

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510(k) Summary

Date Prepared:	July 21, 2023
Submitter:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland Srinivasan Murali SmartCardia SA Phone: +41 7887 50864 Fax: N/A Email: srinivasan.murali@smartcardia.com
Application Correspondent:	Robert Steurer Principal Consultant Steurer Consulting Group 800 Blue Quail Rd. Keller, TX 76248 steurerbob@gmail.com +1 (425) 358-1072
Manufacturing Site:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland
Common Name:	SmartCardia 7L Platform
Classification Name:	Radiofrequency Physiological Signal Transmitter And Receiver
Device Class:	Class II
Primary Classification Regulation:	21 CFR 870.2910
Primary Product Code:	DRG
Secondary Codes:	DSI
Primary Predicate Device:	VitalConnect, Inc.; VitalConnect Biosensor; K192757

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Intended Use / Indications for Use:	The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for: 1. Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 3. Patients with symptoms that may be due to cardiac arrhythmias. These

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may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.

5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.

2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Summary of Substantial Equivalence:

Substantial Equivalence – Intended Use:

The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.

The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

MoMe® Kardia is intended to be used for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac

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arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)

4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. MoMe® Kardia is contraindicated for:

1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias.

Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Substantial Equivalence – Intended Use Comparison Statement:
The indications for use of the primary predicate and the predicate / reference device are substantially equivalent to the SmartCardia SA 7L Platform.

Substantial Equivalence – Technological Characteristics:
The SmartCardia 7L Platform and the predicate/reference devices technological characteristics:

1) They are body worn sensors that communicate wirelessly to a gateway device that transmits the data to a cloud bases server for storage and further analysis.
2) The material used in the predicate device and the SmartCardia 7L body worn device is the same.
   a. The ECG electrodes are a hydrogel component
   b. The adhesive body is a hydrocolloid material.
   c. The predicate/reference device uses individual ECG electrodes connected to the transmitter device via wire leads.
   d. The devices use integrated batteries to power the body worn sensor.
      i. The predicate device uses zinc air and the SmartCardia 7L body worn device uses manganese oxide-lithium.
      ii. Both are disposable and do not require charging.
   e. The predicate device and SmartCardia 7L body worn device both use Bluetooth BLE communication to a gateway.
      i. The predicate device communicates to a tablet,
      ii. The SmartCardia 7L body worn device communicates to a smartphone.
      iii. The predicate/reference device incorporates a cellular transmitter directly into the sensor and transmits via cellular technology to the cloud server.
      iv. These gateways then transmit the data to a cloud server.
3) The VitalConnect predicate device measures more physiological parameters than the SmartCardia 7L Platform.
4) The InfoBionics predicate/reference device measures just ECG and heart rate which is the same as the SmartCardia 7L Platform.

Substantial Equivalence – Technological Characteristics Comparison

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Statement:
The SmartCardia 7L Platform has the same technological characteristics as the predicate and predicate/reference device.

Non-Clinical Bench Performance Testing Summary:

The SmartCardia 7L Platform was tested for compliance with FDA Guidance "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" released October 28, 2003.

Additional non- clinical bench performance testing was done per the following:

- Basic Safety and Essential Performance per IEC 60601-1
- Electromagnetic Compatibility per IEC 60601-2
- Wireless Coexistence testing per FDA Guidance document "Radio Frequency Wireless Technology in Medical Devices, August 14, 2013", and exposure to RFID devices per AIM 7351731.
- Wireless Coexisting testing per ANSI C63.27: 2017
- ECG Monitoring for Ambulatory ECG devices per IEC 60601-2-47
- Life Cycle testing per IEC 60601-11 Home Healthcare
- ECG electrode testing per ANSI/AAMI EC12
- Cleaning and disinfection methods as defined by SmartCardia SA
- ECG Waveform Quality and Wearability
- Effects of Sensor Positioning on ECG Performance
- DVR-66 SCDB ECG Test Results (algorithm testing and reporting) per EC57

Objective(s) of the Test(s):
To test the claimed ranges of measurement provided in the specification and labeling that support the intended use and three monitoring modes of operation: Holter and Extended Holter (Ambulatory electrocardiographic monitoring, Event Monitoring.

Test Methods
Bench testing was performed on an end-to-end system using electronic patient simulators and/or electronic test equipment (signal generators, etc.). This was performed per the applicable standards using production equivalent units.

Pass/Fail Criteria
Pass criteria is compliance with the claimed range and precision provided in the labeling for the SmartCardia 7L Platform. Deviations from the recognized standard criteria are identified in the applicable test report.

Results Summary
Testing showed that the SmartCardia 7L Platform met the pass/fail criteria established by the appropriate standards.
The SmartCardia 7L Platform is contraindicated for use during defibrillation and is visibly labeled to indicate removal during defibrillation. Defibrillator protection testing was performed to ensure there was not excessive energy shunted away from the patient during defibrillation.

To verify the reproduction of the ECG and ensure that there are not significant morphological changes that could impact the

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measurements and/or classifications, SmartCardia SA performed verification testing using a standard 12 lead ECG machine and comparing the morphology and ECG characteristics. The result of this testing is included in the document, DVR-67-01 ECG Waveform Quality and Wearability Report is included in this section.

The ECG detection algorithm was tested per ANSI/AAMI EC57 standard for testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms. The SmartCardia 7L Platform does not claim ST analysis or measurements. Therefore, the sections of the EC57 standard relating to ST measurement is not applicable. Because of the nature of the SmartCardia 7L Platform as a body worn sensor and patch device with the electrodes in close proximity to each other, and not utilizing ECG lead wires such as a traditional ECG device, SmartCardia developed a protocol and database for evaluating the analysis algorithm. The results show that the SmartCardia 7L Platform algorithm detection and reported results for the stated output arrhythmia were satisfactory and met industry norms.

Discussion/Conclusion: Based on a review of the test results and a comparison to the predicate devices characteristics and known specifications, the results show that the SmartCardia 7L Platform is substantially equivalent to the predicate and reference devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7L Revision History

The following revisions are for the 7L Platform

Sensor

(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10993 New Hampshire Avenue
Silver Spring, MD 20993

DATE: August 29, 2023

FROM: Kevin Dang, Biomedical Engineer
CDRH/OPEQ/OHT2/DHT2A/EHRRT

SUBJECT: ECG Consult
K231276/S001 – SmartCardia "7L Platform"

TO: Vincent Do, Biomedical Engineer
CDRH/OPEQ/OHT2/DHT2A

(b)(5)

Digital Signature Concurrence Table	
For each of the specific issues identified in the recommended requests to the applicant above, I provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard or confirmed to the best of my ability (for interactive deficiencies 1-3 sent on 08/22/2023 and interactive deficiency sent on 08/25/2023) that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s)	
Consultant	Kevin Dang -S Digitally signed by Kevin Dang -S Date: 2023.08.29 15:04:50 -04'00'

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: steurerbob@gmail.com <steurerbob@gmail.com>

Sent: Thursday, August 24, 2023 3:01 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Attached is our response to your Interactive Information Request 2.

This will be sent as two emails since the IFU and other files are too large.

(b)(4)

If you need anything else, please let me know.

Best Regards,

Bob Steurer

[cid:image001.png@01D9D691.D45CBDF0]Steurer Consulting Group

http://www.scgconsulting.net<http://www.scgconsulting.net/>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Wednesday, August 23, 2023 8:16 AM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Hi Bob,

That is correct. You can send the responses to me.

Please do not hesitate to let me know if you have any questions.

Thank you,

Vincent

From: steurerbob@gmail.com<mailto:steurerbob@gmail.com> <steurerbob@gmail.com<mailto:steurerbob@gmail.com>>

Sent: Wednesday, August 23, 2023 8:51 AM

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

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Subject: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

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Hi Vincent,

We will be responding as soon as we can, and I will let you know if we need any additional clarification.

I assume all of the responses can be done via email, correct?

Best Regards,

Bob Steurer

[cid:image001.png@01D9D691.D45CBDF0]Steurer Consulting Group

http://www.scgconsulting.net<http://www.scgconsulting.net/>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Tuesday, August 22, 2023 4:21 PM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Subject: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Hi Bob,

For further evaluation of your submission, we would like to request additional details. Please provide a response to the following comments by COB Thursday 08/24:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please let me know if you have any questions.

Thank you,

Vincent

Vincent Do

Lead Reviewer

Cardiac Ablation, Mapping and Imaging Devices Team

Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CDRH | Food and Drug Administration

Tel: (240) 402-4584

Email Address: Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>

[cid:image002.png@01D9D691.D45CBDF0]<http://www.fda.gov/>

[cid:image003.jpg@01D9D691.D45CBDF0]<https://www.facebook.com/FDA>
[cid:image004.jpg@01D9D691.D45CBDF0] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D9D691.D45CBDF0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image006.jpg@01D9D691.D45CBDF0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image007.jpg@01D9D691.D45CBDF0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

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August 30, 2023

SmartCardia SA
% Robert Steurer
Consultant
Steurer Consulting Group LLC
800 Blue Quail Rd
Keller, Texas 76248

Re: K231276
Trade/Device Name: SmartCardia 7L Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DSI
Dated: July 28, 2023
Received: July 28, 2023

Dear Robert Steurer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Shruti N. Mistry -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Thursday, August 24, 2023 3:04 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

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Hi Vincent,

Attached is our response to your Interactive Information Request 2.

(b)(4)

If you need anything else, please let me know.

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Wednesday, August 23, 2023 8:16 AM
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Thank you,

Vincent

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Sent: Wednesday, August 23, 2023 8:51 AM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Subject: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

We will be responding as soon as we can, and I will let you know if we need any additional clarification.

I assume all of the responses can be done via email, correct?

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Tuesday, August 22, 2023 4:21 PM
To: steurerbob@gmail.com
Subject: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Hi Bob,

For further evaluation of your submission, we would like to request additional details. Please provide a response to the following comments by COB Thursday 08/24:

(b)(4)

Please let me know if you have any questions.

Thank you,

Vincent
Vincent Do
Lead Reviewer

Cardiac Ablation, Mapping and Imaging Devices Team
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
Tel: (240) 402-4584
Email Address: Vincent.Do@fda.hhs.gov

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received: *Here*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2564
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4584

Premarket Notification 510(k) Review

Date: August 30, 2023

Reviewer: Vincent Do

510(k)# K231276/S001 Subject: Traditional

Applicant: SmartCardia SA	**Device Trade Name:** SmartCardia 7L Platform
Contact Name: Robert Steurer	**Contact Title:** Consultant
Correspondent Firm: Steurer Consulting Group LLC	**Phone:** (425) 358-1072 **Email:** steurerbob@gmail.com
Received Date: July 28, 2023	**Due Date:** August 30, 2023
Pro Code(s): DRG **Class:** II **Reg #:** 870.2910	**Reg Name:** Radiofrequency Physiological Signal Transmitter And Receiver
Pro Code(s): DSI Class: II Reg #: 870.1025	Reg Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192757	DRG, DSI, MHX	VitalPatch 5D Biosensor - single, VitalPatch 7D Biosensor - single, VitalPatch 5D Biosensor – bag of 20, VitalPatch 7D Biosensor – bag of 20	VitalConnect, Inc.
K160064	DSI	MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System	Infobionic, Inc.

(b)(5)

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.16.00)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s). I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.	
Reviewer Sign-Off	Vincent N. Do -S Digitally signed by Vincent N. Do -S Date: 2023.08.30 13:05:47 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Redacted per FOIA Request 2023-2112 Released by CDRH on 04-07-2023

electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 2.1 (2022-10-07)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. We tested eSTAR submissions up to 1GB in size. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

Q: If an eSTAR is signed, a message is displayed at the top saying changes were made after signing. Why?

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.1 (2022-10-07): Grey text in FDA standards selection no longer disappears when an SDO is selected. Warning

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	(•) New Application/Submission ( ) Additional Information

Records processed under FOIA Request 2021-5105 Released Date: January 19, 2022

Cover Letter / Letters of Reference

Add Attachment	Attach your Cover Letter	?
Open Attachment	Cover Letter Signed.pdf	Delete Attachment
Add Attachment	Attach any Letters of Reference	?

Applicant Information

Contact

Title: Mr. | Last Name: Murali | First Name: Srinivasan

Email: srinivasan.murali@smartcardia.com | Phone Number: +41 7887 50864

Occupation Title: Chief Executive Officer

Company

Company Name: SmartCardia SA

Address - Line 1: EPFL Innovation Park Building C

Address - Line 2:

City: Lausanne | State: | Zip: 1015 | Country/Region: Switzerland

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title: | Last Name: Steurer | First Name: Robert

Email: steurerbob@gmail.com | Phone Number: 425-358-1072

Occupation Title: Consultant

Company

Company Name: Steurer Consulting Group LLC

Address - Line 1: 800 Blue Quail Rd

Address - Line 2:

City: Keller | State: TX | Zip: 76248 | Country/Region: United States

Add Correspondent/Consultant | Delete Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Are there prior related submissions or regulator interaction for the subject device(s)? Yes

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

(b)(4) Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment 002_Prior Coorespondence and Regulator Interaction QSUB Delete Attachment

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A	19-46	Delete Standard

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment 60601-1 Extent of Standard Conformance Checklist.pdf Delete Attachment

Add Standard

IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36	Delete Standard

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collater

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment 60601-2 EMC Extent of Standard Conformance Checklist.pdf Delete Attachment

Add Standard

IEC	60601-1-11 Edition 2.0 2015-01	19-14	Delete Standard

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collate

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment 60601-1-11 Home Healthcare.pdf Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request released by CDRH on 10-02-2024

Add Standard

IEC	60601-2-47 Edition 2.0 2012-02	3-155	Delete Standard

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	60601-2-47 Ambulatory ECG Extend to Standard Conformance	Delete Attachment

Add Standard

IEC	60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131	Delete Standard

Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance ¿ Collate

Are you using this standard for general use, or are you declaring conformity to it?	General Use	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	ISO 60601-1-8 Alarm Standard Checklist.pdf	Delete Attachment

Add Standard

ISO	10993-5 Third edition 2009-06-01	2-245	Delete Standard

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?

Add Standard

ISO	10993-10 Third Edition 2010-08-01	2-174	Delete Standard

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?

Add Standard

ISO	10993-23 First edition 2021-01	2-291	Delete Standard

Biological evaluation of medical devices - Part 23: Tests for irritation

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Add Standard

ANSI AAMI	EC12:2000/(R)2015	3-52	Delete Standard

Disposable ECG electrodes

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity	?
Add Attachment	Standards Details / Supplemental Documentation per ISO/IEC 17050-2	?
Open Attachment	EC12 Disposable ECG Electrodes Checklist.pdf	Delete Attachment

Add Standard

Records processed under FOIA Request 2024-8126 Released by CDRH on 10-02-2024

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

SmartCardia 7L Platform	Model Number/Name	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	No
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	Yes
• Please check the attributes that are applicable to your device.	☒ Cloud Communication ☒ Network connection (active or not) ☒ Wireless communication in any form ☐ USB/serial ports/removable media ☒ Software upgrades (this includes patches) ☐ None of the above
Is the device or a component packaged as sterile?	No
The device/system uses or is... (choose all that apply)	☒ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use device(s) ☒ a reusable multi-patient use device(s)
The environment of use of the device/system includes... (choose all that apply)	☒ Professional Healthcare Facility ☒ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the device a combination product?	No
Is the device electrical (battery or wall powered)?	Yes, it is battery and mains powered
• Does the device/system include wireless technology?	Yes
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

Records processed under FOIA Request 2023/8118, Released by CDRH on 10-02-2024

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

(b)(4)

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	007_Comprehensive Device Description and Principles of	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	008_Device Description Sensor mechanical dwgs.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	010_Description of Device Packaging.pdf	Delete Attachment

Accessories

Redacted per FOIA Exemption (b)(4) 5 USC 552(b)(4) 2018; Released by CDRH on 10-02-2024

Is the device intended to be marketed with accessories? Yes ?

Add Accessory | List all the accessories to be marketed with the submission.

7L Patch | Delete Accessory

Please include a description of each accessory (see help text for the information we request be included). Please also provide the submission number if the accessory was previously marketed (or a statement that it was not). ?

The SmartCardia 7L Patch is a single use component that is disposable. If extended use of the SmartCardia 7L Platform is required, the 7L Patch is replaced. The SmartCardia 7L Patch has not been previously marketed.

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request? No ?

Add Attachment | Please attach Accessory Pictures, Illustrations, Schematics, and/or Diagrams

Open Attachment | 009_SmartCardia 7L Patch Accessory Photo.pdf | Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

SmartCardia 7L Platform

Indications for Use *(Describe)*

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:
1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening
conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

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Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450). ?

Medical Specialty	
Regulation	
Product Code	DSI

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-arrhythmia-detector-and-alarm-guidance-industry-and-fda

Associated Product Code(s) DRG ?

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K192757
Predicate Device Trade Name	VitalPatch
Predicate Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DRG

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K160064
Predicate/Reference Device Trade Name	MoMe Kardia Wireless Ambulatory ECG Monitoring And Dete
Predicate/Reference Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DSI

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Predicates and Substantial Equivalence Summary
Primary Predicate
VitalConnect VitalPatch K192757
Product Code: DRG
Intended Use:
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.
The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

Predicate/Reference Device
InfoBionics MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System K160064
Product Code: DSI
Intended Use:
MoMe® Kardia is intended to be used for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.
MoMe® Kardia is contraindicated for:
1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life

Contains Nonbinding Recommendations

threatening arrhythmias.

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Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Substantial Equivalence Comparison Statement
The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

Substantial Equivalence Comparison Technological Characteristics Statement
The SmartCardia 7L Platform has the same technological characteristics as the predicate device and the predicate/reference device.
1) They are body worn sensors that communicate wirelessly to a gateway device that transmits the data to a cloud bases server for storage and further analysis.
2) The material used in the predicate device and the SmartCardia 7L body worn device is the same.
a. The ECG electrodes are a hydrogel component
b. The adhesive body is a hydrocolloid material.
c. The predicate/reference device uses individual ECG electrodes connected to the transmitter device via wire leads.
d. The devices use integrated batteries to power the body worn sensor.
i. The predicate device uses zinc air and the SmartCardia 7L body worn device uses manganese oxide-lithium.
ii. Both are disposable and do not require charging.
e. The predicate device and SmartCardia 7L body worn device both use Bluetooth BLE communication to a gateway.
i. The predicate device communicates to a tablet,
ii. The SmartCardia 7L body worn device communicates to a smartphone.
iii. The predicate/reference device incorporates a cellular transmitter directly into the sensor and transmits via cellular technology to the cloud server.
iv. These gateways then transmit the data to a cloud server.
3) The VitalConnect predicate device measures more physiological parameters than the SmartCardia 7L Platform.
4) The InfoBionics predicate/reference device measures just ECG and heart rate which is the same as the SmartCardia 7L Platform.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	011_Substantial Equivalence Comparison Table Attachment.pdf	Delete Attachment

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Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	PL-09 Clinician User Guide IFU, Icon and Symbol Table, pages 40, 41, 42, and 43 of 235 (IFU pages 15, 16, 17, 18); PL-17 Technical Manual, pages 186 and 187 of 235
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	MR Unsafe

Package Labeling

Add Attachment

Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.

Open Attachment | 012 Package Labeling.pdf | Delete Attachment

Package Insert / Instructions for Use

Add Attachment

Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Open Attachment | 013_Instructions for Use.pdf | Delete Attachment

Other Labeling

Add Attachment

Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	013_Instructions for Use; PL-08 Patient Guide, page 23 of 235;
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	File 013_Instructions for Use, PL-08 Patient Guide, page 9 of 235; PL-09
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	File 013_Instructions for Use, PL-08 Patient Guide, page 23 of 235, and 24 of 235; PL-09 Clinician

Guidance and Special Controls Adherence

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In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Based on the answers provided in the Device Description section, reprocessing information, but no sterility information, is needed.

Reprocessing

Are cleaning or disinfection or sterilization instructions included in the labeling?	Yes
How many different sets of reprocessing instructions are included (maximum of 4):	(b)(4)

Reprocessing Instructions 1

Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

SmartCardia 7L Sensor, SmartCardia Phone, Charger and charger cable

Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.	013_Instructions for Use, Page 161 of

Cleaning Instructions

Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?	No
Is a Point-of-Use care instruction included (e.g., to prevent drying)?	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable. (Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235;
If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.	N/A
Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235

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Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., "no visual contamination"), and 3) steps the user should repeat if the endpoint is not met.	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235;
If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.	7L Patch is single use, stated in 013_Instructions for

Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

Which types of microbicidal process instructions are present in these instructions?	None (cleaning alone)

Technically Feasible, Understandable, and Comprehensive

Be sure the reprocessing instructions can be understood and reasonably implemented by the end user in the intended reprocessing location. If a device is intended to be reprocessed in the home, then reprocessing steps should include products that are available for use in the home (not sterilizers or high-level disinfectants) and are appropriate for the reprocessing procedure (e.g., baby bottle sanitizers are not recommended for reprocessing most medical devices).

If the device is initially supplied non-sterile to the user and specifies to sterilize the device before use, the device should be prominently labeled "Non-sterile" directly on the individual device label (e.g., as opposed to only on the shipper carton).

When warranted, the labeling should include special warnings or precautions about potential damage to the device from improper reprocessing procedures. These may be related to user safety or emphasize

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conditions that could significantly alter the safety or effectiveness of reprocessing or performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. Not all devices may need this type of warning in the labeling. If you are unsure, check if similar devices have labeling with this type of warning.

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A, no special controls for reprocessing or sterility.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf-life?	2	Years

Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

Device is not a sterile device. Device tested per IEC 60601-1-11 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.	?

Other

Open Attachment	014_Reprocessing_Sterility_Shelf-Life_Documents.pdf	Delete Attachment

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Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? *(See Help Text if multiple materials share the same justification for no testing.)*	(b)(4)

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrogel electrode component

Please state the exact name and any identifiable information for the particular material used.

Hydrogel, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PCSTATUS@fda.hhs.gov or 301-796-5115

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tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)	?
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch	

(b)(4)

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(b)(4)

Comments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 2

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrocolloid adhesive component

Please state the exact name and any identifiable information for the particular material used.

Hydrocolloid, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

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Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No Hydrogel, No Hydrocolloid)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8128 released by CDRH on 10-02-2024

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-3115, Released by CDRH on 10-02-2024

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Records processed under FOIA Request # 2024-6000 CDRH on 10-02-2024

Tissue Contacting Material 3

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, adhesive component

Please state the exact name and any identifiable information for the particular material used.

Adhesive, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A." ?

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No ?
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution) ?
Identify the test article used in testing.	7L Patch (No hydrogel, No hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 4

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, sensor window lens

Please state the exact name and any identifiable information for the particular material used.

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.
Open Attachment	015_ISO 10993 Biocompatibility Test Reports.pdf Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, software, cybersecurity, and interoperability information is needed.

Software

Software Level of Concern (LOC) Determination

Does the Software qualify as Blood Establishment Computer Software?	(b)(4)
Is the Software intended to be used in combination with a drug or biologic?	
Is the Software an accessory to a medical device that has a Major LOC?	
Prior to mitigation of hazards, could a failure of the Software result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a) Does the Software control a life supporting or life sustaining function? b) Does the Software control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c) Does the Software control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d) Does the Software provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e) Does the Software provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	
Is the Software an accessory to a medical device that has a Moderate LOC?	(b)(4)
Prior to mitigation of hazards, could a failure of the Software result in Minor Injury, either to a patient or to a user of the device?	
Could malfunction of, or a latent design flaw in, the software lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	

Based on the questions answered above, your LOC is determined to be: (b)(4)

The software documentation below is recommended for the level of concern specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Software Description

Add Attachment — Please attach a description of the software / firmware that includes: a textual description of the software / firmware, the version number of the software / firmware, the input parameters (user inputs), and the output parameters (device actions).

Open Attachment — 016_Software Description.pdf — Delete Attachment

Records processed under FOIA Request 2024-4118 released by CDRH on 10-02-2024

Software Documentation

Add Attachment	Device Hazard Analysis	?
Open Attachment	Device Hazard Analysis.pdf	Delete Attachment
Add Attachment	Software Requirements Specifications (SRS)	?
Open Attachment	SW Requirements Specification (b)(4) Design Inputs.pdf	Delete Attachment
Add Attachment	Architecture Design Chart	?
Open Attachment	(b)(4) SmartCardia 7L Platform Software Architecture.pdf	Delete Attachment
Add Attachment	Software Design Specifications (SDS)	?
Open Attachment	Software Design Specification (SDS).pdf	Delete Attachment
Add Attachment	Traceability Analysis/Matrix	?
Open Attachment	Tracability Analysis-Matrix (b)(4) Design Inputs Trace Matrix.pdf	Delete Attachment
Add Attachment	Software Development Environment/Life Cycle Process Description	?
Open Attachment	SW Development EnvironmentLifeCycle ProcessDescription.pdf	Delete Attachment
Add Attachment	Verification & Validation Testing	?
Open Attachment	Verification and Validation Testing.pdf	Delete Attachment
Add Attachment	Revision Level History	?
Open Attachment	Software Information SmartCardia Revision History.pdf	Delete Attachment
Add Attachment	Unresolved Anomalies	?
Open Attachment	Unresolved Anomalies.pdf	Delete Attachment

Cybersecurity

Add Attachment	Risk Management	?
Open Attachment	017_Cybersecurity Risk Management.pdf	Delete Attachment
Add Attachment	Cybersecurity Management Plan / Plan for Continuing Support	?
Open Attachment	017_Cybersecurity Plan and Design.pdf	Delete Attachment

Please specifically cite the attachment(s) and page number(s) where the cybersecurity labeling is located. (Note: If there is separate cybersecurity labeling for the device, please attach this in the Labeling section above.)	013_Instructions for Use, PL-09 Clinician User Guide, pages	?

Interoperability

How many Electronic Interfaces are there?	3	?

Electronic Interface 1

Name the Electronic Interface	7L Sensor to SmartCardia Phone, Bluetooth BLE

Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 2	
Name the Electronic Interface	SmartCardia Phone to SmartCardia back end, cellular
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 3	
Name the Electronic Interface	SmartCardia back end to SmartCardia 7L Web Browser, wifi
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes

Records maintained by CDRH, Not Releasable to the Public unless Redacted in Accordance with FOIA 10 Privacy Act and Trade Secret Procedures

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Based on the answers provided in the Device Description section, EMC and wireless technology information is needed.

Electromagnetic Compatibility (EMC)

How many devices/accessories/components were subjected to EMC testing (maximum of 4)? (b)(4)

EMC Test 1

Device Specific EMC Considerations

Please select the highest possible risk associated with this device(s) resulting from potential malfunction, disruption, or degradation due to electromagnetic interference (EMI) that could cause harm to the patient, user, or operator.

Deaths or Serious Injuries: Medical device-related deaths or **serious injuries** include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to a death or injury or illness that is life-threatening, results in permanent impairment or damage to the body, or requires medical or surgical intervention to prevent permanent harm to the body.

Non-Serious Adverse Events: Medical device-related non-serious adverse events include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to minor, temporary or medically reversible injuries that do not meet the criteria for classification as a medical device-related serious injury.

No Reported Or Potential Harm: Medical device-related events without reported or potential harm include medical device nonconformities that have no related harm, medical device malfunctions that have no related harm, and procedure-related complications with no related harm.

(b)(4)

Was testing performed according to a recognized edition of IEC 60601-1-2 and, if so, was an ASCA test summary report provided? Please attach any summaries/reports in the "EMC, Wireless & EMT Documentation" section below.	(b)(4)
Please list the Essential Performance that is specific to the device, or provide a rationale why the device has no Essential Performance, in the space below.	

1. The SmartCardia 7L Platform shall provide correct data output for the vital sign parameters that it measures.

Please provide the page number(s) in the summary/report that include pass/fail criteria specific to the device that are based on the device functions, intended use, and Essential Performance. It is recommended that all device functions that are associated with basic safety or Essential performance be tested and include device-specific pass/fail criteria.	021_Pages 10 and 11 of 305 (Pages 8, 9 of test report)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8218, Released by CDRH on 10-02-2024

If the device under test is not the final finished version, please provide a justification for why the differences don't affect EMC. If the device under test is the final finished version, please state this.	
The device tested is a pre-production unit that represents the final finished version of the product. There were no changes to hardware from the pre-production device tested to the production unit.	
Please provide the page number(s) in the summary/report that include a description of the device/system configuration that adequately addresses and monitors the specific functions of the device that were tested.	021_Pages 8 and 9 of 305 (pages 6 and 7 of test report)
If the wireless technology is used in the medical device to achieve its intended use, was it "On" and communicating with other medical device subsystems or ancillary equipment during EMC testing?	Yes

EMC Emissions and Immunity Test Information

Please provide the page number(s) in the summary/report where the CISPR 11 emission limits are located.	021_Pages 16, 17 of 305; Pages, 23 and
If the device includes any smart batteries that can be removed from the device for recharging, were the batteries tested as a standalone component during ESD testing?	Inapplicable
Please provide the page number(s) in the summary/report where the IEC 61000-4-2 electrostatic discharge (ESD) immunity test levels and test results (or observations) are located.	021_Page 30 of 305 (test report page 28)
Please provide the page number(s) in the summary/report where the IEC 61000-4-3 radiated RF electromagnetic field immunity test levels and test results (or observations) are located.	021_Pages 33 and 35 of 305 (test report pages 31,33)
Please provide the page number(s) in the summary/report where the proximity field immunity test levels and test results (or observations) from IEC 60601-1-2 Sec 8.10 and Table 9 are located.	021_Pages 33, 35, and 37 of 305 (test report pages 31, 33,
Please provide the page number(s) in the summary/report where the IEC 61000-4-8 power frequency magnetic field immunity test levels and test results (or observations) are located.	021_Page 45 of 305 (test report page 43)
Please provide the page number(s) in the summary/report where the IEC 61000-4-6 conducted disturbances induced by RF fields immunity test levels and test results (or observations) are located.	021_Page 43 of 305 (test report page 41)
Please provide the page number(s) in the summary/report where the IEC 61000-4-4 electrical fast transient/burst immunity test levels and test results (or observations) are located.	021_Page 39 of 305 (test report page 37)
Please provide the page number(s) in the summary/report where the IEC 61000-4-5 surge immunity test levels and test results (or observations) are located.	021_Page 41 of 305 (test report page 39)
Please provide the page number(s) in the summary/report where the IEC 61000-4-11 voltage dips, short interruptions, and voltage variations immunity test levels and test results (or observations) are located.	021_Page 47 of 305 (test report page 45)

Questions? Contact CDRH/OCE/DPH at CARTLEOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-6128, Released by CDRH on 10-02-2024

Please provide the page number(s) in the summary/report where test data for the specifications in Section 20 (RF immunity, category R) of RTCA DO-160 are located. Alternatively, please specifically cite the attachment and page number where the labeling mitigation that cautions against the use of the device in an aircraft is located.	PL-09, Instructions for Use, page 124; PL-17 Technical Manual, page 32	?

If there were any degradations or observations noted during the testing, describe how the device(s) continued to meet the essential performance during these degradations or observations.

Add Attachment	Please add an attachment (e.g., Summary Report) that demonstrates that the device passed testing according to IEC 60601-4-2. If a Declaration of Conformity was used, choose TR 60601-4-2 in the Standards section above, and indicate you are declaring conformity to it (i.e., it is not for general use). Then attach a statement here indicating this standard is included in the eSTAR generated Declaration of Conformity in the Administrative Documentation section below.	?
Open Attachment	018_EMC Summary Report for (b)(4)	Delete Attachment

Emitters, Allowances, Deviations & Modifications

If any of the referenced standard's allowances were used during the testing (e.g., lowered ESD immunity), please provide these below. ?

If there were any deviations from the referenced standard, please describe these below.

Add Attachment	Please add an attachment that includes descriptions of all modifications, as well as a statement indicating that all changes or modifications will be incorporated in the device intended for marketing. Not providing an attachment indicates no modifications were made in order to pass any of the EMC tests. In addition, be sure you include an adequate assessment of whether these modifications might impact other aspects of the device (e.g., performance, biocompatibility). It is recommended that the attachment contain information to demonstrate that the modifications would have no impact on the other aspects or that the modified device was used for the other performance tests.

Records processed under FOIA Request 2023-5128, Released by CDRH on 10-02-2024

Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to common EM emitters including but not limited to: radio-frequency identification (RFID) readers, security systems (e.g., metal detectors or electronic article surveillance (EAS)), wireless power transfer (WPT), and 5G cellular signals. Security systems may be excluded if the device is only intended for use in a Professional Healthcare Facility environment.	018_Page 1 and 2 "Results Summary"
Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to unique medical emitters, such as electrocautery, MRI, electrosurgical units, and diathermy devices. Alternatively, if the intent is to caution against exposure to these or other specific potential electromagnetic disturbance sources, please specifically cite the attachment(s) and page number(s) where the instructions describe avoiding the source or other mitigations.	013_Instructions for Use; Warnings and Cautions are included in PL-09 IFU against exposure to other specific potential EMC disturbances.

Device Labeling

Please specifically cite the attachment(s) and page number(s) where the recommended separation distances and appropriate environment(s) of use are located in the labeling. This information is analogous to the Guidance Tables 1 through 8 from the 3rd edition of IEC 60601-1-2.	013_Instructions for Use; PL-09, Instructions for Use, pages 148 to 155 of 235 (IFU pages 123 to
Please specifically cite the attachment(s) and page number(s) where the performance of the device that was determined to be Essential Performance and a description of what the operator can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances are located in the labeling.	013_Instructions for Use; Page 148 of 235 (IFU page 123); Page 210 of 235 (TM page 31)
Please specifically cite the attachment(s) and page number(s) where the compliance for each emissions and immunity standard or test specified by the collateral standard (e.g., emissions class and group and immunity test level) are located in the labeling.	013_Instructions for Use; PL-09, Instructions for Use, pages 148 to 155 of 235 (IFU pages 123 to
Please specifically cite the attachment(s) and page number(s) where any deviations from the collateral standard and allowances used are described in the labeling. Type "N/A" if not applicable.	N/A

Wireless Technology

How many separate wireless functions are there (maximum of 5)?	2

Wireless Function 1

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

Wireless Bluetooth link from 7L Sensor to SmartCardia Phone to transmit patient data.
Delay in treatment is the primary risk category for failure of the wireless link.
Mitigation is implemented to store all data internal to the 7L Sensor so when a link is broken, the data are

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

re-transmitted when the link is restored.

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Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The BLE link shall pass all digitized data from the sensor to the SmartCardia phone which is in the RF chamber.

Please select all the technologies that apply to this wireless function:

☒ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☐ Cellular ☐ Other

Bluetooth

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 019_Wireless Coexistence and RFID Testing_BlueTooth.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

(b)(4)

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	

(b)(4)

Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	(b)(4)
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use, pages 013_148
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use, pages 013_148 of 235 through 013_155 of 235
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Wireless Function 2

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

(b)(4)

Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The Cellular link is expected to disconnect while in the RF Chamber Data corrupted or lost packets due to RF interference shall be retransmitted when the interference is removed. Pass criteria is a continuous ECG waveform file reviewed in the SmartCardia backend at the conclusion of the test.

Please select all the technologies that apply to this wireless function:

☐ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☒ Cellular ☐ Other

Cellular

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 020_Wireless Coexistence and RFID Testing_Cellular.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

The Functional Wireless Performance (FWP) of the SmartCardia 7L Platform was monitored using the Key Performance Indicators listed in the attached test report, pages 020_Page 16 of 36 and 020_Page 17 of 36.

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	

(b)(4)

Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	(b)(4)
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use, pages 013_148
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use, pages 013_148 of 235 through 013_155 of 235
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The SmartCardia 7L Platform was tested for compliance with the following standards to verify the electrical, mechanical, and thermal safety considerations:

- IEC 60601-1 General Requirements for Basic Safety and Essential Performance
  - o Essential Performance – Defibrillation Performance (b)(4)
- IEC 60601-1-2 Collateral Standard, Electromagnetic Disturbances – Requirements and Tests
  - o Wireless Coexistence (ANSI C63.27) and Exposure to RFID (AIM 7351731)
- IEC 60601-1-11 Collateral Standard, Medical Equipment used in the Home Healthcare Environment
- IEC 60601-2-47 Requirements for Ambulatory ECG Systems
- IEC 60601-1-8 General requirements, tests and guidance for Alarm Systems in Medical Equipment
- EC12 Requirements for Disposable ECG Electrodes
- ISO 10993-5 Biological Evaluation for Cytotoxicity
- ISO 10993-10 Biological Evaluation for Sensitivity

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(b)(4)

The SmartCardia 7L Platform was tested for energy reduction to verify defibrillation safety required by IEC 60601-1 ed3, second amendment clause 8.5.5.2.
The energy reduction test was performed as directed in the standard and the results of the test are provided in IEC 60601-1 report from (b)(4) This is included in the file 022_Performance Testing – Bench.

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.	
Open Attachment	021_EMC, Wireless, & EMT Test Reports.pdf	Delete Attachment

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Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.	K192757

Records processed under FOIA Request 2023-8118, Released by CDRH on 10-02-2024

Add Attachment	Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.	?

Other Non-Clinical Evidence

Open Attachment	022_Performance Testing - Bench.pdf	Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

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If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request 2022-8116 Released by CDRH on 10-02-2024

References

Is literature referenced in the submission? Yes

Add Attachment | Please add legible reprints or a summary of each article in English.

Open Attachment | 023_Reference Literature.pdf | Delete Attachment

Please include a discussion of how each article is applicable to support the submission.

Summary of Literature Supporting the SmartCardia 7L Platform
Published scientific papers or documents are referenced to support the SmartCardia 7L Platform.

1. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part IV: The ST Segment, T and U Waves, and the QT Interval. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society

Pentti M. Rautaharju, MD, PhD; Borys Surawicz, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC

(b)(4)

2. Cleveland Clinic: Center for Continuing Education, Atrial Fibrillation; Cantillon, Daniel J, Amuthan, Ram. August 2018 www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/atrial-fibrillation/

(b)(4)

3. Hannun, A.Y., Rajpurkar, P., Haghpanahi, M. et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nature Medicine 25, 65–69 (2019).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DIDSACORRHTRISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

4. Steven Walfish, November 30, 2016, FOI Services Teleconference TC161130 Presentation, Slide 'Sample Size for Proportions'. https://www.foiservices.com/tc-docs/tc161130/TC161130A.pdf

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Administrative Documentation

Add Attachment	General Summary of Submission/Executive Summary	?
Open Attachment	023_General Summary of Submission-Executive Summary.pdf	Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.	Yes
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	No

Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.	?
Open Attachment	User Fee Cover Sheet.pdf	Delete Attachment

Please enter in the User Fee Payment Identification Number.	(b)(4)	?

Show User Fee Introduction

Records processed under FOIA Request # 2024-4000 on 2024

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of SmartCardia SA, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Srinivasan Murali

Digitally signed by Srinivasan Murali
Date: 2023.05.02 22:09:10 +02'00'

Date Signed: 2023-05-02

510(k)#: For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Declaration of Conformity

Application #

Company Name	SmartCardia SA
Company Address	EPFL Innovation Park Building C Lausanne 1015 Switzerland
Device Trade Name	SmartCardia 7L Platform

The object of the declaration described above is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:201	19-46
IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
IEC	60601-1-11 Edition 2.0 2015-01	19-14
IEC	60601-2-47 Edition 2.0 2012-02	3-155
ISO	10993-5 Third edition 2009-06-01	2-245
ISO	10993-10 Third Edition 2010-08-01	2-174
ISO	10993-23 First edition 2021-01	2-291
ANSI AAMI	EC12:2000/(R)2015	3-52

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of:	LAUSANNE, SWITZERLAND	2023.05.02
Full Name and Function:	Srinivasan Murali, CEO	
Signature	Srinivasan Murali Digitally signed by Srinivasan Murali Date: 2023.05.02 22:12:19 +02'00'	

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510(k) Summary

Prepared on: 2023-05-02

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Verification and Released by CDRH on 10-02-2024

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

Please submit this eSTAR PDF for review to the Center for Devices and Radiological Health (CDRH) using the CDRH Portal. You do not need to send any documentation in physical form using the postal service.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-CBERSTATUS@fda.hhs.gov or 301-796-6113

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(b)(4) Product User Needs and Design Inputs

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(b)(4) Verification Protocol - Notifications (Alerts/Alarms) Software

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4) Verification Test Results - Notifications (Alerts/Alarms) Software

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Audio Alarm Testing Report

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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016_K231276_S001Device Hazard Analysis (b)(4)

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Device Hazard Analysis

(b)(4)

Risk Management Plan

Risk Analysis Summary

Risk Management Report

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Risk Management Summary

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4) Risk Management Report - 7L Platform

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231276

Device Name
SmartCardia 7L Platform

Indications for Use *(Describe)*

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Redacted per FOIA Request 2023-2112 Released by CDRH on 01-17-2024

electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 2.1 (2022-10-07)*

STATUS: eSTAR COMPLETE

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. We tested eSTAR submissions up to 1GB in size. If your eSTAR is greater than 1GB, file handling may be delayed. Large attachments will increase save times.

Q: If an eSTAR is signed, a message is displayed at the top saying changes were made after signing. Why?

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.1 (2022-10-07): Grey text in FDA standards selection no longer disappears when an SDO is selected. Warning

Application/Submission Type

If none of the attachments to a question are relevant to the question, or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Application Purpose	(•) Premarket Notification 510(k) ( ) De Novo ( ) Premarket Application PMA

Show Application Introduction

Application Type *(Choose Abbreviated if you are submitting a Safety & Performance based submission.)*	(•) Traditional ( ) Abbreviated ( ) Special

Show Application Type Introduction

Application Sub-Type *(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)*	(•) New Application/Submission ( ) Additional Information

Records released under FDA Request 2021-3345 Released Date: 10-25-2021

Cover Letter / Letters of Reference

Add Attachment	Attach your Cover Letter	?
Open Attachment	Cover Letter Signed.pdf	Delete Attachment
Add Attachment	Attach any Letters of Reference	?

Applicant Information

Contact

Title: Mr. | Last Name: Murali | First Name: Srinivasan

Email: srinivasan.murali@smartcardia.com | Phone Number: +41 7887 50864

Occupation Title: Chief Executive Officer

Company

Company Name: SmartCardia SA

Address - Line 1: EPFL Innovation Park Building C

Address - Line 2:

City: Lausanne | State: | Zip: 1015 | Country/Region: Switzerland

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title: | Last Name: Steurer | First Name: Robert

Email: steurerbob@gmail.com | Phone Number: 425-358-1072

Occupation Title: Consultant

Company

Company Name: Steurer Consulting Group LLC

Address - Line 1: 800 Blue Quail Rd

Address - Line 2:

City: Keller | State: TX | Zip: 76248 | Country/Region: United States

Add Correspondent/Consultant | Delete Correspondent/Consultant

Pre-Submission Correspondence & Previous Regulator Interaction

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Are there prior related submissions or regulator interaction for the subject device(s)? Yes

Add Submission

Please provide the submission number(s) of prior related submission(s) as defined above, regardless of outcome. If none, type "N/A."

(b)(4) Delete Submission

Add Attachment

Please upload copies of prior regulatory feedback (e.g., letter, meeting minutes, submission feedback) regarding this device and/or data and/or information to support this submission. Please specify the location in the current submission where additional information requests in prior submissions were addressed, or provide a rationale for not responding to those additional information requests.

Open Attachment 002_Prior Coorespondence and Regulator Interaction QSUB Delete Attachment

Standards

Add Standard

Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. The recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators use drop-downs populated with their recognized Standards.

ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A	19-46	Delete Standard

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment 60601-1 Extent of Standard Conformance Checklist.pdf Delete Attachment

Add Standard

IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36	Delete Standard

Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collater

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment 60601-2 EMC Extent of Standard Conformance Checklist.pdf Delete Attachment

Add Standard

IEC	60601-1-11 Edition 2.0 2015-01	19-14	Delete Standard

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collate

Are you using this standard for general use, or are you declaring conformity to it? Declaration of Conformity

Add Attachment Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment 60601-1-11 Home Healthcare.pdf Delete Attachment

Records processed under FOIA Request released by CDRH on 10-02-2024

Add Standard

IEC	60601-2-47 Edition 2.0 2012-02	3-155	Delete Standard

Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | 60601-2-47 Ambulatory ECG Extend to Standard Conformance | Delete Attachment

Add Standard

IEC	60601-1-8:2006 and A1:2012 [Including AMD 2:2021]	5-131	Delete Standard

Medical Electrical Equipment - Part 1-8: General requirements for basic safety and essential performance ¿ Collate

Are you using this standard for general use, or are you declaring conformity to it?	General Use

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Open Attachment | ISO 60601-1-8 Alarm Standard Checklist.pdf | Delete Attachment

Add Standard

ISO	10993-5 Third edition 2009-06-01	2-245	Delete Standard

Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO	10993-10 Third Edition 2010-08-01	2-174	Delete Standard

Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Add Standard

ISO	10993-23 First edition 2021-01	2-291	Delete Standard

Biological evaluation of medical devices - Part 23: Tests for irritation

Are you using this standard for general use, or are you declaring conformity to it?	Declaration of Conformity

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request released by CDRH on 10-02-2024

Add Standard

ANSI AAMI	EC12:2000/(R)2015	3-52	Delete Standard

Disposable ECG electrodes

Are you using this standard for general use, or are you declaring conformity to it? | Declaration of Conformity | ?

Add Attachment | Standards Details / Supplemental Documentation per ISO/IEC 17050-2 | ?

Open Attachment | EC12 Disposable ECG Electrodes Checklist.pdf | Delete Attachment

Add Standard

Records processed under FOIA Request 2024-8127 Released by CDRH on 10-02-2024

Device Description

Listing of Device(s)

Add Device | Provide the Product Trade Name and (optionally) Model Number/Name

SmartCardia 7L Platform	Model Number/Name	Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining?	No
Are there any direct or indirect tissue contacting components?	Yes
• Is the device or a component an implant?	No
Does the device use software/firmware?	Yes
• Is the device, or does it contain, digital health technology?	Yes
• Please check the attributes that are applicable to your device.	☒ Cloud Communication ☒ Network connection (active or not) ☒ Wireless communication in any form ☐ USB/serial ports/removable media ☒ Software upgrades (this includes patches) ☐ None of the above
Is the device or a component packaged as sterile?	No
The device/system uses or is... (choose all that apply)	☒ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use device(s) ☒ a reusable multi-patient use device(s)
The environment of use of the device/system includes... (choose all that apply)	☒ Professional Healthcare Facility ☒ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the device a combination product?	No
Is the device electrical (battery or wall powered)?	Yes, it is battery and mains powered
• Does the device/system include wireless technology?	Yes
Please check the attributes that are applicable to your device. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

Description

Please provide a Device Description Summary below, and ensure it includes an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties.

Records processed under FOIA Request 2023/8118, Released by CDRH on 10-02-2024

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must provide this device description information in the textbox below, in accordance with 21 CFR 807.92(a)(4). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DEVICE DESCRIPTION SUMMARY TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

(b)(4)

Add Attachment	Comprehensive Device Description and Principles of Operation Documentation	?
Open Attachment	007_Comprehensive Device Description and Principles of	Delete Attachment
Add Attachment	Device Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the device does not have a physical form.	
Open Attachment	008_Device Description Sensor mechanical dwgs.pdf	Delete Attachment
Add Attachment	Description of Device Packaging	?
Open Attachment	010_Description of Device Packaging.pdf	Delete Attachment

Accessories

Redacted per Freedom of Information Act (FOIA) 2018; Released by CDRH on 10-02-2024

Is the device intended to be marketed with accessories? Yes

Add Accessory | List all the accessories to be marketed with the submission.

7L Patch | Delete Accessory

Please include a description of each accessory (see help text for the information we request be included). Please also provide the submission number if the accessory was previously marketed (or a statement that it was not).

The SmartCardia 7L Patch is a single use component that is disposable. If extended use of the SmartCardia 7L Platform is required, the 7L Patch is replaced. The SmartCardia 7L Patch has not been previously marketed.

Under section 513(f)(6), are you requesting risk-based classification of an accessory that is not explicitly identified in a classification regulation, or has not been included in a cleared 510(k), approved PMA, or granted De Novo request? No

Add Attachment | Please attach Accessory Pictures, Illustrations, Schematics, and/or Diagrams

Open Attachment | 009_SmartCardia 7L Patch Accessory Photo.pdf | Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Device Description. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you will provide in the Classification section below to determine whether a device specific guidance exists for your device. Type “N/A” if no device specific guidance, regulation, or special controls exist for your device type. If you type “N/A,” and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2023

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

Device Name

SmartCardia 7L Platform

Indications for Use *(Describe)*

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

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SmartCardia 7L Platform contraindications:
1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening
conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Records processed under FOIA Request 2024-8118 Released by CDRH on 10-02-2024

Classification

Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g, PAE and 21 CFR 890.3450).

Medical Specialty	
Regulation	
Product Code	DSI

The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/class-ii-special-controls-guidance-document-arrhythmia-detector-and-alarm-guidance-industry-and-fda

Associated Product Code(s)	DRG

Predicates and Substantial Equivalence

Predicate and Reference Devices

Primary Predicate

Is this a Preamendments or Exempt device without a submission number?	No
Predicate Submission Number (e.g., K210001)	K192757
Predicate Device Trade Name	VitalPatch
Predicate Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DRG

Add Predicate/Reference Device | Delete Predicate/Reference Device

Predicate/Reference Device

Is this a Preamendments or Exempt device without a submission number?	No
Predicate/Reference Submission Number (e.g., K210001)	K160064
Predicate/Reference Device Trade Name	MoMe Kardia Wireless Ambulatory ECG Monitoring And Dete
Predicate/Reference Device Primary Product Code	
Medical Specialty	
Regulation	
Product Code	DSI

Add Predicate/Reference Device | Delete Predicate/Reference Device

Substantial Equivalence Comparison

If the device has different indications for use in comparison to the predicate device(s), describe why the differences do not constitute a new intended use. If the indications for use are the same, state this in the text box below.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), and the Indications are different in comparison to your predicate device(s), you must include the information from 21 CFR 807.92(a)(5) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE RATIONALE TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

If the device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the predicate device(s) identified above, include a summary in the memo box below of the technological characteristics of the new device in comparison to those of the predicate device(s). Or, if the device has different technological characteristics from the predicate device(s), include a summary of how the technological characteristics of the device compare to a legally marketed device(s) identified above.

If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include the information from 21 CFR 807.92(a)(6) in this rationale. The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE DESCRIPTION TEXTBOX BELOW. CONFIDENTIAL INFORMATION CAN BE INCLUDED IN THE ATTACHMENT(S).

Predicates and Substantial Equivalence Summary
Primary Predicate
VitalConnect VitalPatch K192757
Product Code: DRG
Intended Use:
The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall outside selected parameters.
The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.

Predicate/Reference Device
InfoBionics MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System K160064
Product Code: DSI
Intended Use:
MoMe® Kardia is intended to be used for:
1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation)
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath)
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.
MoMe® Kardia is contraindicated for:
1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life

threatening arrhythmias.

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Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.

Substantial Equivalence Comparison Statement
The indications for use of the primary predicate and the predicate/reference device are substantially equivalent to the SmartCardia SA 7L Platform.

Substantial Equivalence Comparison Technological Characteristics Statement
The SmartCardia 7L Platform has the same technological characteristics as the predicate device and the predicate/reference device.
1) They are body worn sensors that communicate wirelessly to a gateway device that transmits the data to a cloud bases server for storage and further analysis.
2) The material used in the predicate device and the SmartCardia 7L body worn device is the same.
a. The ECG electrodes are a hydrogel component
b. The adhesive body is a hydrocolloid material.
c. The predicate/reference device uses individual ECG electrodes connected to the transmitter device via wire leads.
d. The devices use integrated batteries to power the body worn sensor.
i. The predicate device uses zinc air and the SmartCardia 7L body worn device uses manganese oxide-lithium.
ii. Both are disposable and do not require charging.
e. The predicate device and SmartCardia 7L body worn device both use Bluetooth BLE communication to a gateway.
i. The predicate device communicates to a tablet,
ii. The SmartCardia 7L body worn device communicates to a smartphone.
iii. The predicate/reference device incorporates a cellular transmitter directly into the sensor and transmits via cellular technology to the cloud server.
iv. These gateways then transmit the data to a cloud server.
3) The VitalConnect predicate device measures more physiological parameters than the SmartCardia 7L Platform.
4) The InfoBionics predicate/reference device measures just ECG and heart rate which is the same as the SmartCardia 7L Platform.

Add Attachment	Please attach your Substantial Equivalence Comparison in tabular format. Please ensure the table(s) includes a comparison of the Indications for Use as well as a comparison of the pertinent technology characteristics of your device and your predicate device(s). If your submission is intended for the safety and performance pathway, then you should satisfy the Substantial Equivalence comparison as outlined in the relevant guidance. Please open the link in the help text for more information.	?
Open Attachment	011_Substantial Equivalence Comparison Table Attachment.pdf	Delete Attachment

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Labeling

You must submit proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied (21 CFR 807.87(e)). We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your device if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).	PL-09 Clinician User Guide IFU, Icon and Symbol Table, pages 40, 41, 42, and 43 of 235 (IFU pages 15, 16, 17, 18); PL-17 Technical Manual, pages 186 and 187 of 235
What is the Magnetic Resonance (MR) safety status for the device(s) in the submission?	MR Unsafe

Package Labeling

Add Attachment — Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the device. This includes, but is not limited to, the device packaging and sterile packaging.

Open Attachment | 012 Package Labeling.pdf | Delete Attachment

Package Insert / Instructions for Use

Add Attachment — Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your device. This includes instructions that may be downloaded or viewed on a website.

Open Attachment | 013_Instructions for Use.pdf | Delete Attachment

Other Labeling

Add Attachment — Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.

Specific Labeling

Please specifically cite the attachment and page number where the prescription statement or "Rx only" exists in the labeling.	013_Instructions for Use; PL-08 Patient Guide, page 23 of 235;
Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.	File 013_Instructions for Use, PL-08 Patient Guide, page 9 of 235; PL-09
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.	File 013_Instructions for Use, PL-08 Patient Guide, page 23 of 235, and 24 of 235; PL-09 Clinician

Guidance and Special Controls Adherence

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In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Labeling. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Reprocessing, Sterility, and Shelf-Life

Based on the answers provided in the Device Description section, reprocessing information, but no sterility information, is needed.

Reprocessing

Are cleaning or disinfection or sterilization instructions included in the labeling?	Yes
How many different sets of reprocessing instructions are included (maximum of 4):	(b)(4)

Reprocessing Instructions 1

Please identify the device(s), and/or accessory(ies), and/or component(s) that are covered by this set of instructions.

SmartCardia 7L Sensor, SmartCardia Phone, Charger and charger cable

Please specifically cite the attachment(s) and page number(s) where the cleaning/disinfection instructions are located in the labeling.	013_Instructions for Use, Page 161 of

Cleaning Instructions

Some devices (e.g., some orthopedic implants) are provided clean and are only subjected to end-user sterilization. Is the device single-use and provided clean so that cleaning instructions are unnecessary and are not included in the labeling?	No
Is a Point-of-Use care instruction included (e.g., to prevent drying)?	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the disassembly/reassembly instructions are located. Type "N/A" if not applicable. (Note: If disassembly of the device is necessary for adequate reprocessing, specific instructions for disassembly and reassembly should be provided.)	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions to “thoroughly clean” the device (or similar text) are included in the labeling? Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235;
If the labeling recommends special accessories for cleaning, please specifically cite the attachment(s) and page number(s) or section(s) where the instructions include details on special accessories (e.g., brush size, brush materials, detergent category) if applicable. Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include how to use accessories (e.g., medical washers) or reference accessory labeling. Type "N/A" if not applicable.	N/A
Please specifically cite the attachment(s) and page number(s) where the instructions include specifications for cleaning (e.g., times, temperatures, cleaning agents, dilution/concentration, rinses including duration or volume, time, and appropriate final rinse water quality). Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235

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Please specifically cite the attachment(s) and page number(s) where the instructions include: 1) visual inspection, 2) an inspection endpoint (e.g., "no visual contamination"), and 3) steps the user should repeat if the endpoint is not met.	013_Instructions for Use, page 18 of 235; page 161 of 235; page 223 of 235
Please specifically cite the attachment(s) and page number(s) where the instructions include mid-process drying (i.e., drying after cleaning) recommendations. Type "N/A" if not applicable.	013_Instructions for Use, page 18 of 235; page 161 of 235;
If lubricating agents are recommended, do the reprocessing instructions recommend the use of a class of lubricating agent (e.g., water soluble lubricants) after cleaning that is compatible with the medical device, its intended use, and with any subsequent processing steps such as sterilization.	Inapplicable
Please specifically cite the attachment(s) and page number(s) where the instructions include reuse life limits (e.g., number of uses, inspection specifications or performance tests). Type "N/A" if not applicable.	7L Patch is single use, stated in 013_Instructions for

Microbicidal Process

The questions below are intended to help you determine the appropriate reprocessing steps after cleaning, if applicable. General recommendations are described in Criterion 3 of FDA's Reprocessing Guidance, and are summarized below:

- Devices that contact normally sterile areas of the body should be sterilized.
- Devices that contact mucosal membranes or non-intact skin should be (steam) sterilized, unless the device design does not permit steam sterilization (e.g., device materials cannot withstand sterilization). In that instance, devices should be high-level disinfected.
  - Optional chemical sterilization (such as ethylene oxide or hydrogen peroxide sterilization) instructions may also be provided for devices that are high-level disinfected.
- Low/intermediate-level disinfection or cleaning alone may be acceptable for devices that contact intact skin or do not directly contact the patient.

These are general principles, and there may be exceptions.

Which types of microbicidal process instructions are present in these instructions?	None (cleaning alone)

Technically Feasible, Understandable, and Comprehensive

Be sure the reprocessing instructions can be understood and reasonably implemented by the end user in the intended reprocessing location. If a device is intended to be reprocessed in the home, then reprocessing steps should include products that are available for use in the home (not sterilizers or high-level disinfectants) and are appropriate for the reprocessing procedure (e.g., baby bottle sanitizers are not recommended for reprocessing most medical devices).

If the device is initially supplied non-sterile to the user and specifies to sterilize the device before use, the device should be prominently labeled "Non-sterile" directly on the individual device label (e.g., as opposed to only on the shipper carton).

When warranted, the labeling should include special warnings or precautions about potential damage to the device from improper reprocessing procedures. These may be related to user safety or emphasize

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conditions that could significantly alter the safety or effectiveness of reprocessing or performance of the device. For example, some devices may have unsealed seams/crevices through which excessive liquid disinfectant could reach the interior of the device and damage it. In such cases, the labeling should caution users about this potential hazard and provide specific use instructions to prevent it, such as avoiding the application of excess liquid to the device. Not all devices may need this type of warning in the labeling. If you are unsure, check if similar devices have labeling with this type of warning.

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Reprocessing or Sterility. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

N/A, no special controls for reprocessing or sterility.

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls regarding reprocessing or sterility, provide a rationale for this alternative approach below.

Shelf-Life

Does your device have a shelf-life?	Yes	?
What is the proposed shelf-life?	2	Years

Provide a summary of the methods used to support the sterility and performance of the device over its proposed shelf-life. Alternatively, provide a rationale for why testing to establish shelf-life is not applicable.

Device is not a sterile device. Device tested per IEC 60601-1-11 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Reprocessing, Sterility, and Shelf-Life Documents

Add Attachment	Please attach any Sterility, Cleaning, Shelf-Life and Reuse documentation that you believe is pertinent to the review of your device. Choose the attachment type in the dropdown for each attachment.	?

Other

Open Attachment	014_Reprocessing_Sterility_Shelf-Life_Documents.pdf	Delete Attachment

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Biocompatibility

Based on the answer provided in the Device Description section, biocompatibility information is needed.

Tissue Contacting Products/Components/Materials

How many tissue contacting products/components/materials are there? *(See Help Text if multiple materials share the same justification for no testing.)* **(b)(4)**

Tissue Contacting Material 1

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrogel electrode component

Please state the exact name and any identifiable information for the particular material used.

Hydrogel, **(b)(4)** **(b)(4)**

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	**(b)(4)**

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility

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tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

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(b)(4)

Comments

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

documentation error did not impact assessment of the study endpoints.

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Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 2

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, Hydrocolloid adhesive component

Please state the exact name and any identifiable information for the particular material used.

Hydrocolloid, (b)(4)

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	K192757

If you are aware of a previously submitted device using the same material with similar nature of contact, please provide any pertinent information to compare your device to the device/test article in the previously submitted biocompatibility assessment. Any changes in formulation, processing, sterilization, geometry (including surface characteristics) and the addition of other chemicals (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents) should be addressed to support use of the previous biocompatibility assessment (e.g., no additional biocompatibility testing is necessary).

Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

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Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No Hydrogel, No Hydrocolloid)

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

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Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 3

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, adhesive component

Please state the exact name and any identifiable information for the particular material used.

Adhesive (b)(4)
(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, No hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

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Tissue Contacting Material 4

Identify the device(s) / accessory(ies) / component(s) that directly or indirectly contacts the tissue.

SmartCardia 7L Patch, sensor window lens

Please state the exact name and any identifiable information for the particular material used.

(b)(4)

If color additives are included, please identify them here. If no color additives are included, state "N/A."

N/A

Choose intended contact of the particular material.	Direct
Please provide the FDA submission number (e.g., K210001) if you are aware of a previously submitted device using the same material with similar nature of contact.	
Is there a potential for repeat exposure?	No
Choose the type of tissue contact of your tissue contacting material.	Surface Device: Skin
Duration of Contact	(b)(4)

The type of tissue contact and duration of contact will determine the types of Biocompatibility endpoints that we recommend be assessed, based on the Biocompatibility Guidance Document. These endpoints will display as tabs below, and FDA recommends that complete test reports be provided for biocompatibility tests performed for these endpoints. If you used an alternative test method than the options provided, or you did not conduct the test, please provide an explanation or justification (e.g., the device component is identical in materials/formulation and processing to a legally marketed device) in the Comments section for each test method. **If you select an item that includes a star (*) in any of the drop down menus below, provide supporting evidence or justification for the selection in the comments box at the bottom of each test.** A starred (*) selection within the Accreditation Scheme for Conformity Assessment (ASCA) Pilot indicates a deviation. Per the ASCA guidance, for ASCA testing, the complete test report should be provided in addition to the ASCA summary test report.

Cytotoxicity | Sensitization | Irritation

Cytotoxicity Testing

What type of cytotoxicity testing was conducted?	Extraction Method (MEM Elution)
Identify the test article used in testing.	7L Patch (No hydrogel, no hydrocolloid)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, cell abnormalities, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Sensitization Testing

What type of sensitization testing was conducted?	Guinea Pig Maximization Test (GPMT)
Identify the test article used in testing (e.g., final sterilized device, component of final sterilized device, other with description).	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Close Tab

Irritation Testing

What type of irritation testing was conducted?	Intracutaneous Irritation Test
Identify the test article used in testing.	7L Patch

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Comments

Please summarize justifications, non-traditional test methods, deviations, animal deaths, etc, below.

Close Tab

Biocompatibility Reports and Documentation

Add Attachment	Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.
Open Attachment	015_ISO 10993 Biocompatibility Test Reports.pdf Delete Attachment

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Software/Firmware & Cybersecurity/Interoperability

Based on the answers provided in the Device Description section, software, cybersecurity, and interoperability information is needed.

Software

Software Level of Concern (LOC) Determination ?

Does the Software qualify as Blood Establishment Computer Software?	(b)(4)
Is the Software intended to be used in combination with a drug or biologic?	
Is the Software an accessory to a medical device that has a Major LOC?	
Prior to mitigation of hazards, could a failure of the Software result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following: a) Does the Software control a life supporting or life sustaining function? b) Does the Software control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators? c) Does the Software control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury? d) Does the Software provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death? e) Does the Software provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	
Is the Software an accessory to a medical device that has a Moderate LOC?	(b)(4)
Prior to mitigation of hazards, could a failure of the Software result in Minor Injury, either to a patient or to a user of the device?	
Could malfunction of, or a latent design flaw in, the software lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	

Based on the questions answered above, your LOC is determined to be: (b)(4)

The software documentation below is recommended for the level of concern specified. Click on the blue help text buttons for details about what is recommended in the documentation for each.

Software Description ?

Add Attachment — Please attach a description of the software / firmware that includes: a textual description of the software / firmware, the version number of the software / firmware, the input parameters (user inputs), and the output parameters (device actions).

Open Attachment — 016_Software Description.pdf — Delete Attachment

Records processed under FOIA Request 2024-4118 released by CDRH on 10-02-2024

Software Documentation

Add Attachment	Device Hazard Analysis
Open Attachment	Device Hazard Analysis.pdf — Delete Attachment
Add Attachment	Software Requirements Specifications (SRS)
Open Attachment	SW Requirements Specification (b)(4) Design Inputs.pdf — Delete Attachment
Add Attachment	Architecture Design Chart
Open Attachment	(b)(4) SmartCardia 7L Platform Software Architecture.pdf — Delete Attachment
Add Attachment	Software Design Specifications (SDS)
Open Attachment	Software Design Specification (SDS).pdf — Delete Attachment
Add Attachment	Traceability Analysis/Matrix
Open Attachment	Tracability Analysis-Matrix (b)(4) Design Inputs Trace Matrix.pdf — Delete Attachment
Add Attachment	Software Development Environment/Life Cycle Process Description
Open Attachment	SW Development EnvironmentLifeCycle ProcessDescription.pdf — Delete Attachment
Add Attachment	Verification & Validation Testing
Open Attachment	Verification and Validation Testing.pdf — Delete Attachment
Add Attachment	Revision Level History
Open Attachment	Software Information SmartCardia Revision History.pdf — Delete Attachment
Add Attachment	Unresolved Anomalies
Open Attachment	Unresolved Anomalies.pdf — Delete Attachment

Cybersecurity

Add Attachment	Risk Management
Open Attachment	017_Cybersecurity Risk Management.pdf — Delete Attachment
Add Attachment	Cybersecurity Management Plan / Plan for Continuing Support
Open Attachment	017_Cybersecurity Plan and Design.pdf — Delete Attachment

Please specifically cite the attachment(s) and page number(s) where the cybersecurity labeling is located. (Note: If there is separate cybersecurity labeling for the device, please attach this in the Labeling section above.)	013_Instructions for Use, PL-09 Clinician User Guide, pages

Interoperability

How many Electronic Interfaces are there?	3

Electronic Interface 1

Name the Electronic Interface	7L Sensor to SmartCardia Phone, Bluetooth BLE

Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 2	
Name the Electronic Interface	SmartCardia Phone to SmartCardia back end, cellular
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes
Electronic Interface 3	
Name the Electronic Interface	SmartCardia back end to SmartCardia 7L Web Browser, wifi
Is the electronic interface inactive (i.e. not meant to connect, exchange, or use data with or from other medical devices, products, technologies, or systems)?	Yes

EMC, Wireless, Electrical, Mechanical, and Thermal Safety

Records redacted for Content Requirements not applicable to this Device Type. 10 Pages redacted

Based on the answers provided in the Device Description section, EMC and wireless technology information is needed.

Electromagnetic Compatibility (EMC)

How many devices/accessories/components were subjected to EMC testing (maximum of 4)? (b)(4)

EMC Test 1

Device Specific EMC Considerations

Please select the highest possible risk associated with this device(s) resulting from potential malfunction, disruption, or degradation due to electromagnetic interference (EMI) that could cause harm to the patient, user, or operator.

Deaths or Serious Injuries: Medical device-related deaths or **serious injuries** include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to a death or injury or illness that is life-threatening, results in permanent impairment or damage to the body, or requires medical or surgical intervention to prevent permanent harm to the body.

Non-Serious Adverse Events: Medical device-related non-serious adverse events include events (including procedure-related complications) in the use of the medical device that have caused or could cause or contribute to minor, temporary or medically reversible injuries that do not meet the criteria for classification as a medical device-related serious injury.

No Reported Or Potential Harm: Medical device-related events without reported or potential harm include medical device nonconformities that have no related harm, medical device malfunctions that have no related harm, and procedure-related complications with no related harm.

(b)(4)

Was testing performed according to a recognized edition of IEC 60601-1-2 and, if so, was an ASCA test summary report provided? Please attach any summaries/reports in the "EMC, Wireless & EMT Documentation" section below.	(b)(4)
Please list the Essential Performance that is specific to the device, or provide a rationale why the device has no Essential Performance, in the space below.	

1. The SmartCardia 7L Platform shall provide correct data output for the vital sign parameters that it measures.

Please provide the page number(s) in the summary/report that include pass/fail criteria specific to the device that are based on the device functions, intended use, and Essential Performance. It is recommended that all device functions that are associated with basic safety or Essential performance be tested and include device-specific pass/fail criteria.	021_Pages 10 and 11 of 305 (Pages 8, 9 of test report)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8218, Released by CDRH on 10-02-2024

If the device under test is not the final finished version, please provide a justification for why the differences don't affect EMC. If the device under test is the final finished version, please state this.	
The device tested is a pre-production unit that represents the final finished version of the product. There were no changes to hardware from the pre-production device tested to the production unit.	
Please provide the page number(s) in the summary/report that include a description of the device/system configuration that adequately addresses and monitors the specific functions of the device that were tested.	021_Pages 8 and 9 of 305 (pages 6 and 7 of test report)
If the wireless technology is used in the medical device to achieve its intended use, was it "On" and communicating with other medical device subsystems or ancillary equipment during EMC testing?	Yes

EMC Emissions and Immunity Test Information

Please provide the page number(s) in the summary/report where the CISPR 11 emission limits are located.	021_Pages 16, 17 of 305; Pages, 23 and
If the device includes any smart batteries that can be removed from the device for recharging, were the batteries tested as a standalone component during ESD testing?	Inapplicable
Please provide the page number(s) in the summary/report where the IEC 61000-4-2 electrostatic discharge (ESD) immunity test levels and test results (or observations) are located.	021_Page 30 of 305 (test report page 28)
Please provide the page number(s) in the summary/report where the IEC 61000-4-3 radiated RF electromagnetic field immunity test levels and test results (or observations) are located.	021_Pages 33 and 35 of 305 (test report pages 31,33)
Please provide the page number(s) in the summary/report where the proximity field immunity test levels and test results (or observations) from IEC 60601-1-2 Sec 8.10 and Table 9 are located.	021_Pages 33, 35, and 37 of 305 (test report pages 31, 33,
Please provide the page number(s) in the summary/report where the IEC 61000-4-8 power frequency magnetic field immunity test levels and test results (or observations) are located.	021_Page 45 of 305 (test report page 43)
Please provide the page number(s) in the summary/report where the IEC 61000-4-6 conducted disturbances induced by RF fields immunity test levels and test results (or observations) are located.	021_Page 43 of 305 (test report page 41)
Please provide the page number(s) in the summary/report where the IEC 61000-4-4 electrical fast transient/burst immunity test levels and test results (or observations) are located.	021_Page 39 of 305 (test report page 37)
Please provide the page number(s) in the summary/report where the IEC 61000-4-5 surge immunity test levels and test results (or observations) are located.	021_Page 41 of 305 (test report page 39)
Please provide the page number(s) in the summary/report where the IEC 61000-4-11 voltage dips, short interruptions, and voltage variations immunity test levels and test results (or observations) are located.	021_Page 47 of 305 (test report page 45)

Questions? Contact CDRH/OSEL/DIDSI CARLOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-6128, Released by CDRH on 10-02-2024

Please provide the page number(s) in the summary/report where test data for the specifications in Section 20 (RF immunity, category R) of RTCA DO-160 are located. Alternatively, please specifically cite the attachment and page number where the labeling mitigation that cautions against the use of the device in an aircraft is located.	PL-09, Instructions for Use, page 124; PL-17 Technical Manual, page 32	?

If there were any degradations or observations noted during the testing, describe how the device(s) continued to meet the essential performance during these degradations or observations.

Add Attachment	Please add an attachment (e.g., Summary Report) that demonstrates that the device passed testing according to IEC 60601-4-2. If a Declaration of Conformity was used, choose TR 60601-4-2 in the Standards section above, and indicate you are declaring conformity to it (i.e., it is not for general use). Then attach a statement here indicating this standard is included in the eSTAR generated Declaration of Conformity in the Administrative Documentation section below.	?
Open Attachment	018_EMC Summary Report fc (b)(4)	Delete Attachment

Emitters, Allowances, Deviations & Modifications

If any of the referenced standard's allowances were used during the testing (e.g., lowered ESD immunity), please provide these below. ?

If there were any deviations from the referenced standard, please describe these below.

Add Attachment	Please add an attachment that includes descriptions of all modifications, as well as a statement indicating that all changes or modifications will be incorporated in the device intended for marketing. Not providing an attachment indicates no modifications were made in order to pass any of the EMC tests. In addition, be sure you include an adequate assessment of whether these modifications might impact other aspects of the device (e.g., performance, biocompatibility). It is recommended that the attachment contain information to demonstrate that the modifications would have no impact on the other aspects or that the modified device was used for the other performance tests.

Records processed under FOIA Request 2023-5128, Released by CDRH on 10-02-2024

Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to common EM emitters including but not limited to: radio-frequency identification (RFID) readers, security systems (e.g., metal detectors or electronic article surveillance (EAS)), wireless power transfer (WPT), and 5G cellular signals. Security systems may be excluded if the device is only intended for use in a Professional Healthcare Facility environment.	018_Page 1 and 2 "Results Summary"
Please provide the page number(s) in the summary/report that demonstrate EMC of the device when exposed to unique medical emitters, such as electrocautery, MRI, electrosurgical units, and diathermy devices. Alternatively, if the intent is to caution against exposure to these or other specific potential electromagnetic disturbance sources, please specifically cite the attachment(s) and page number(s) where the instructions describe avoiding the source or other mitigations.	013_Instructions for Use; Warnings and Cautions are included in PL-09 IFU against exposure to other specific potential EMC disturbances.

Device Labeling

Please specifically cite the attachment(s) and page number(s) where the recommended separation distances and appropriate environment(s) of use are located in the labeling. This information is analogous to the Guidance Tables 1 through 8 from the 3rd edition of IEC 60601-1-2.	013_Instructions for Use; PL-09, Instructions for Use, pages 148 to 155 of 235 (IFU pages 123 to
Please specifically cite the attachment(s) and page number(s) where the performance of the device that was determined to be Essential Performance and a description of what the operator can expect if the Essential Performance is lost or degraded due to electromagnetic disturbances are located in the labeling.	013_Instructions for Use; Page 148 of 235 (IFU page 123); Page 210 of 235 (TM page 31)
Please specifically cite the attachment(s) and page number(s) where the compliance for each emissions and immunity standard or test specified by the collateral standard (e.g., emissions class and group and immunity test level) are located in the labeling.	013_Instructions for Use; PL-09, Instructions for Use, pages 148 to 155 of 235 (IFU pages 123 to
Please specifically cite the attachment(s) and page number(s) where any deviations from the collateral standard and allowances used are described in the labeling. Type "N/A" if not applicable.	N/A

Wireless Technology

How many separate wireless functions are there (maximum of 5)?	2

Wireless Function 1

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

Wireless Bluetooth link from 7L Sensor to SmartCardia Phone to transmit patient data.
Delay in treatment is the primary risk category for failure of the wireless link.
Mitigation is implemented to store all data internal to the 7L Sensor so when a link is broken, the data are

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re-transmitted when the link is restored.

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Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The BLE link shall pass all digitized data from the sensor to the SmartCardia phone which is in the RF chamber.

Please select all the technologies that apply to this wireless function:

☒ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☐ Cellular ☐ Other

Bluetooth

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 019_Wireless Coexistence and RFID Testing_BlueTooth.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

The Functional Wireless Performance (FWP) of the SmartCardia 7L Platform was monitored using the Key Performance Indicators listed in the attached test report, pages 019_Page 16 of 36 and 019_Page 17 of 36.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	(b)(4)
Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use, pages 013_148
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use, pages 013_148 of 235 through 013_155 of 235
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Wireless Function 2

Wireless Link

Specify the device function to be implemented wirelessly and risks associated with failure, disruption, or delay of communication. Please consider inherent risks due to complete wireless communication loss as well as risks identified by the sponsor during their risk analysis process. Additionally, please consider the safeguards and redundancies that might be built into the wireless function when considering the risk. (If more than one function is specified, please use the dropdown directly above to indicate the number of functions, and address each separately)

Wireless Cellular link from the SmartCardia Phone to the SmartCardia back end cloud server.
Delay in treatment is the primary risk category for failure of the wireless link.
Mitigation is implemented to store all data internal to the 7L Sensor so when a wireless link is broken, the data are re-transmitted when the link is restored.

Please choose the most appropriate choice for the risk of the wireless function (which may not be the same as the risk of the device). The risks of the wireless function are defined in AAMI TIR69.

Negligible: failure of the wireless function could result, as a maximum, in inconvenience or temporary discomfort. Commonly, this category of function is related to no foreseeable hazards to patients or users. This includes data that, if delayed, disrupted, or lost, will result at most as an inconvenience but with no risk to patient safety.

Minor (Tier 3): failure of the wireless function could result in temporary injury or impairment not requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, does not significantly impact the patient's health or medical device's intended use. These can include hazards associated with minor harms or contributing factors in decision-making.

Moderate (Tier 2): failure of the wireless function could result in injury or impairment requiring professional medical intervention. This includes data that, if delayed, disrupted, or lost, could result in a delay of therapy.

Major (Tier 1): failure of the wireless function could result in death or serious injury. This includes critical data for patient health, critical therapy, high priority alarms, remote programming, and other information and signals necessary for life-sustaining or life-supporting activities.

(b)(4)

What is the Quality of Service (QoS) of the device?

The necessary level of performance in a data communications system is defined as: The Cellular link is expected to disconnect while in the RF Chamber Data corrupted or lost packets due to RF interference shall be retransmitted when the interference is removed. Pass criteria is a continuous ECG waveform file reviewed in the SmartCardia backend at the conclusion of the test.

Please select all the technologies that apply to this wireless function:

☐ Bluetooth ☐ Wifi ☐ ZigBee ☐ RFID ☒ Cellular ☐ Other

Cellular

Is the wireless function secure by enabling the security features embedded in the wireless technology or by other means (e.g., application level encryption)? Yes

Environment of Use

Are other wireless products able to connect and transmit to the wireless network of the subject device? No

Wireless Coexistence Testing

Add Attachment | Coexistence Testing

Open Attachment | 020_Wireless Coexistence and RFID Testing_Cellular.pdf | Delete Attachment

Please describe the Functional Wireless Performance (FWP).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Please describe the pass/fail criteria for the FWP and be sure to clarify how each criterion was quantified and measured.	(b)(4)

Was the coexistence testing conducted to Tier 1 (per the risk category chosen above)?	(b)(4)
Were the Equipment Under Test (EUT) and its companion device both exposed to the unintended signal?	
Was the functional wireless performance (FWP) maintained during the testing? If not, were adequate mitigations provided?	

RF Wireless Labeling

Please specifically cite the attachment(s) and page number(s) where the wireless specifications are included (QoS, frequency, power, operating distance, security).	Labeling Attachment 013_Instructions for Use, pages 013_148
Please specifically cite the attachment(s) and page number(s) where the risks and mitigations about wireless use included (precautions for proximity to other wireless products and recommendations for separation distances from such products).	Labeling Attachment 013_Instructions for Use, pages 013_148 of 235 through 013_155 of 235
If device degradations were observed during coexistence testing, please specifically cite the attachment(s) and page number(s) where the labeling has information about how to mitigate this issue. Type "N/A" if not applicable.	N/A

Electrical, Mechanical, and Thermal Summary

Please summarize the Electrical, Mechanical and Thermal Testing of your device, or summarize why testing was not needed. Please ensure any standards cited here are also cited in the Standards subsection within the first part of this template (located after Applicant, Correspondent, and Pre-Submission Correspondence).

The SmartCardia 7L Platform was tested for compliance with the following standards to verify the electrical, mechanical, and thermal safety considerations:

- IEC 60601-1 General Requirements for Basic Safety and Essential Performance
  - o Essential Performance – Defibrillation Performance (b)(4)
- IEC 60601-1-2 Collateral Standard, Electromagnetic Disturbances – Requirements and Tests
  - o Wireless Coexistence (ANSI C63.27) and Exposure to RFID (AIM 7351731)
- IEC 60601-1-11 Collateral Standard, Medical Equipment used in the Home Healthcare Environment
- IEC 60601-2-47 Requirements for Ambulatory ECG Systems
- IEC 60601-1-8 General requirements, tests and guidance for Alarm Systems in Medical Equipment
- EC12 Requirements for Disposable ECG Electrodes
- ISO 10993-5 Biological Evaluation for Cytotoxicity
- ISO 10993-10 Biological Evaluation for Sensitivity

• ISO 10993-23 Biological Evaluation for Intracutaneous Irritation

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(b)(4)

The SmartCardia 7L Platform was tested for energy reduction to verify defibrillation safety required by IEC 60601-1 ed3, second amendment clause 8.5.5.2.
The energy reduction test was performed as directed in the standard and the results of the test are provided in IEC 60601-1 report from (b)(4) This is included in the file 022_Performance Testing – Bench.

EMC, Wireless, & EMT Documentation

Add Attachment	Please attach the documentation pertaining to the Electromagnetic Compatibility Testing (e.g., EMC test reports/summaries), Safeguards, Wireless Testing, and Electrical, Mechanical and Thermal Testing of your device.	
Open Attachment	021_EMC, Wireless, & EMT Test Reports.pdf	Delete Attachment

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Performance Testing

Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No

If the determination of substantial equivalence is also based on an assessment of performance data, we recommend you fill out the text boxes below. If no testing was necessary, state this in the respective field below. If you choose to use the 510(k) summary produced for you at the end of this template (in the Administrative Documentation page), you must include this information, in accordance with 21 CFR 807.92(b). The contents of the 510(k) Summary will be made publicly available on the FDA website if your device is cleared.

THEREFORE, ONLY ENTER NONCONFIDENTIAL INFORMATION IN THE SUMMARY TEXTBOXES BELOW.

Provide a brief discussion of the nonclinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. If any guidance documents or FDA recognized consensus standards were used/referenced for testing, cite these here.

Provide a summary discussion of the clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence. Refer to the help text for a list of the details we recommend be included regarding the subjects and clinical evidence. If no clinical data were necessary, please type "Not Applicable." (There should not be any patient identifier information in the summary.)

State the conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified above.

Bench Testing

Provide the predicate device submission number (e.g., K180001) that is the best comparator for the testing attached below.	K192757

Records processed under FOIA Request 2023-6118, Released by CDRH on 10-02-2024

Add Attachment	Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission.	?

Other Non-Clinical Evidence

Open Attachment	022_Performance Testing - Bench.pdf	Delete Attachment

Guidance and Special Controls Adherence

In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.

(b)(4)

Records processed under FOIA Request 2023-8118, Released by CDRH on 10-02-2024

If you choose to use an alternative approach in comparison to what is stated in the applicable guidance or special controls, please provide a rationale for this alternative approach below.

Records processed under FOIA Request # 2024-3116 Released by CDRH on 10-02-2024

References

Is literature referenced in the submission? Yes

Add Attachment | Please add legible reprints or a summary of each article in English.

Open Attachment | 023_Reference Literature.pdf | Delete Attachment

Please include a discussion of how each article is applicable to support the submission.

Summary of Literature Supporting the SmartCardia 7L Platform
Published scientific papers or documents are referenced to support the SmartCardia 7L Platform.

1. AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part IV: The ST Segment, T and U Waves, and the QT Interval. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society

Pentti M. Rautaharju, MD, PhD; Borys Surawicz, MD, FAHA, FACC; Leonard S. Gettes, MD, FAHA, FACC

(b)(4)

2. Cleveland Clinic: Center for Continuing Education, Atrial Fibrillation; Cantillon, Daniel J, Amuthan, Ram. August 2018 www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/atrial-fibrillation/

(b)(4)

3. Hannun, A.Y., Rajpurkar, P., Haghpanahi, M. et al. Cardiologist-level arrhythmia detection and classification in ambulatory electrocardiograms using a deep neural network. Nature Medicine 25, 65–69 (2019).

(b)(4)

Questions? Contact FDA/CDRH/OCE/DIDT at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

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4. Steven Walfish, November 30, 2016, FOI Services Teleconference TC161130 Presentation, Slide 'Sample Size for Proportions'. https://www.foiservices.com/tc-docs/tc161130/TC161130A.pdf

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Administrative Documentation

Add Attachment	General Summary of Submission/Executive Summary	?
Open Attachment	023_General Summary of Submission-Executive Summary.pdf	Delete Attachment

The Truthful and Accurate Statement is required for all 510(k) types (21 CFR 807.87(k)). It is a legally binding statement that provides additional assurance that the data submitted in the 510(k) is truthful and accurate and that no material fact has been omitted. This statement must be signed by a responsible person of the applicant company; it cannot be signed by a consultant to the applicant. If you are a responsible party of the 510(k) owner, this statement will be automatically produced and signed with your electronic signature (click the Administrative Documentation help text above to learn how to obtain an electronic signature). Ensure the signature you use to sign this application is for the owner of the 510(k), or, if you are not a responsible party of the 510(k) owner, attach a Truthful and Accurate statement below.

Weblink: Truthful and Accurate Statement

Are you a responsible party of the owner for this 510(k) Premarket Notification, and will you be electronically signing this application for submission? If you are unable to sign PDF documents with a valid electronic signature, choose No.	Yes
Would you like to attach a 510(k) Statement or Summary? If you do not attach a 510(k) Statement or Summary, and you provided all of the data necessary to produce a 510(k) Summary, then a 510(k) Summary will be produced by this form. If you choose to submit a 510(k) Summary instead of a 510(k) Statement, be aware that the data provided in the 510(k) Summary will be publicly available if your 510(k) is cleared. As a result, be sure no confidential information is included in the 510(k) Summary. If you choose to submit a 510(k) Statement, be aware that you must provide summary information to anyone who requests it.	No

Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.	?
Open Attachment	User Fee Cover Sheet.pdf	Delete Attachment

Please enter in the User Fee Payment Identification Number.	(b)(4)	?

Show User Fee Introduction

Records processed under FOIA Request # 2024-4000 on 2024

Truthful & Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Chief Executive Officer of SmartCardia SA, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Srinivasan Murali

Digitally signed by Srinivasan Murali
Date: 2023.05.02 22:09:10 +02'00'

Date Signed: 2023-05-02

510(k)#: For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

Declaration of Conformity

Application #

Company Name	SmartCardia SA
Company Address	EPFL Innovation Park Building C Lausanne 1015 Switzerland
Device Trade Name	SmartCardia 7L Platform

The object of the declaration described above is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ANSI AAMI	ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:201	19-46
IEC	60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	19-36
IEC	60601-1-11 Edition 2.0 2015-01	19-14
IEC	60601-2-47 Edition 2.0 2012-02	3-155
ISO	10993-5 Third edition 2009-06-01	2-245
ISO	10993-10 Third Edition 2010-08-01	2-174
ISO	10993-23 First edition 2021-01	2-291
ANSI AAMI	EC12:2000/(R)2015	3-52

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of:	LAUSANNE, SWITZERLAND	2023.05.02
Full Name and Function:	Srinivasan Murali, CEO	
Signature	Srinivasan Murali Digitally signed by Srinivasan Murali Date: 2023.05.02 22:12:19 +02'00'	

Records processed under FOIA Request # 2023-4753 by CDRH on 10-02-2023

510(k) Summary

Prepared on: 2023-05-02

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2024-5411 released by CDRH on 10-02-2024

Verification

The following sections are complete:
Application/Submission Type
Cover Letter / Letters of Reference
Administrative Information
Device Description
Indications for Use
Classification
Predicates and Substantial Equivalence
Labeling
Reprocessing, Sterility, and Shelf-Life
Biocompatibility
Software/Firmware & Cybersecurity/Interoperability
EMC, Wireless, Electrical, Mechanical, and Thermal Safety
Performance Testing
References
Administrative Documentation

Export Data	If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

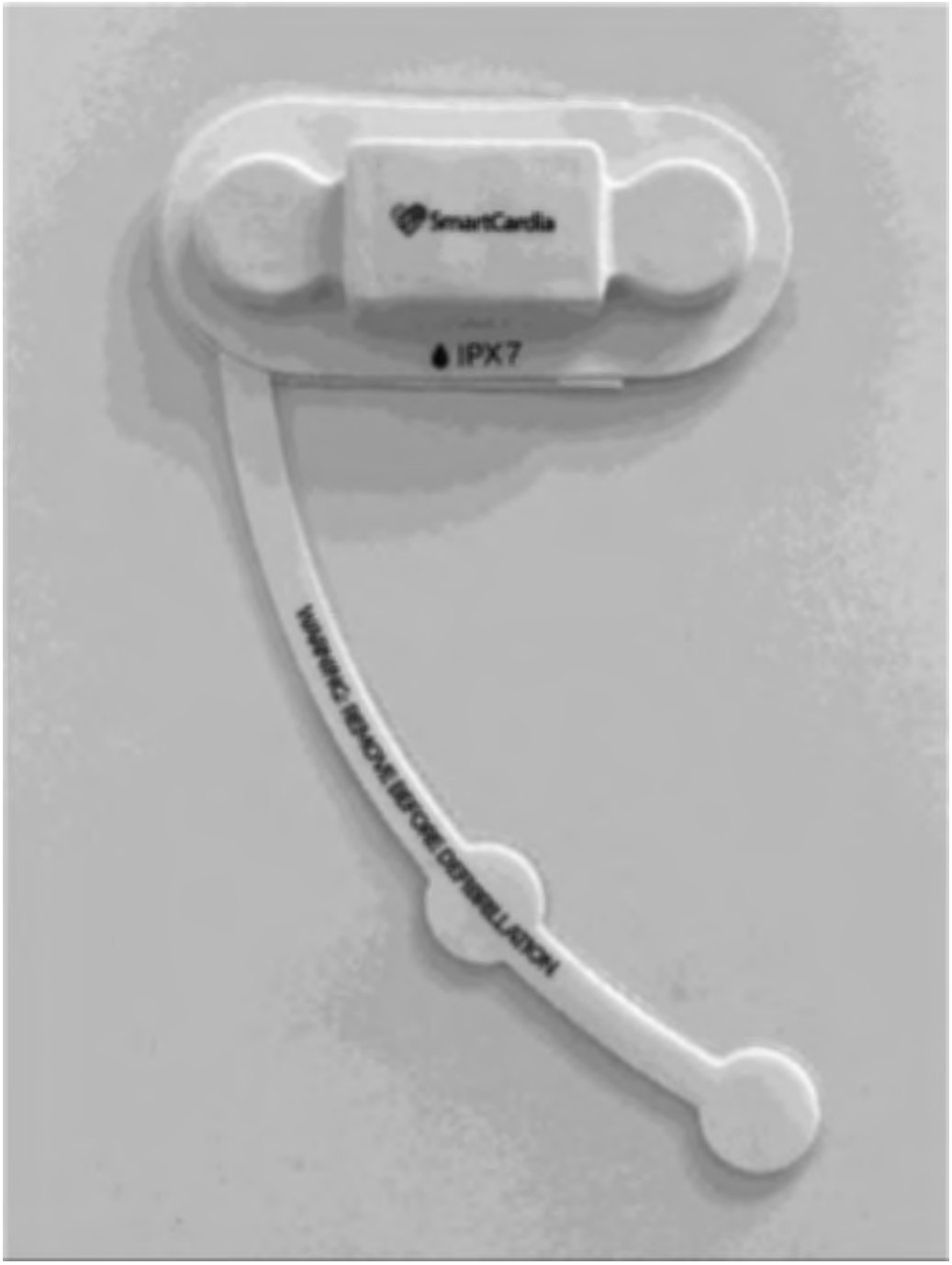
Please submit this eSTAR PDF for review to the Center for Devices and Radiological Health (CDRH) using the CDRH Portal. You do not need to send any documentation in physical form using the postal service.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-CBSTATUS@fda.hhs.gov or 301-796-6113

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

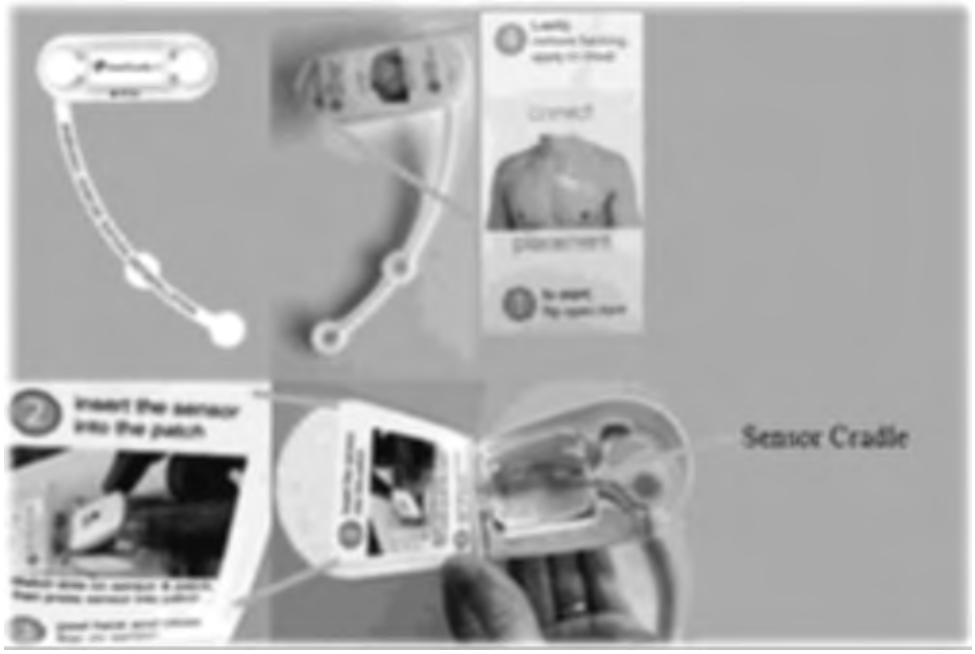
010_SmartCardia 7L Patch Accessory Photos

SmartCardia 7L Patch – top side, away from patient



Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

SmartCardia 7L Patch, Sensor Cradle



Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Mechanical Drawings and Materials – 7L Sensor

Questions? Contact FDA/CDRH/OSE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Intracutaneous Reactivity Test (ISO) – Final Report

Questions? Contact FDA/CDRH/OCE/DIDP at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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012 Package Labeling - Kit Box and Inserts

- Kit Box Labeling
- SmartCardia Patch Card
- SmartCardia Phone Insert Card
- SmartCardia 7L Sensor Box
- SmartCardia 7L Kit - Insert Card, Assemble and Attach 7L Patch

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- Kit Box Labeling

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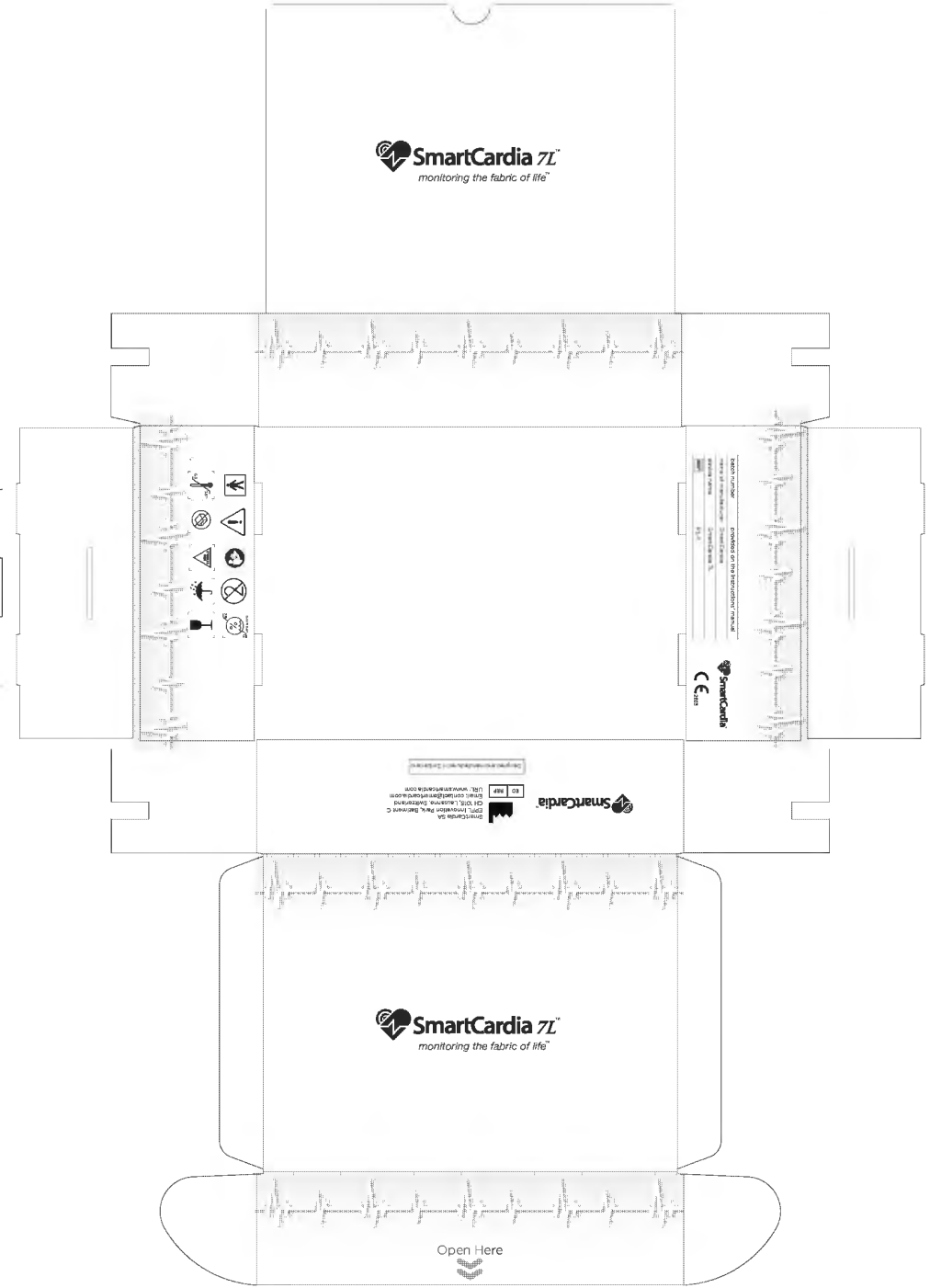
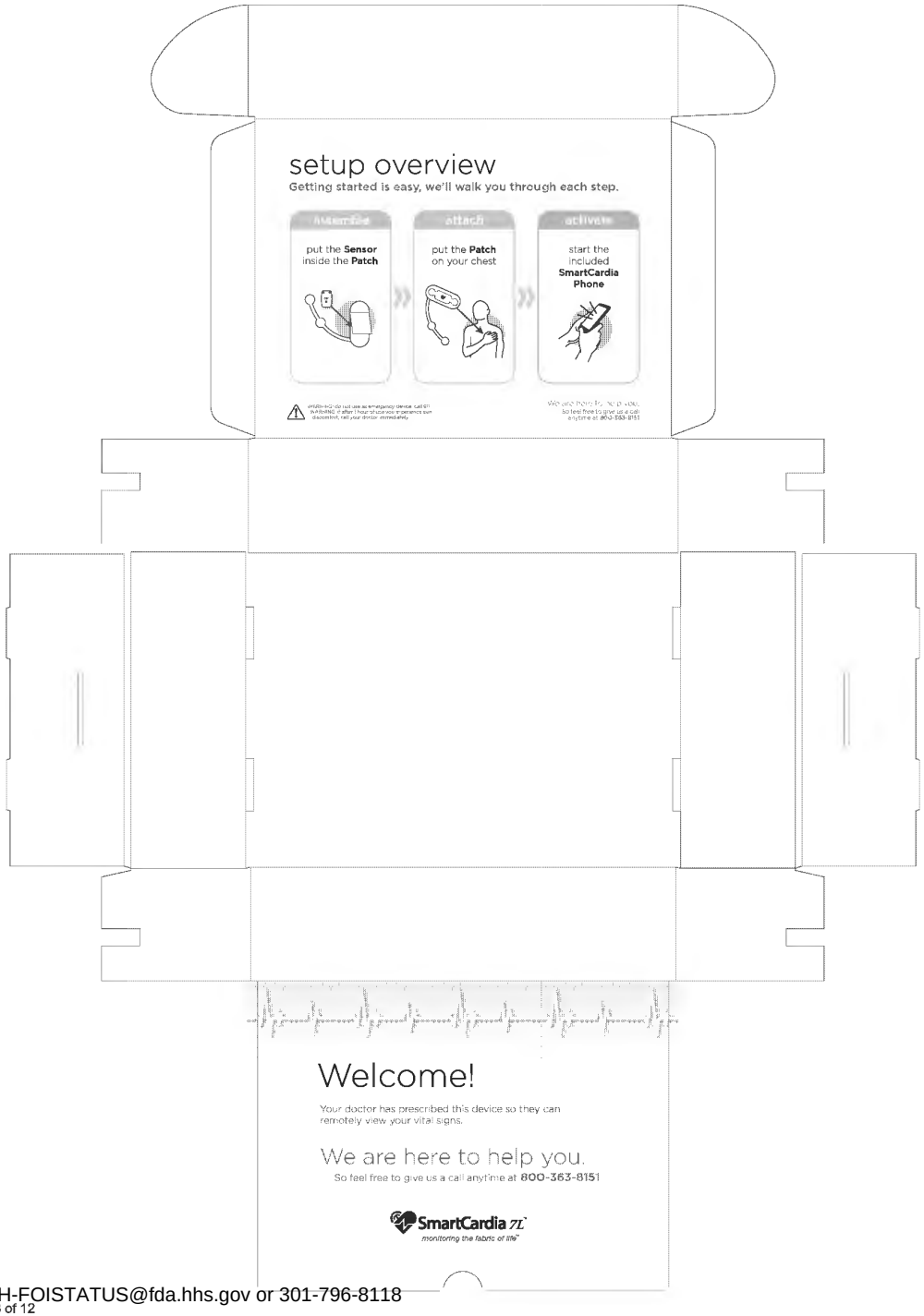
Kit / Box Packaging





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- SmartCardia Patch Card

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SmartCardia

IPX7 with Sensor

WARNING REMOVE BEFORE DEFIBRILLATION

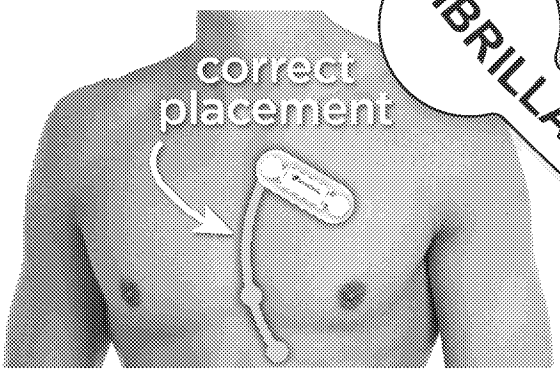
attaching your patch

1. prepare skin by shaving, cleaning and drying this area

2. remove clear backing from patch assembly & apply to chest as shown below

LATEX

NOTE: failure to prepare skin area can make removal of patch painful.



We are here to help you. So feel free to give us a call anytime at **800-363-8151**.

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- SmartCardia Phone Insert Card

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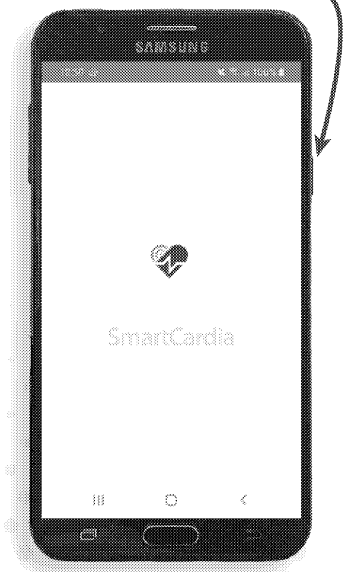
getting started

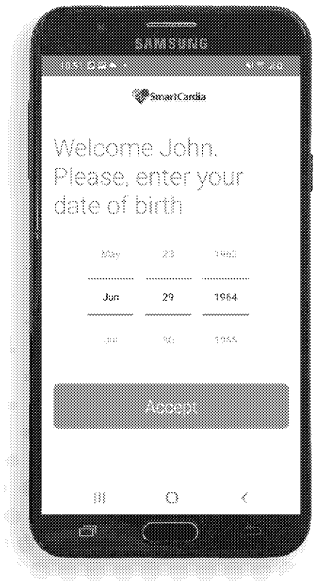
push side button to turn on phone



NOTE: you cannot make personal phone calls on this phone.

signing in

when your name is displayed on the screen, enter your date of birth and you're all set!



some important icons to know

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- SmartCardia Sensor Box

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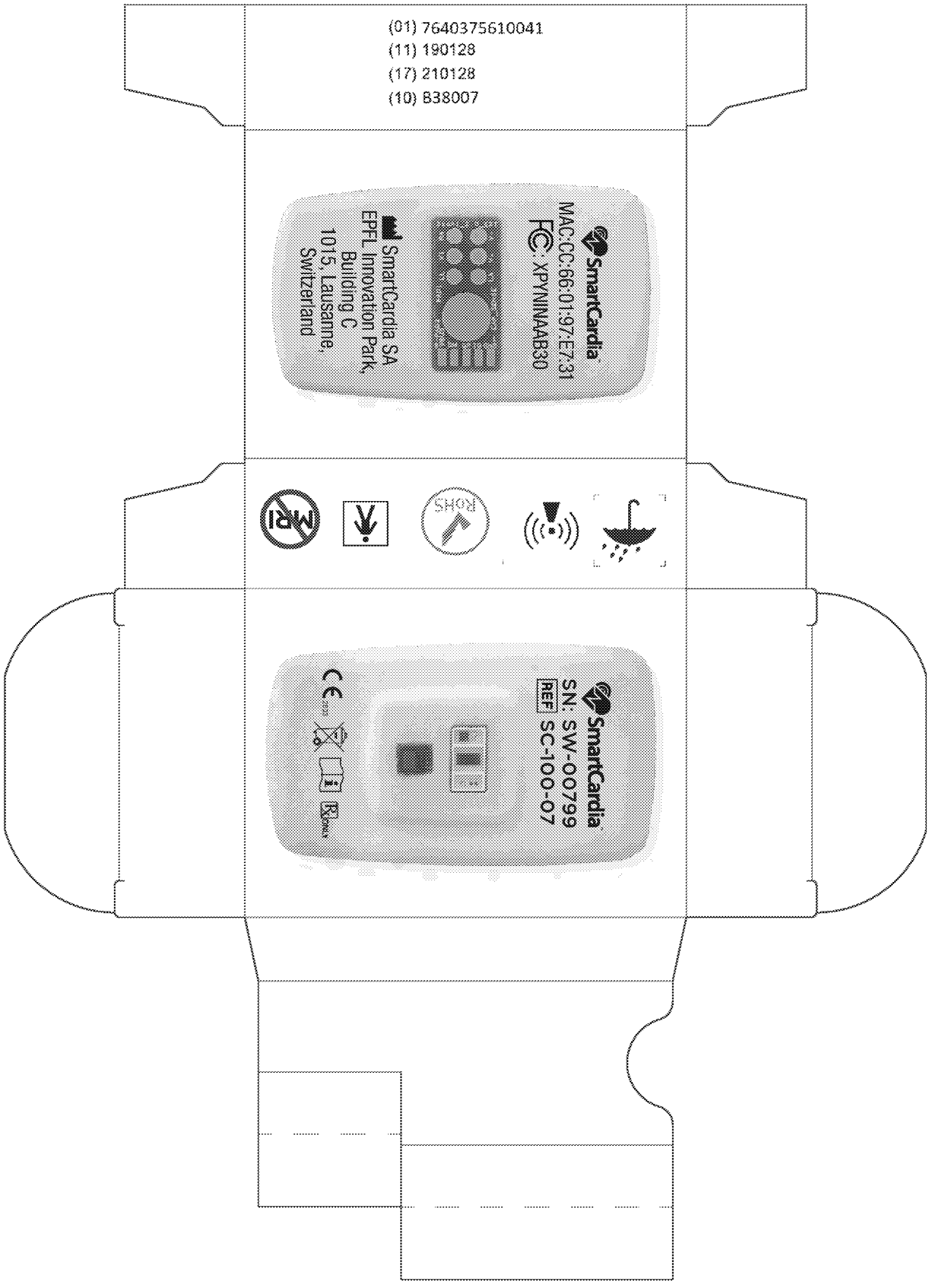

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- SmartCardia 7L Kit - Insert Card, Assemble, and Attach 7L Patch

Questions? Contact FDA/CDRH/OCE/DIDP at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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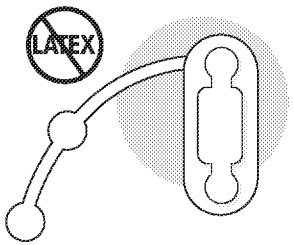
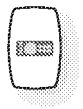
let's get started - assembling your patch

what you'll need:



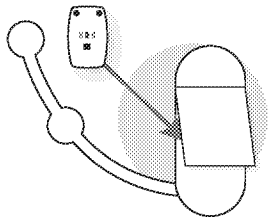
disposable Patch
IPX5



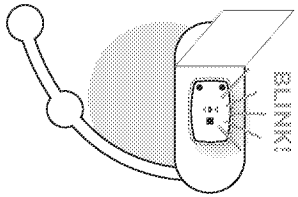
non-disposable Sensor
℞ ONLY IPX7

(located in the bottom of this box)

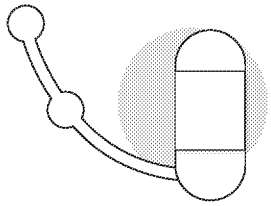
what you'll do:



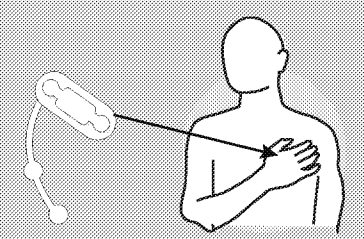
1. lift flap & insert **Sensor** into **Patch**



2. insert until the **Sensor** connects to **Patch** (the LED lights)



3. remove plastic cover/label, close and seal flap to **Patch**



attaching your patch

follow instructions on the back of this card to apply **Patch** to your chest

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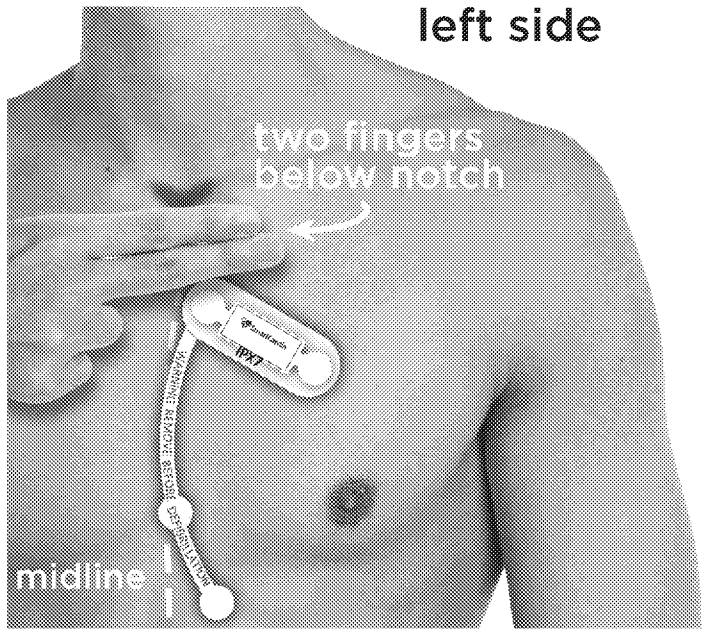
attaching your patch

1. prepare skin by shaving, cleaning and drying this area
(chest hair should be clipped or shaved)

NOTE: failure to prepare skin area can make removal of patch difficult

2. remove clear plastic backing from **Patch** assembly and take the following steps to attach **Patch** to your chest as shown

- place your two right fingers below notch at top of chest midline
- attach **Patch** just below your two fingers
- position electrode tail on mid-line and under left breast
- **Patch** should be at an angle toward your left armpit



We are here to help you. So feel free to give us a call anytime at **800-363-8151**

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020_Wireless Coexistence and RFID Testing - Cellular

Wireless Coexistence Test Report

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019_Wireless Coexistence and RFID Testing - Bluetooth

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019_Wireless Coexistence and RFID Testing - Bluetooth

RFID Test Report

(b)(4)

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018_Summary Report – EMC Performance Relative to (b)(4)

(b)(4)

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014_Reprocessing, Sterility, and Shelf-Life Documents

- Attachment E for IFU
- (b)(4) - Validation of the Manual Cleaning Process using Mild Detergent
- (b)(4) - Performance Accelerated Lifecycle Testing; REPORT NUMBER (b)(4)

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Attachment E Reprocessing, Cleaning, and Disinfection

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CONSULTING REPORT

CONSULTING OFFICE

(b)(4)

SPONSOR

(b)(4)
SmartCardia
EPFL Innovation Park, Building C
Lausanne, 1015
Switzerland

CONFIDENTIAL

PROJECT

Low Level Disinfection (LLD) Effectiveness

DEVICE

SmartCardia 7L System (b)(4)

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SmartCardia SA

TEST REPORT

SCOPE OF WORK

Performance Accelerated Lifecycle Testing

REPORT NUMBER

(b)(4)

ISSUE DATE

24-June-2022

PAGES

8

(b)(4)

(b)(4)

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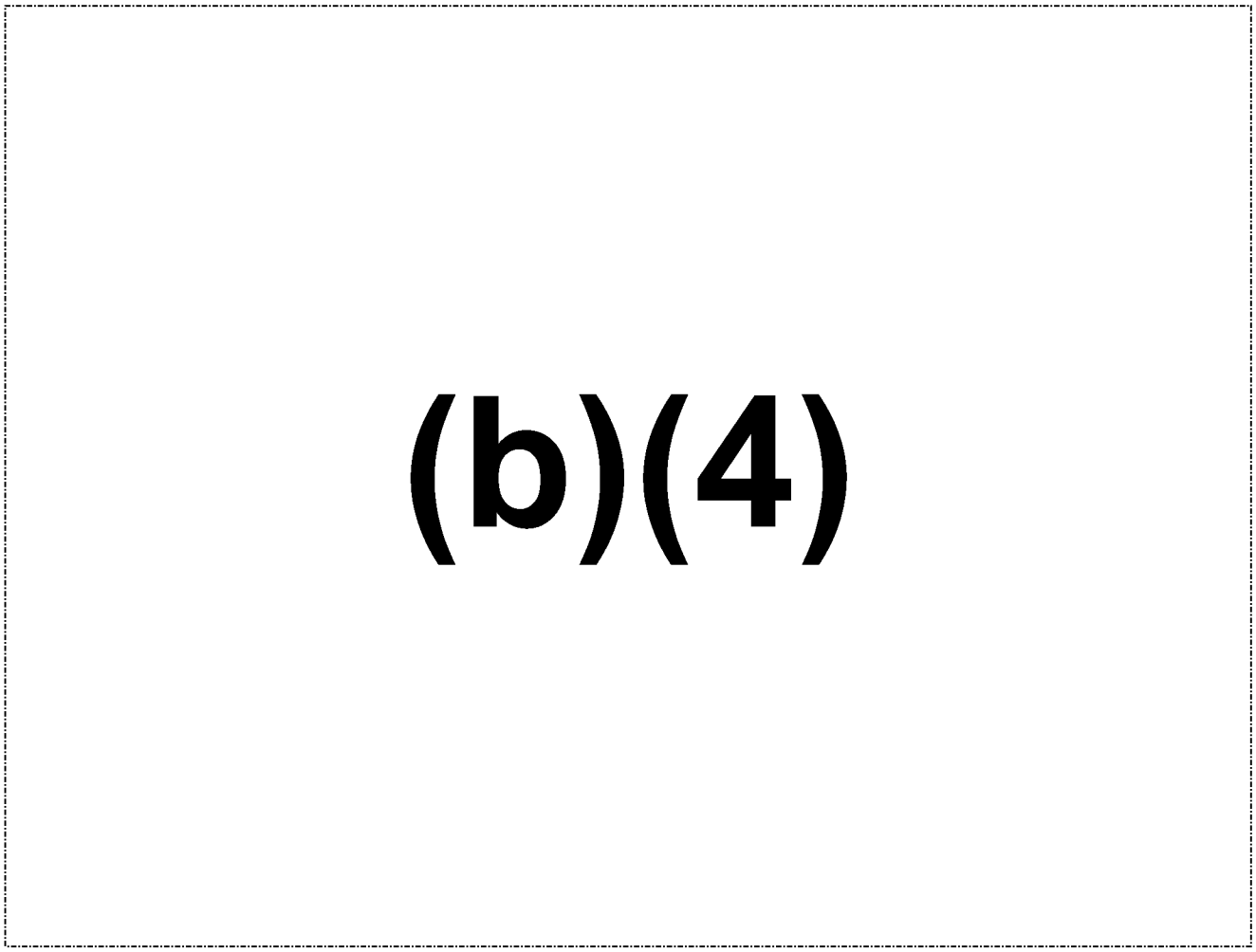
Reference: (b)(4) Cybersecurity Plan



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Cybersecurity Documentation

- Cybersecurity Management Plan

(b)(4) Cybersecurity Design Document

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7L Revision History

The following revisions are for the 7L Platform

Sensor

(b)(4)

© SmartCardia SA 2022

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SmartCardia 7L Platform List of Unresolved Anomalies

- SmartCardia is not aware of any unresolved anomalies that have an impact on safety or effectiveness for the 7L Platform

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Verifiacation and Validation Testing

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(b)(4) Verification and Validation Plan

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(b)(4) Verification Test Results - Physical Requirements, Hardware

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(b)(4) Verification Test Results - ECG Hardware

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(b)(4) Verification Test Results - Sensor CPU/Memory Hardware

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(b)(4) Verification Test Results - BLE Sensor Hardware (BH)

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4) Verification Test Results - Backend Hardware

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4)

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(b)(4)

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4) Verification Test Results – Labeling

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4) Kit Shipping Verification Test Report

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Verification Test Results (b)(4) Software

Questions? Contact FDA/CDRH/OCE/DDI at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Verification Test Results - ECG Cloud/Server Software

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(4) Verification Test Results - Notifications (Alerts/Alarms) Software

(b)(4) Alarm Visibility Protocol

(b)(4) Alarm Visibility Test Results

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Verification Test Results - Sensor to Mobile Link Software

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(b)(4) Verification Test Results - Battery Indicator Software

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(b)(4) Verification Test Results - Mobile SW Application Software

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(b)(4) Verification Test Results - Frontend Web Software

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(b)(4) Verification Test Results - Backend Software

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(b)(4) Verification Test Results - Web Browser Review (b)(4) Software

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(b)(4)

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(b)(4) Verification Test Results - Cybersecurity Requirements

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Human Factors Testing and Product Validation

(b)(4) Use Related Risk Analysis – Patient
User Related Risk Analysis – Clinician
(b)(4) Formative Test Plan – Patient
(b)(4) Formative Test Report – Patient
(b)(4) Formative Test Plan – Clinician
(b)(4) Formative Test Report – Clinician
(b)(4) Human Factors Validation (Summative) Test Protocol
(b)(4) Human Factors Validation Test Report
(b)(4) Validation Report (Research Collective)
(b)(4) Product Validation Protocol
(b)(4) Product Validation Report

(b)(4)

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Use Related Risk Analysis – Patient

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(b)(4) User Related Risk Analysis – Clinician

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(b)(4) Formative Test Plan – Patient

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Formative Test Report – Patient

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(b)(4) Formative Test Plan – Clinician

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(b)(4) Human Factors Validation (Summative) Test Protocol

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Human Factors Validation Test Report

(b)(4) Validation Report (Research Collective

(b)(4)

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Human Factors Engineering & Usability Engineering Report for the SmartCardia 7L Platform

Prepared for
SmartCardia, Inc.

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DIDat CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Software Development Environment/Life Cycle Process Description

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(b)(4) SmartCardia 7L Platform Software Architecture

SmartCardia	(b)(4)			
	SmartCardia 7L Platform Software Architecture			
	Issued by: **Quality Assurance**	Rev. (b)(4)	Confluence Version: (b)(4)	Effective Date: 12.04.2023

(b)(4)

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013_Instructions for Use

- PL-08 SmartCardia 7L Patient Guide
- PL-09 SmartCardia 7L Clinician User Guide
- PL-10 SmartCardia 7L Clinician QRG
- PL-17 SmartCardia 7L Platform Technical Manual

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PL-08 SmartCardia 7L Patient Guide

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· PL-10 SmartCardia 7L Clinician QRG

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PL-17 SmartCardia 7L Platform Technical Manual

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Substantial Equivalence Comparison Technological Characteristics Table Attachment

Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
Indications for Use	The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall	MoMe® Kardia is intended to be used for: 1.Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2.Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation) 3.Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath) 4.Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring. 5.ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.	The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for: 1. Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath). 4. Patients recovering from cardiac surgery or	The indications for use of the predicate and predicate/reference devices are substantially equivalent to the SmartCardia SA 7L Platform.

Questions? Contact FDA/CDRH/OCE/DHT at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Characteristic	Predicate Device VitalConnect Biosensor (K192757)	Predicate/Reference MoMe Kardia (K160064)	SmartCardia 7L Platform	Discussion of Major Differences
	outside selected parameters. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.	MoMe® Kardia is contraindicated for: 1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias. Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.	interventional procedures who are indicated for outpatient arrhythmia monitoring. 5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures. The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home. SmartCardia 7L Platform contraindications: 1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening	

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
			conditions such as lethal arrhythmias is required. 2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation. 2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.	
Intended Use	For monitoring and collection of physiological data in home and healthcare settings for patients 18 years or older and can include a notification of vital sign data outside selected parameters	For monitoring of physiological data in home and healthcare settings, for ECG reporting and arrhythmia detection in patients with non-life-threatening arrhythmias	For monitoring and collection of physiological data in home and healthcare settings, for patients 18 years or older and can include notification of vital sign data outside selected parameters; and for ECG reporting and arrhythmia detection in patients with non-life-threatening arrhythmias	Same
Number of ECG electrodes	2 electrodes, single lead ECG	3 electrodes	4 electrodes	Using multiple electrodes and deriving additional ECG vectors provides additional information for the clinician. This does not affect safety or effectiveness.

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
Number of channels transmitted	1 channel	2 channels	3 channels	Same.
Parameters Monitored	Heart rate, electrocardiogram (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, activity (including step count), and posture (body position relative to gravity including fall)	Heart rate, electrocardiogram (ECG)	Heart Rate, electrocardiogram (ECG signal),	Same as predicate /reference device
Heart Rate Accuracy	<±5 or 10% Beats per Minute, whichever is greater	Not available	± 3 BPM	Same
Function in the presence of Pacemaker Pulse	No, Heart Rate values (including heart rate variability and R-R interval) is not available for patients with pacemakers	Yes	Yes	Same as predicate/reference device
Analysis Channels	1	1	1	Same
Arrhythmia detection	Proprietary, Located on Server	Proprietary, Located on Server	Proprietary, Located on Server	Same
Arrhythmia Types Detected	Atrial Fibrillation, Pause, Sinus Arrhythmia, Sinus Bradycardia, Sinus Tachycardia, Supraventricular Tachycardia, 2nd Degree	Atrial Fibrillation, Atrial Fibrillation (new onset and High HR AFib), Pause, Bradycardia (low heart rate), Tachycardia (high heart rate), 2nd Degree AV Block, Complete Heart Block,	Atrial Fibrillation, Bradycardia, Tachycardia, Pauses, Presence of VEB, Ventricular Couplets, Ventricular Short Runs, Ventricular Long Runs,	Same. The SmartCardia 7L Platform detects the same arrhythmia types and does detect non-life-threatening arrhythmia in the same

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
	AV Block, Ventricular Bigeminy, Ventricular Trigeminy, Prolonged PR, Wide QRS, Prolonged QT Interval	Ventricular Fibrillation, Ventricular Tachycardia	Ventricular Tachycardia, Presence of SVEB, Supraventricular Couplets, Supraventricular Short Runs, Supraventricular Long runs, Ventricular / Supraventricular Bigeminy / Trigeminy.	manner as the predicate/reference devices. Heart Rate and Atrial Fibrillation are real-time notifications which is the same as the VitalConnect Platform. All other arrhythmias are detected and triggered as an event in the stored retrospective Holter data for later verification and report compilation.
Battery Type	Disposable zinc air	Li Ion Rechargeable	Disposable Manganese Oxide-lithium	Substantially equivalent.
Data Acquisition	Body worn sensor plus VistaTablet gateway	Body worn sensor / transmitter (MoMe) with cellular communication gateway included	Body worn sensor plus SmartCardia Phone gateway	Same
Data Transmission	BLE to VistaTablet, WiFi to cloud server	Cellular from MoMe to cloud server	BLE to phone, Cellular or WiFi to cloud server	Same
User Event Trigger	Yes, push button on sensor	Yes, push button on sensor	Yes, event button on phone	Same
Use Environment	Physician practice, clinics, healthcare settings, sensor use in home	Physician practice, clinics, healthcare settings, sensor use in home	Physician practice, clinics, healthcare settings, sensor use in home	Same
Data Storage and Report Generation Environment	Remote cloud based	Remote cloud based	Remote cloud based	Same
Prescription Use	Yes	Yes	Yes	Same

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
Clinician access to patient data	Yes	Yes	Yes	Same
Operating	Temperature: 10 – 40 ^{0}C	Temperature: 5 – 40 ^{0}C	Temperature: Operating: +5	Similar, operating
(b)(4)				
Water Ingress	Waterproof with adhesive overlay	Not Available	Waterproof – tested to IPX7	Same
Defibrillator Protection	Yes	No	No. Passes energy reduction test	Similar to predicate
Electrode type	Hydrogel	Not Available	Hydrogel	Same
Patch Adhesive	Hydrocolloid	Not Available	Hydrocolloid	Same

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510(k) Premarket Notification SmartCardia SA
SmartCardia 7L Platform
Comprehensive Device Description

Device Description

The SmartCardia SA 7L Platform is a system comprising a wireless sensor component (the 7L Sensor), an adhesive patch (the 7L Patch) to which the 7L Sensor connects, a mobile component (the SmartCardia Phone), and a cloud-based backend server that houses the patient database. The SmartCardia Phone is an Android OS mobile phone that is configured and provided by SmartCardia such it can only be used by the SmartCardia mobile application (it does not function as a usable phone, only as a mobile gateway for the SmartCardia patient data). The data are viewed on the SmartCardia Phone, and via a SmartCardia Web Browser application. The 7L Sensor and 7L Patch make up a body worn device and consists of the *reusable* electronic 7L Sensor and a *disposable* adhesive 7L Patch into which the 7L Sensor is inserted and connection is made. The sensor and patch assembly adheres to the chest and contains the batteries to power the connected reusable sensor to be able to wirelessly measure various physiological parameters (Electrocardiogram, and heart rate) of the patient. The patch includes hydrogel electrodes and hydrocolloid material adhesive.
The reusable *7L Sensor* and SmartCardia phone are returned for reprocessing and preparation for their next use. The reprocessing instructions are included in the SmartCardia 7L Platform Clinician User Guide (Instructions for Use) and the *PL-17 SmartCardia 7L Platform Technical Manual*.

(b)(4)

Data are wirelessly communicated from the 7L Sensor to the SmartCardia Phone via Bluetooth Low Energy (BLE) . The SmartCardia Phone is an Android OS phone that is pre-configured and provided by SmartCardia as part of the system. The SmartCardia Phone running the SmartCardia application communicates patient data to the back-end cloud-based server hosted by Amazon Web Services (AWS). The back-end server receives and stores the data transferred by the SmartCardia Phone, hosts the 7L Web browser, provides supplemental analysis, and communicates the results to the clinician.

The 7L Web Browser provides real time monitoring for the patient's ECG and can display alarm signals for Heart Rate (high and low) and for Atrial Fibrillation. The heart rate alarm limit settings are user selectable from the default limit settings. In addition, the clinician can set non alarm event e-mail notifications for atrial fibrillation new onset, high heart rate atrial fibrillation, bradycardia new onset, pause, and tachycardia new onset in the analysis component on the back-end server. These events do not provide real-time alarm notifications , but the clinician can enable notifications to be sent via email, and mark the event in the database for review.

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(b)(4)

Modes of Operation

The SmartCardia 7L Platform supports three types monitoring or levels of service modes:

1. Holter Monitoring (up to 48 hours, and Extended Holter Monitoring > 48 hours up to 14 days)
2. Event Monitoring (up to 48 hours, and >48 hours up to 14 days)

(b)(4)

The SmartCardia 7L Platform has the following characteristics:

a. It is non-invasive and has no significant safety risks,
b. It uses electrode and ECG technology that is the same as that of the predicate device K192757,
c. It is used in conjunction with other symptoms and tests to aid the physician in the diagnosis or monitoring of patients with cardiac arrhythmia.

Patient and Clinician User Interaction

Patient interaction consists of the following:

1) The clinician or healthcare professional applies the 7L Sensor to the patient chest. This may be done by the patient as well, without clinician intervention,
2) The clinician or healthcare professional admits the patient to the SmartCardia 7L Platform which couples the sensor, phone, and patient identification. The service begins when the patient identifies their name on the SmartCardia phone and correctly enters their date of birth (patient name and date of birth provide authentication). The clinician also sets up or verifies the account (with proper patient information) with the SmartCardia backend server for monitoring,
3) The Patient can enter an event by pressing a button on the SmartCardia Phone to tag the event for review. This will present a list of symptoms for the patient to attach to the event,
4) The patient may be directed to replace the disposable 7L Patch if needed during monitoring (example. Low battery indicated during longer term monitoring),
5) The patient is directed to remove the 7L Sensor from the 7L Patch after monitoring is complete,
6) The patient is directed to return the 7L Sensor and the SmartCardia Phone and its charger to the physician.

Performance Specifications

The SmartCardia SA, 7L Platform technical characteristics and performance specifications are described in the following table:

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Characteristic	SmartCardia SA, 7L Platform (This Submission)
Intended Use	The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for: 1. Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath). 4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring. 5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures. The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home. SmartCardia 7L Platform contraindications: 1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required. 2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.
Processing	
ECG/Heart Rate	The 7L Patch consists of four electrodes embedded in an adhesive 'patch' attached to the patient chest. From these electrodes, the ECG can be presented as 7 leads. These are identified as Leads A, B, C, D, E, F, G. The four electrodes transmit three independent vectors of ECG. These are combined to show the ECG presentation of one, three, or 7 ECG leads.

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Characteristic	SmartCardia SA, 7L Platform (This Submission)
	The heart rate and analysis is calculated from the single channel of the patch using the lead that is identified as "A"
HR accuracy	+/- 3 Beats per minute
Battery	(b)(4)
Battery Life	14 days continuous operation
Applicable Standards	
Wireless BLE	Bluetooth Low Energy (BLE) v5.0 minimum
Risk Management	ISO 14971:2019 Medical devices – Application of risk management to medical devices
Quality Management System	ISO 13485:2016 Medical devices – Quality management system – requirements for regulatory purposes
Software	AAMI/ANSI/IEC 62304:2006/A1:2016 Medical Device Software – Software Life Cycle Processes
Electrical Safety	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
Electromagnetic Compatibility	IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Wireless Coexistence	USEMCSC C63.27-2021, American National Standard for Evaluation of Wireless Coexistence
RFID Immunity	AIM Standard 7351731: 2021-06-04, Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard
Home Healthcare Environment	IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Ambulatory ECG	IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
Arrhythmia (report formatting)	ANSI/AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms
Biocompatibility	ISO 10993 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, Part 10: Tests for irritation and skin sensitization; and Part 23: Intracutaneous Reactivity test
Water Ingress (IPX7 rating)	BS EN 60529:1992+A2:2013 Degrees of protection by enclosures (IP code)

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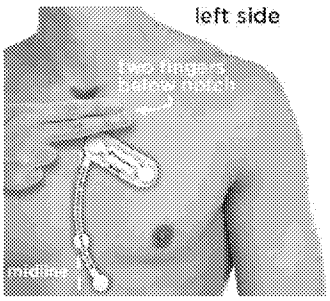
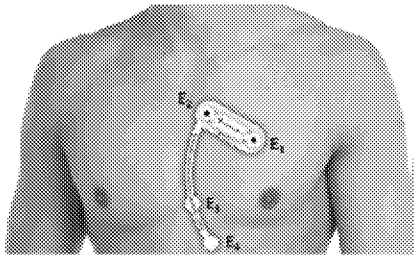
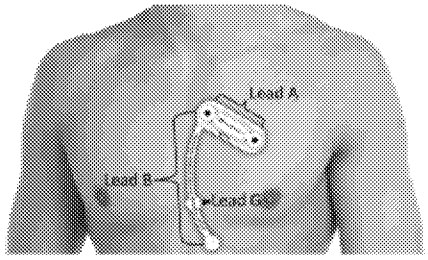
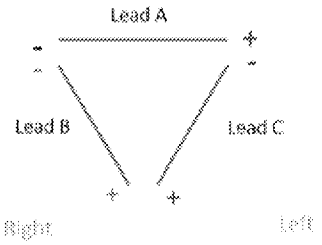


The SmartCardia 7L Sensor/7L Patch is positioned as indicated in the figure at left using two fingers to place the top of the 7L Sensor/7L Patch assembly below the suprasternal notch. The middle electrode is located on the mid-line of the sternum to ensure consistent location for ECG monitoring.

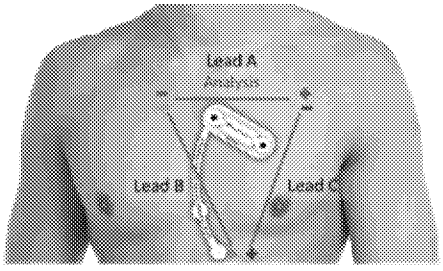
The SmartCardia 7L system provides up to seven channels of ECG for viewing. This is derived from 4 electrodes integrated into the Patch. The identification of the electrodes, the ECG vectors transmitted, and the relationship of the ECG channels to the electrodes is shown below.







Acquired signals- Lead A, Lead B, Lead G
Analysis is done on Lead A only
Derived signals- Lead, C, Lead D, Lead E, Lead F



ECG Channels Available for Analysis and Display
Lead A = E1 - E2
Lead B = E4 - E2
Lead C = ECG A - ECG B

Lead D = (ECG A - ECG C) / 2
Lead E = (ECG A + ECG B) / 2
Lead F = (ECG B + ECG C) / 2

Lead G = E3 - (ECG A + ECG B + ECG C) / 3

Analysis is done on Lead A only.

As shown in the above figures, the 7L Patch with 7L Sensor, contains the ECG electrodes and the wireless BLE component is in the 7L Sensor.

Analysis is performed on ECG Lead A only.

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Variants

The SmartCardia 7L Platform (part number (b)(4)) is offered in a *single variant* that includes the following components:

(b)(4)

*The 7L Patch is a disposable single-patient use accessory. The 7L Patch can be provided separately since it contains the batteries for the system and may require replacement if longer term Holter monitoring is required (> 14 days).

Accessories

The following accessories are offered with the SmartCardia SA, 7L Platform. These accessories have not received prior 510(k) clearance.

1) (b)(4) 7L Patch, an adhesive chest patch with 4 electrodes

Labeling Accessories:

2) PL-08, SmartCardia 7L Instructions for use – Patient
3) PL-09, SmartCardia 7L Instructions for use – Clinician
4) PL-10, SmartCardia 7L Quick Start Guide - Clinician
5) PL-17, SmartCardia 7L Technical Manual

Device Background

The SmartCardia 7L Platform has been created as a wearable wireless physiological monitoring system to continuously stream ECG data in near real time. Data are transmitted from ECG sensors via Bluetooth Low Energy (BLE) to a mobile phone (Android operating system) which in turn communicates this data to the SmartCardia backend. (b)(4)

(b)(4)

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Patient Contact Components and Materials

The SmartCardia SA 7L Patch is the only patient contact materials or components which has surface-contacting electrodes and an adhesive surface to be worn by the patient. The SmartCardia SA 7L Sensor is fully enclosed in the SmartCardia SA 7L Patch and does not contact the patient. The duration of contact can be up to 14 days.

The nature of body contact and duration of contact (prolonged (b)(4), places the 7L Patch in category B per FDA Guidance "Use of International Standard ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued September 4, 2020. The patient contact materials consist of hydrogel and hydrocolloid. A list of the materials is included in this section. A copy of the biocompatibility test reports is included in *Section 15 Biocompatibility*. Figure 10-6 shows the mechanical stack-up drawing of the SmartCardia 7L Patch that contacts the patient. The materials that are in patient contact are identified in Table 1 below.

Table 1, Patient Contact Materials

Material	Description	Manufacturer	Contact Duration	Contact Area*
(b)(4)				

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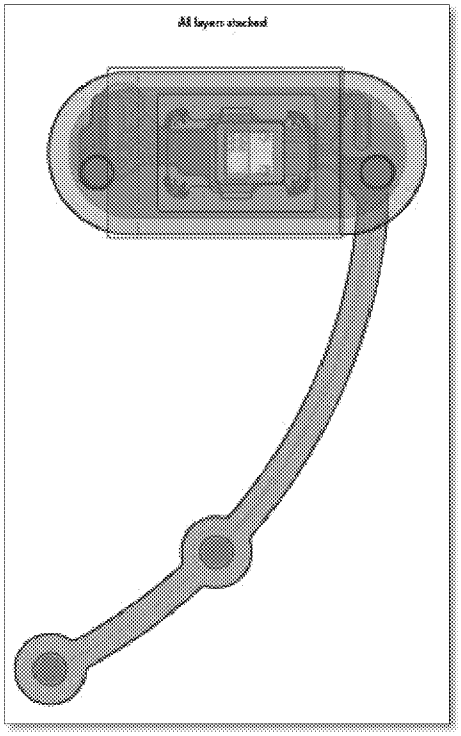
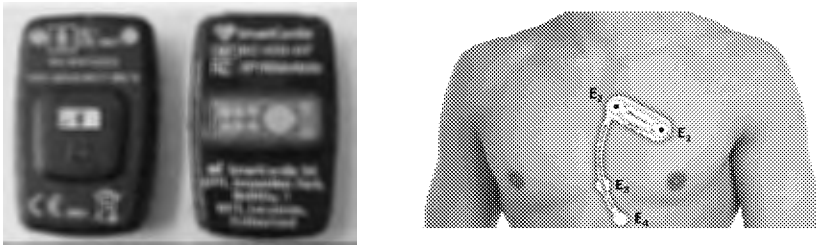


Figure 10-4 7L Patch – Mechanical View (All layers Attached).

In Figure 10-4, the circles show the ECG electrodes. *Figure 10-5* shows photos of the 7L Sensor (front and back) and the 7L Patch assembly on the patient's chest.



Patient Side Patch Side

Figure 10-5 Left to right: Sensor skin side, Sensor connector side, 7L Patch on the chest

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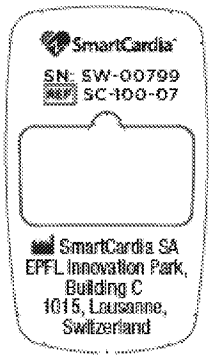
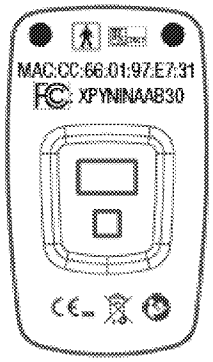
Device Description Packaging

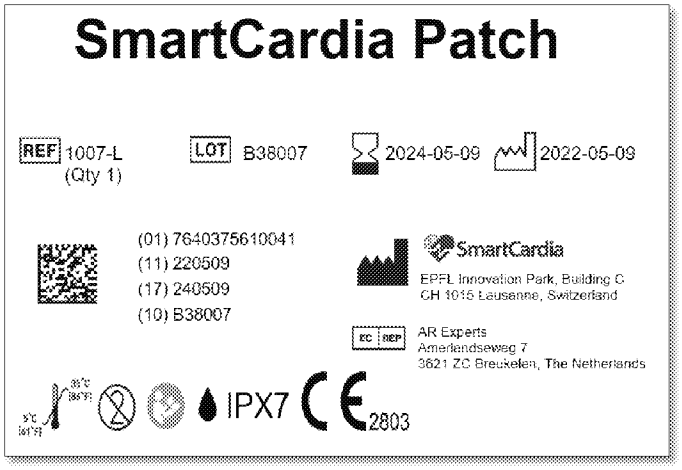
The SmartCardia 7L Platform is packaged as a kit which includes a carton box, inserts with instructions, and IFU. The drawings for those are included with “Labeling”, “Package Labeling”.

The 7L Sensor is an encapsulated sensor that is labeled appropriately with manufacturer's identification and information related to regulations. Labels are laser etched onto the front and rear of the sensor to ensure lifetime readability.





The item that is considered an accessory is the 7L Patch as it can be sold as a separate part and used if the desired monitoring time is greater than 14 days. This is designated as part number DS-33, 7L Patch, an adhesive chest patch with 4 electrodes. The 7L Patch is packaged in a foil pouch that is labeled as shown.



Foil Pouch Label

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Foil Pouch packaging w/label

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021_EMC Wireless, and EMT Test Reports

- IEC 60601-2 EMC (b)(4)
  Report No. (b)(4)

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Device Hazard Analysis

(b)(4) Risk Management Plan

Risk Analysis Summary

Risk Management Report

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(b)(4) Risk Management Report - 7L Platform

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(b)(4) Product User Needs and Design Inputs

SmartCardia	Device Specifications (b)(4)			
	Product User Needs and Design Inputs			
	Issued by: **Quality Assurance**	Rev.: (b)(4)	Confluence Version : (b)(4)	Effective Date: 25.04.2023

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(b)(4) Product User Needs and Design Inputs

SmartCardia	Device Specifications (b)(4)			
	Product User Needs and Design Inputs			
	Issued by: **Quality Assurance**	Rev.: (b)(4)	Confluence Version: (b)(4)	Effective Date: 25.04.2023

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(b)(4)

Device Hazard Analysis

Safety Analysis

IEC 62304:2006+AMD1:2015 Medical Device Software - Software life cycle process applies a risk management approach to the software life cycle. This requires the manufacturer to apply a risk management process complying with ISO 14971 Medical devices - Application of risk management to medical devices.

In compliance with the IEC 62304:2006+AMD1:2015 Medical Device Software - Software life cycle standard, the software safety classification is determined as either class A, B, or C according to the risk of harm to the patient, operator, or other people resulting from a hazardous situation to which the software can contribute to a worst-case-scenario as shown in the following figure.

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(b)(4)

Traceability Analysis

As stated earlier, traceability is defined in the following document:

(b)(4)

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(b)(4)

Off-The-Shelf (OTS) Software

OTS Basic Documentation

(b)(4)

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Extent of Standard Conformance: **IEC 60601-1 Summary Report Table**

This summary provides a high-level conformance review. For detailed descriptions including sub-clauses see (b)(4) (b)(4), October 14, 2021

IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
4	**General Requirements**				
4.1	Requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse	Yes			
4.2	Risk Management	Yes			
4.3	Essential Performance	Yes	(b)(4)		022_Performance Testing, page 306
4.4	Expected Service Life	Yes			014_Reprocessing_Sterility_Shelf-Life Report, pages 4-96
4.5	Equivalent Safety, Alternative Methods of Risk Control	NA			Alternate means for addressing risk are not used.
4.6	Patient Contact Part The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS shall be subject to the requirements for APPLIED PARTS.	Yes			
4.7	Single Fault Condition	Yes			
4.8	Components of ME Equipment	Yes			
4.9	High-Integrity Components	NA			No high integrity components
4.10	Power Supply	Yes			
4.10.1	ME EQUIPMENT shall be suitable for connection to a SUPPLY MAINS, be specified for connection to a separate power supply or be powered by an INTERNAL ELECTRICAL POWER SOURCE. Alternatively, a combination of these sources may be used.	Yes	(b)(4)		
4.10.2	ME Equipment intended to be connected to supply mains	NA			(b)(4)

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
					(b)(4)
4.11	Power Input	NA			
5	**General Requirements for testing**				
5.1	Type Tests	NA			Testing was conducted
	The results of the RISK ANALYSIS are used to determine which combination(s) of simultaneous faults are to be tested.	Yes			(b)(4)
5.2	Number of Samples	Yes			
5.3	Ambient temp., humidity, pressure; tests conducted within the environmental conditions specified in the technical description	Yes			
5.4	**Other Conditions**				
	a) Test under least favorable conditions as stated in IFU	Yes			
	b) Adjustments set to least favorable conditions as stated in IFU	NA			(b)(4)
	c) Tests within limits of cooling chemical or liquid	NA			No cooling liquid required
	d) When cooling water is used, use potable water	NA			No cooling liquid required
5.5	Supply voltages				
	a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations is taken into account.	NA			(b)(4)
	b) ME EQUIPMENT marked with a RATED frequency range is tested at the least favorable frequency within that range	NA			No external power connections (AC or DC) used
	c) ME EQUIPMENT designed for more than one RATED voltage, or for both a.c. and d.c., is tested in conditions (described in 5.4) related to the least favorable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It could be necessary to perform some tests more than once in	Yes			(b)(4)

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Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	order to establish which supply configuration is least favorable.				
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered:	NA			Not connected to external DC power source
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favorable conditions:	Yes			
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	NA			(b)(4)
5.6	Repairs and modifications	NA			
5.7	Humidity preconditioning treatment	Yes			
5.8	Sequence of Tests	Yes			
5.9	Determination of Applied Parts and Accessible Parts				
5.9.1	Applied Parts identified	Yes			
5.9.2	Accessible Parts				
5.9.2.1	Use of test finger	Yes			022_Performance Testing, page 114 ; (b)(4) (b)(4)
5.9.2.2	Use of test hook	NA			No Openings
5.9.2.3	Conductive parts of controls accessible after removal of knobs	NA			No Such Parts
6	**Classification of ME Equipment**				
6.2	Protection against electric shock	Yes			(b)(4)
6.3	Water Ingress or particulate matter	Yes			
6.4	Methods of Sterilization	NA			Not provided sterile, no sterilization requirement
6.5	Use in Oxygen Rich Environment	NA			(b)(4)
6.6	Mode of Operation	Yes			Continuous Operation
7	**Identification, Marking, Documents**				
7.1.1	Usability of identification, marking and documents	Yes			014_Reprocessing_Sterility_Shelf-Life Report, pages 4-96

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
7.1.2	Legibility of identification, marking and documents	Yes			014_Reprocessing_Sterility_Shelf-Life Report, pages 4-96
7.1.3	Durability of identification, marking and documents	Yes	(b)(4)		014_Reprocessing_Sterility_Shelf-Life Report, pages 4-96
7.2	Marking on the outside of ME Equipment				
7.2.1	Marking on Equipment	Yes			
7.2.2	Identification	Yes			
7.2.3	Accompanying Document	Yes			
7.2.4	Accessories	Yes			
7.2.5	Equipment intended to receive power from other equipment	NA			(b)(4)
7.2.6	Connection to supply mains	NA			
7.2.7	Electrical input power from supply mains	NA			
7.2.8	Output Connectors	Yes			
7.2.9	IP Classification	Yes		IPX7 rating identified at clause 6.3 and verified by UL	IPX7 identified in IFU and on 7L Patch labeling, not marked on 7L Sensor body.
7.2.10	Applied Parts	Yes			Type BF
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	NA			Not type B
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1	Yes			
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1	NA			Not type CF
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1	NA			No defibrillation protected applied parts used
	Proper symbol marked adjacent to or on connector for APPLIED PART:	NA			No defibrillation protected applied parts used

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	Safety sign 2 of Table D.2 placed near relevant outlet	NA			No defibrillation protected applied parts used
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use	NA			(b)(4)
7.2.11	Mode of Operation for Continuous Operation	Yes			
7.2.12	Fuses	NA			No replaceable fuses
7.2.13	Physiological effects (safety signs and warning statements)	NA			(b)(4)
7.2.14	High voltage terminal devices	NA			No high voltage used
7.2.15	Cooling conditions	NA			No cooling used
7.2.16	Mechanical Stability	NA			Body worn device, not applicable per clause 9.4
7.2.17	Protective Packaging	Yes			
	Marking with safety sign for premature unpacking	NA			(b)(4)
	Risk Management File includes risk associated with premature unpacking	Yes			
	Packaging of sterile equipment or accessories indicates sterilization method	NA			Not provided sterile, no sterilization requirements
7.2.18	External Pressure Source	NA			No external source of pressure
7.2.19	Functional Earth Terminals	NA			No functional Earth terminals used
7.2.20	Removable protective means	NA			No such protective means
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms:	NA			Not mobile equipment
7.3	**Marking on inside of Equipment**				
7.3.1	Heating elements	NA			No heating elements
7.3.2	High Voltage Parts	NA			No high voltage parts
7.3.3	Type of battery and mode of insertion (if applicable)	Yes			(b)(4)
7.3.4	Fuses, thermal cut-outs, over-current releases	NA			No fuses, thermal cut-outs, over-current releases are in the device
7.3.5	Protective Earth Terminals	NA			No Earth terminals
7.3.6	Functional Earth Terminals	NA			No Earth terminals
7.3.7	Supply Terminals	NA			No supply terminals
7.3.8	Temperature of supply terminals	NA			No supply terminals
7.4	**Marking of Controls and Instruments**				

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
7.4.1	Power Switches	NA			No power switch
7.4.2	Control Devices	NA			No control devices or switches
7.4.3	Units of Measure	Yes			(b)(4)
7.5	**Safety Signs**				
	Safety sign with established meaning used	Yes			
	Risk management identifies markings used to convey warnings	Yes			
	Affirmative statements used	Yes			
	Safety sign proper colors	Yes			
	Safety notices included precautions or instructions on how to reduce risks	Yes			(b)(4)
	Safety signs including any supplementary text or symbols described in IFU	Yes			013_Instructions for Use, pages 40-43
	Language of safety signs are in a language acceptable to the intended operator	Yes			
7.6	**Symbols**				
7.6.1	Explanation of Symbols	Yes			
7.6.2	Symbols from Annex D	Yes			
7.6.3	Symbols for controls and performance	Yes			
7.7	**Colors**				
7.7.1	Protective Earth Conductor	NA			No protective Earth
7.7.2	Protective Earth Connection	NA			No Earth Connection
7.7.3	Green and Yellow insulation	NA			No Earth conductors
7.7.4	Neutral Conductor	NA			No Neutral Conductor
7.7.5	Power Supply Cord Conductors	NA			No power supply cord
7.8	**Indicator Lights and Controls**				
7.8.1	Colors of indicator lights	Yes			Complies with standard
7.8.2	Red used only for emergency control	Yes		Per IEC 60601-1-8	(b)(4)
7.9	**Accompanying Documents**				
7.9.1	General	Yes			
	Electronic documents	NA			Documents not provided electronically
	Documents consistent with education, training, and other	Yes			(b)(4)

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	needs of individuals for whom they are intended				(b)(4)
7.9.2	**Instructions for Use**				
7.9.2.1	Use as intended by manufacturer	Yes			
7.9.2.2.	Warning and Safety Notices	Yes			
7.9.2.3	Equipment specified for connection to a separate supply	Yes			(b)(4)
7.9.2.4	Electrical Power Source	Yes			
7.9.2.5	Equipment Description	Yes			
7.9.2.6	Installation	NA			No installation procedures required
7.9.2.7	Isolation from power supply mains	NA			Internally powered only
7.9.2.8	Start-up Procedure	Yes			
7.9.2.9	Operating Instructions	Yes			
7.9.2.10	Messages	Yes			
7.9.2.11	Shutdown Procedure	Yes			
7.9.2.12	Cleaning, disinfection, and sterilization	Yes			
7.9.2.13	Maintenance – instructions for preventive inspection, calibration, maintenance and its frequency	Yes			
7.9.2.14	Accessories, supplementary equipment, used material	Yes			
	Other equipment providing power to ME SYSTEM sufficiently described	NA			System does not receive power from other equipment
7.9.2.15	Environmental Protection	Yes			
7.9.2.16	Reference to technical description	Yes			
7.9.2.17	Equipment emitting radiation	NA			Does not emit radiation
7.9.2.18	Equipment provided sterile	NA			Not provided sterile
7.9.2.19	Unique version identifier	Yes			
7.9.3	**Technical Description**				
7.9.3.1	General	Yes			
7.9.3.2	Replacement of fuses, power supply cords, others	Yes			
7.9.3.3	Circuit diagrams, component part lists, etc.	NA			Device not repairable
7.9.3.4	Mains Isolation	NA			Internally powered only
8	**Protection against electrical hazards from ME Equipment**				
8.1	Fundamental rule of protection against electrical shock	Yes			
8.2	**Requirements related to power source**				
8.2.1	Connection to a separate power source	NA			Previously evaluated by certified power supply for phone

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
8.2.2	Connection to an external d.c. power source	NA			Previously evaluated by certified power supply for phone
8.3	Classification of applied parts	Yes			(b)(4)
8.4	**Limitation of voltage, current or energy**				
8.4.1	Patient connections intended to deliver current	Yes			
8.4.2	**Accessible Parts including applied parts**				
	a) The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT	Yes			
	b) * The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS other than PATIENT CONNECTIONS shall not exceed the limits for TOUCH CURRENT	Yes			
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately Instructed. The voltage to earth or to other ACCESSIBLE PARTS shall not exceed 42,4 V peak a.c. or 60 V d.c. in NORMAL CONDITION or in SINGLE FAULT CONDITION.	Yes			
	d) The voltage and energy limits specified in c) above also apply	NA			No such parts, device has no openings
	e) Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the ACCESS COVER is opened	NA			(b)(4)
8.4.3	ME Equipment intended to be connected to a power source by a plug	NA			
8.4.4	Internal capacitive circuits	NA			No such parts
8.5	**Separation of parts**				
8.5.1	Means of Protection (MOP)				
8.5.1.1	Two Means of Protection (MOP)	Yes			
8.5.1.2	Means of patient protection (MOPP)	Yes			

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
8.5.1.3	Means of Operator Protection (MOOP)	NA			No MOOP used
8.5.2	**Separation of Patient Connections**				
8.5.2.1	F-Type Applied Parts	NA			Device is one all-inclusive applied part.
8.5.2.2	Type B Applied Parts	NA			No type B applied parts
8.5.2.3	Patient Leads	NA			No patient cable
8.5.3	Maximum Mains Voltage	NA			No mains voltage
8.5.4	**Working Voltage**				
	General	Pass			No d.c. ripple present, no defibrillator-protected parts used, no motors provided.
8.5.5	**Defibrillation-Proof Applied Parts**				
8.5.5.1	Defibrillation Protection	NA			Not Defibrillator Proof, Warning on patch and in IFU to remove before defibrillation
8.5.5.2	Energy Reduction Test	Yes	(b)(4)		022_Performance Testing, page 327
8.6	**Protective earthing, functional earthing, and potential equalization of ME Equipment**				
8.6.1	Applicability of requirements	NA			No earthing connections
8.6.2	Protective Earth Terminal	NA			Not class I equipment. No PE
8.6.3	Protective earthing of moving parts	NA			Not class I equipment. No PE
8.6.4	Impedance and current-carrying capability	NA			Not class I equipment. No PE
8.6.5	Surface coatings	NA			Not class I equipment. No PE
8.6.6	Plugs and sockets	NA			Not class I equipment. No PE
8.6.7	Potential equalization conductor	NA			No potential equalization terminals used
8.6.8	Function Earth Terminal	NA			No potential equalization terminals used
8.6.9	Class II ME Equipment	NA			Not class II equipment. Phone charger previously evaluated and certified
8.7	**Leakage Currents and Patient Auxiliary Currents**				
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3	Yes			
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7	Yes			

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
8.7.2	Single Fault Conditions	Yes			
8.7.3	Allowable values				
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b.	Yes			
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz	Yes			
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (ITNC, ITSFC)	Yes			
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (IENC, IESFC)	NA			Not class I equipment, no PE
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device	Yes			
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION.	N/A			No functional earth terminals used
8.7.4	Leakage and patient auxiliary currents Measurement	Yes			
8.8	**Insulation**				
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing	Yes			
8.8.2	Distance through solid insulation or use of thin sheet metal	N/A			(b)(4)
8.8.3	Dielectric Strength	Yes			
8.8.4	**Insulation other than wire insulation**				
8.8.4.1	Mechanical strength and resistance to heat	Yes			
	Risk Management File	Yes			

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests				
	Tests conducted in absence of satisfactory evidence for resistance to heat:	Yes			
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus	Yes			022_Performance Testing – Bench, Pages 436-438
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C):	NA			No such parts
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	NA			No such parts
8.8.4.2	Resistance to Environmental Stress. The insulating characteristics and mechanical strength of any MEANS OF PROTECTION shall be so designed or protected that it is not likely to be impaired by environmental stresses including deposition of dirt or by dust resulting from wear of parts within the ME EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in 8.9.	Yes			
8.9	**Creepage Distances and Air Clearances**				
8.9.1.1	Creepage distance and air clearances	Yes			
8.9.2	**Application**				
	a) * For insulation in the MAINS PART between parts of opposite polarity, the minimum	Yes			(b)(4)

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	CREEPAGE DISTANCES and AIR CLEARANCES are not required if short circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not result in a HAZARDOUS SITUATION.				
8.9.3	**Spaces filled by insulating compound**				
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	Yes			(b)(4)
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage)	Yes			
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	NA			
8.9.4	Minimum spacing of grooves transvers to the creepage distances considered a means of operator protection adjusted based on pollution degree	Yes			(b)(4)
8.10	**Components and Wiring**				
8.10.1	Fixing of components	Yes			
8.10.2	Fixing of wiring	Yes			
8.10.3	Connections between different parts of Equipment	NA			No such connections or cords provided
8.10.4	**Cord-connected hand-held parts and cord-connected foot-operated control devices**				
8.10.4.1	Limitation of operating voltages	NA			No cord-connected hand-held or foot-operated controls used
8.10.4.2	Connection Cords	NA			No cord-connected hand-held or foot-operated controls used
8.10.5	Mechanical protection of wiring	Yes			
8.10.6	Guiding rollers for insulated conductors	NA			No guiding rollers
8.10.7	Insulation of internal wiring	NA			No internal wiring
8.11	**Mains Parts, Components and Layout**				

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
8.11.1	Isolation from the supply mains	NA			(b)(4)
8.11.2	Multiple socket outlets	NA			No multiple socket outlets
8.11.3	**Power Supply Cords**				
8.11.3.1	Mains Plug not fitted with more than one power supply cord	NA			(b)(4)
8.11.3.2	Power cord types	NA			
8.11.3.3	Cross-sectional area of power supply cord conductors	NA			
8.11.3.4	Appliance Couplers	NA			
8.11.3.5	Cord Anchorage	NA			
8.11.3.6	Cord Guards	NA			
8.11.4	**Mains Terminal Devices**				
8.11.4.1	General Requirements for Mains Terminal Devices	NA			Not permanently installed device
8.11.4.2	Arrangement of Mains Terminal Devices	NA			(b)(4)
8.11.4.3	Fixing of mains terminals	NA			
8.11.4.4	Connections to mains terminals	NA			
8.11.4.5	Accessibility of the connection	NA			
8.11.5	Mains fuses and over-current releases	NA			
8.11.6	Internal Wiring of the Mains Part	NA			
9	**Protection against mechanical hazards of ME Equipment and ME Systems**				
9.1	Mechanical Hazards of ME Equipment	NA	(b)(4)		None of these identified hazards
9.2	**Hazards associated with moving parts**				
9.2.1	General	NA			No moving parts

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
9.3	Hazard associated with surfaces, corners, and edges	Yes			
9.4	Instability Hazards	NA			Equipment is body worn
9.5	**Expelled Parts**				
9.5.1	Protective Means of protection against expelled parts	Yes			(b)(4)
9.5.2	Cathode Ray Tubes	NA			Not used
9.6	Acoustic Energy	NA			Device does not produce acoustic energy or vibration
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	NA			No such parts
9.8	Hazards with support systems	NA			No such parts
10	**Protection against unwanted and excessive radiation hazards**				
10.1	X-Radiation				
10.1.1	ME Equipment not intended to produce diagnostic or therapeutic X-radiation	NA			Device does not produce diagnostic or therapeutic X-radiation
10.1.2	ME Equipment intended to produce diagnostic or therapeutic X-radiation	NA			Device does not produce diagnostic or therapeutic X-radiation
10.2	Alpha, beta, gamma, neutron and other particle radiation	NA			Device does not generate alpha, beta, gamma, neutron, and other particles
10.3	Microwave radiation	NA			Device does not produce microwave radiation
10.4	Lasers and light-emitting diodes (LEDs)	NA			Not a laser or LED device in this context
10.5	Other visible electromagnetic radiation	NA			Does not produce other visible electromagnetic radiation
10.6	Infrared radiation	NA			Does not produce infrared radiation in this context.
10.7	Ultraviolet radiation	NA			Does not produce ultraviolet radiation
11	**Protection against Excessive Temperatures and Other Hazards**				
11.1	**Excessive temperatures in ME Equipment**				
11.1.1	Maximum temperature during normal use	Yes			
11.1.2	**Temperature of applied parts**				
11.1.2.1	Applied parts intended to supply heat to the patient	NA			Not intended to apply heat to patient
11.1.2.2	Applied parts not intended to supply heat to the patient	Yes			
11.1.3	Measurements	NA			All applicable tests were conducted

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
11.1.4	Guards	NA			No guards used
11.2	**Fire Prevention**				
11.2.1	Strength and rigidity required to prevent fire in ME Equipment	Yes			
11.2.2	ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS	NA			Device is not used in Oxygen rich environments
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS	NA			Device is not used in Oxygen rich environments
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	Yes			
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anesthetics	NA			Not intended for use in presence of flammable anesthetics.
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	NA			Not intended for use in conjunction with flammable agents
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization, and compatibility with substances used with the ME EQUIPMENT**				
11.6.1	General	Yes			
11.6.2	Overflow in ME Equipment	NA			Does not use liquids in normal use
11.6.3	Spillage on ME Equipment and ME System ad determined by risk management file	Yes			
11.6.4	Leakage	NA			Device does not contain liquids to leak
11.6.5	Ingress of water or particulate matter into ME Equipment	Yes			
11.6.6	Cleaning and disinfection of ME Equipment and ME Systems	Yes			
11.6.7	Sterilization	NA			Not sterile equipment
11.6.8	Compatibility with substances used with the ME Equipment	Yes			
11.7	Biocompatibility of ME Equipment	Yes	(b)(4)		
11.8	Interruption of the power supply / supply mains to ME Equipment	Yes			
12	**Accuracy of controls and instruments and protection against hazardous outputs**				
12.1	Accuracy of controls and instruments	Yes			
12.2	Usability	Yes	(b)(4)		Usability test report (b)(4) (b)(4) performance testing bench

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
12.3	Alarm Systems compliance with IEC 60601-1-8.	Yes	(b)(4)		Test Report Performance Testing Bench
12.4	Protection against hazardous output				
12.4.1	Intentional exceeding of safety limits addressed in risk management file	Yes			
12.4.2	Indication of parameters relevant to safety addressed in risk management file	Yes			
12.4.3	Accidental selection of excessive output values	NA			No outputs to the patient
12.4.4	Incorrect Output addressed in risk management file	Yes			
12.4.5	Diagnostic or therapeutic radiation	NA			Device does not provide diagnostic or therapeutic radiation
12.4.6	Diagnostic or therapeutic acoustic pressure	NA			Device does not provide diagnostic or therapeutic acoustic pressure
13	**Hazardous Situations and fault conditions**				
	Specific hazardous situations	Yes			(b)(4)
14	**Programmable Electrical Medical Systems**				
14.1	General	Yes			(b)(4)
14.2	Documentation	Yes			
14.3	Risk Management Plan	Yes			
14.4	PEMS Development Life-Cycle	Yes			
14.5	Problem Resolution	Yes			
14.6	Risk Management Process	Yes			
14.7	Requirement Specification	Yes			
14.8	Architecture	Yes			
14.9	Design and Implementation	Yes			
14.10	Verification	Yes			
14.11	PEMS Validation	Yes			

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IEC 60601-1:2005 MOD Medical Electrical Equipment – Part 1: General Requirements for basic safety and essential performance					Recognition: # 19-4
Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
14.12	Modification	Yes			(b)(4)
14.13	Connection of PEMS by Network/Data Coupling to other Equipment	NA			Not connected to other equipment that is outside of the control of the manufacturer
15	**Construction of ME Equipment**				
15.1	Arrangements of controls and indicators of ME Equipment	Yes			Usability test report (b)(4) (b)(4) See Performance testing bench
15.2	Serviceability	NA			Not Serviceable
15.3	Mechanical Strength	Yes			
15.3.1	General	Yes			
15.3.2	Push Test	Yes			
15.3.3	Impact Test	Yes			
15.3.4	Drop Test	Yes			
15.3.5	Rough Handling Test	NA			Not Mobile Equipment
15.3.6	Mold Stress Relief	Yes			
15.3.7	Intended use, expected service life	Yes			
15.4	**ME Equipment components and general assembly**				
15.4.1	Construction of Connectors	NA			No accessible connectors
	Plugs for patient connections	Yes			(b)(4)
15.4.2	Temperature and Overload Control Devices	NA			No such devices
15.4.3	**Batteries**				
15.4.3.1	Housing	Yes			
15.4.3.2	Connection	NA			Batteries are not replaceable
15.4.3.3	Protection against overcharging	NA			Batteries are not rechargeable
15.4.3.4	Lithium Batteries	Yes			(b)(4)
15.4.3.5	Excessive current and voltage protection	Yes			
15.4.4	Indicators	NA			Body worn device, no indicator lights
15.4.5	Risks associated with Pre-set controls	Yes			
15.4.6	Actuating parts of controls of ME Equipment	NA			No actuating parts or controls on the device
15.4.7	Cord-connected hand-held and foot-operated control devices	NA			No such cord or foot controls
15.4.8	Internal wiring of ME Equipment	NA			No aluminum wires used
15.4.9	Oil Containers	NA			No oil containers used

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Conformance with Standards Sections – Testing performed by: (b)(4)					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
15.5	Mains Supply Transformers of ME Equipment and Transformers	NA			Battery operated device, no mains supply
16	ME Systems	Yes			
16.1	Unacceptable risk after installation	Yes			
16.2	Accompanying Documents	Yes			
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM	NA			Does not receive its power from other equipment in an ME System
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)	Yes			(b)(4)
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed	NA			No such connection
16.6	Leakage Currents	Yes			
16.7	Complied with applicable requirements of Clause 9	NA			No moving parts or others
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Yes			
16.9	ME Systems connections and wiring	NA			Connection between equipment is via wireless connections, no multiple socket outlets
17	Electromagnetic Compatibility	Yes	(b)(4)		021_EMC, Wireless, & EMT Test Reports
Annex G	Protection against HAZARDS of ignition of flammable anaesthetic mixtures	N/A			Not rated AP or APG
Annex L	Insulated winding wires for use without interleaved insulation	N/A			No multi-layer or spirally wrapped wire insulation in any wound components used

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Extent of Standard Conformance: **IEC 60601-1-2 Summary Report Table**.

IEC 60601-1-2:2014 Ed 4.0 Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests					FDA Recognition No.: # 19-8
Conformance with Standards Sections – Testing performed by: (b)(4) file 021_EMC Wireless, and EMT Test Reports, page 2 of 51					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
4	**General Requirements**				
4.1	Risk Management Process	Yes			
4.2	Non ME Equipment Used in an ME System	Yes			(b)(4)
4.3	General Test Conditions				Section Heading
4.3.1	Tested in representative conditions consistent with intended use	Yes			
4.3.2	Use of Artificial Hand	N/A			Use of artificial hand not required
4.3.3	Power Input voltages and frequencies per Table 1 in standard	Yes			
5	**ME Equipment and ME Systems Identification, Marking and Documents**				
5.1	Use in a shielded location environment	N/A			Not intended to be used in a shielded location
5.2	**Accompanying Documents**				
5.2.1	Instructions for Use				
5.2.1.1	General – In addition to 7.9.2 of the general standard, the IFU shall include the following				Section heading
	a statement of the environment of use	Yes			
	description of what the operator can expect if essential performance is lost or degraded due to EM DISTURBANCES	Yes			
	Warning statement (similar to): "WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally." [The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM may provide a description or list of equipment with which the ME EQUIPMENT or ME SYSTEM has been tested in a stacked or adjacent configuration and with	Yes			Included in "Attachment B Electromagnetic Compatibility" in 013_Instructions for Use, page 149 of 235, page 211 of 235.

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	which stacked or adjacent use resulted in normal operation.]				
	a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY).	Yes			
	Warning Statement (similar to): WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.	Yes			Included in "Attachment B Electromagnetic Compatibility" in 013_Instructions for Use, page 148 of 235, page 210 of 235.
	Warning Statement (similar to): WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.	Yes			Included in "Attachment B Electromagnetic Compatibility" 013_Instructions for Use, page 149 of 235, page 211 of 235.
5.2.1.2	Class A equipment per CISPR 11				Section Heading
	In addition to the requirements of 7.9.2 of the general standard, for ME EQUIPMENT and ME SYSTEMS that are classified class A according to CISPR 11, the instructions for use shall include the following note: NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	N/A			Device is Class B

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5.2.2	**Technical Description**				
5.2.2.1	Applicable to all ME Equipment and ME Systems				Section Heading
	In addition to the requirements of 7.9.3 of the general standard, the technical description shall describe precautions to be taken to prevent adverse events to the PATIENT and OPERATOR due to ELECTROMAGNETIC DISTURBANCES.	Yes			Included in "Attachment B Electromagnetic Compatibility", warnings and cautions, 013_Instructions for Use, page 149 of 235, page 211 of 235.
	a. the compliance for each EMISSIONS and IMMUNITY standard or test specified by this collateral standard, e.g. EMISSIONS class and group and IMMUNITY TEST LEVEL;	Yes			Included in "Attachment B Electromagnetic Compatibility" in IFU, pages 148-155 of 235; (b)(4) (b)(4)
	b. any deviations from this collateral standard and allowances used;	Yes			
	c. all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for the EXPECTED SERVICE LIFE.	Yes			Included in "Attachment B Electromagnetic Compatibility" in IFU, pages 148-155 of 235; (b)(4) (b)(4)
5.2.2.2	Requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT				Section Heading
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location (see 7.1.5), the technical description shall include the following information:	N/A			Not intended or specified for use only in a shielded location
	a. a warning to the effect that: "WARNING: Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services";	N/A			Not intended or specified for use only in a shielded location
	b. specifications for the shielded location, including: – minimum RF shielding effectiveness; – for each cable that enters or exits the shielded location, the minimum RF filter attenuation; – the frequency range(s) over which the specifications apply;	N/A			Not intended or specified for use only in a shielded location

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	c. recommended test methods for measurement of RF shielding effectiveness and RF filter attenuation;	N/A			Not intended or specified for use only in a shielded location
	d. one or more of the following and a recommendation that a notice containing this information be posted at the entrance(s) to the shielded location: – a specification of the EMISSIONS characteristics of other equipment allowed inside the shielded location with the ME EQUIPMENT or ME SYSTEM; – a list of specific equipment allowed; – a list of types of equipment prohibited.	N/A			Not intended or specified for use only in a shielded location
5.2.2.3	Requirements applicable to ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation				Section Heading
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that intentionally receives RF electromagnetic energy for the purpose of its operation (RF receivers), the technical description shall include the following information: – each frequency or frequency band of reception; – the preferred frequency or frequency band, if applicable; and – the bandwidth of the receiving section of the ME EQUIPMENT in those bands.	N/A			Does not intentionally receive RF electromagnetic energy for the purpose of its operation
5.2.2.4	Requirements applicable to ME EQUIPMENT that includes RF transmitters				Section Heading
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT that includes RF transmitters, the technical description shall include each frequency or frequency band of transmission, the type and frequency characteristics of the modulation and the EFFECTIVE RADIATED POWER.	Yes			Included in "Attachment B Electromagnetic Compatibility" in IFU, pages 148-155 of 235; (b)(4) (b)(4)
5.2.2.5	Requirements applicable to PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS				Section Heading

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	In addition to the requirements of 7.9.3 of the general standard, for PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS for which the exemption specified in 8.6 from the testing requirements of IEC 61000-4-3 is used, the technical description shall include the following information:	N/A			Not permanently or large equipment or system
	a. a statement that an exemption has been used and that the equipment has not been tested for radiated RF IMMUNITY over the entire frequency range 80 MHz to 6 000 MHz;	N/A			Does not intentionally receive RF electromagnetic energy for the purpose of its operation
	b. a warning to the effect that "WARNING: This equipment has been tested for radiated RF immunity only at selected frequencies, and use nearby of emitters at other frequencies could result in improper operation"; and	N/A			Does not intentionally receive RF electromagnetic energy for the purpose of its operation
	c. a list of the frequencies and modulations used to test the IMMUNITY of the ME EQUIPMENT or ME SYSTEM.	N/A			Does not intentionally receive RF electromagnetic energy for the purpose of its operation
5.2.2.6	Requirements applicable to ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT				Section Heading
	In addition to the requirements of 7.9.3 of the general standard, for ME EQUIPMENT and ME SYSTEMS that claim compatibility with HF SURGICAL EQUIPMENT, the technical description shall include a statement of HF SURGICAL EQUIPMENT compatibility and the conditions of INTENDED USE during HF surgery.	N/A			Does not claim compatibility with HF Surgical Equipment
6	Documentation of the tests				
6.1	General				Section Heading
	The documentation of the tests shall contain all the information necessary to facilitate adequate planning (test plan) and execution (test report) of the tests so that they can be readily reproduced.	Yes			
6.2	Test Plan				Section Heading
	Prior to the start of formal testing, a detailed test plan shall be provided to the test laboratory. Deviations from the test plan shall be documented in the test report.	Yes			(b)(4)

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	See Annex G for guidance on the recommended content of a test plan.				
6.3	Test Report				Section Heading
	Meets requirements of clause 9	Yes			
7	**ELECTROMAGNETIC EMISSIONS requirements**				
7.1	Protection of radio services and other equipment				Section Heading
7.1.1	General				Section Heading
	Unless otherwise specified herein, ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 11. See Annex C of this standard for guidance on classification according to CISPR 11.	Yes			
7.1.2	Operating Modes				Section Heading
	During EMISSIONS testing, the ME EQUIPMENT or ME SYSTEM shall be tested in the modes that maximize EMISSIONS. In addition to testing for EMISSIONS in active modes, inclusion of standby mode should be considered. The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.	Yes			
7.1.3	Multimedia equipment				Section Heading
	Multimedia equipment connected to ME EQUIPMENT and ME SYSTEMS shall comply with CISPR 32. If CISPR 32 class A equipment is supplied as part of an ME SYSTEM, the ME SYSTEM shall be classified class A. NOTE Multimedia equipment includes INFORMATION TECHNOLOGY EQUIPMENT (ITE).	N/A			No multimedia equipment connected
7.1.4	Subsystems				Section Heading
	Compliance with CISPR 11 may be demonstrated by testing each subsystem of an ME SYSTEM on a subsystem basis, provided the requirements of CISPR 11 for evaluation of equipment that interacts with other equipment to form a system are met.	N/A			No subsystems present
7.1.5	Specified for use in shielded location SPECIAL ENVIRONMENT				Section Heading
	a. The specified RF shielding effectiveness and RF filter attenuation shall; – be expressed in dB; – be rounded to the nearest integer; and	N/A			Not specified for use in shielded location

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	– be at least 20 dB.				
	b. The RF shielding effectiveness and RF filter attenuation specification shall include the frequency range over which the RF shielding effectiveness and RF filter attenuation apply, and this frequency range shall be at least one decade in width.	N/A			Not specified for use in shielded location
	c. The specified value(s) for minimum RF filter attenuation shall be identical to the specified value(s) for minimum RF shielding effectiveness in each frequency range for which they are specified.	N/A			Not specified for use in shielded location
	d. In frequency ranges for which the minimum RF shielding effectiveness and RF filter attenuation are not specified or are specified to be less than 20 dB, the RF shielding effectiveness and RF filter attenuation shall be assumed to be 0 dB for the purpose of this collateral standard.	N/A			Not specified for use in shielded location
7.1.6	ME EQUIPMENT and ME SYSTEMS that include radio equipment				Section Heading
	ME EQUIPMENT and ME SYSTEMS that include radio equipment (e.g. RF transmitters, receivers, transceivers) and have been tested together with the radio equipment and found to comply with applicable national radio regulations are exempt from testing to CISPR ELECTROMAGNETIC DISTURBANCE requirements, provided the EMISSIONS limits of the applicable national radio regulations are less than or equal to the corresponding applicable CISPR ELECTROMAGNETIC DISTURBANCE limits. ME EQUIPMENT and ME SYSTEMS that include RF transmitters are exempt from the EMISSIONS requirements of this collateral standard in the dedicated transmission band of the transmitter. Otherwise, and for ME EQUIPMENT and ME SYSTEMS intended only for countries with no national radio regulations, the EMISSIONS requirements of this collateral standard shall apply.	N/A			Not applicable to subject device

7.1.7	ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices				Section Heading
	The scope of this collateral standard includes ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices. Examples include motor-driven electromedical apparatus such as simple dental drills and simple operation tables. Unless the ME EQUIPMENT intentionally generates RF energy or is intended for illumination, it may be classified in accordance with CISPR 14-1. If so, the corresponding limits of CISPR 14-1 shall apply.	N/A			No functions performed by motors and switching regulators
7.1.8	ME EQUIPMENT and ME SYSTEMS containing X-ray generators				Section Heading
	For diagnostic X-ray generators and ME SYSTEMS that include X-ray generators operating in INTERMITTENT MODE, the quasi-peak limits to discontinuous radiated and conducted DISTURBANCES can be relaxed by 20 dB. This relaxation does not apply to average limits.	N/A			Does not contain X-ray generator
7.1.9	PATIENT physiological simulation				Section Heading
	If PATIENT physiological simulation is required for normal operation of the ME EQUIPMENT or ME SYSTEM, it shall be provided during the test. PATIENT physiological simulation shall not provide, to PATIENT-COUPLED connections, an intentional conductive or capacitive connection to earth during testing except as specified in 4.3.2.	Yes			
7.1.10	Artificial Hand				Section Heading
	The artificial hand requirements of CISPR 11 apply to mains terminal disturbance EMISSIONS testing (see the NOTE in Table 1) with the additional requirement that PATIENT-COUPLED parts of ME EQUIPMENT and ME SYSTEMS and ME EQUIPMENT intended to be HAND-HELD shall be terminated during the test as specified in 4.3.2.	N/A			No mains terminal, body-worn battery operated, non-rechargeable battery

7.1.11	Patient-coupled cables				Section Heading
	PATIENT-COUPLED cables shall be considered interconnecting cables in accordance with the requirements of CISPR 11.	N/A			No patient cables, electrodes integrated into body worn device
7.1.12	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS				Section Heading
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods:	N/A			Not permanently installed, not a large ME Equipment
	– on a test site as a system;	N/A			Not permanently installed, not a large ME Equipment
	– on a test site on a subsystem basis;	N/A			Not permanently installed, not a large ME Equipment
	– *in situ* as a system at the premises of a RESPONSIBLE ORGANIZATION.	N/A			Not permanently installed, not a large ME Equipment
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS that comply with CISPR 11 group 1 class A or class B limits may be tested *in situ* and shall comply with the CISPR 11 limits for equipment measured on a test site.	N/A			Not permanently installed, not a large ME Equipment
7.2	Protection of the Public Mains Network				Section Heading
7.2.1	Harmonic Distortion				Section Heading
	ME EQUIPMENT AND ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase and that are intended to be connected to the PUBLIC MAINS NETWORK shall comply with the requirements of IEC 61000-3-2. If ME EQUIPMENT or an ME SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-2.	Yes			
7.2.2	Voltage Fluctuations and Flicker				Section Heading
	ME EQUIPMENT AND ME SYSTEMS with a RATED a.c. mains network voltage greater than or equal to 220 V a.c. line-to-neutral and less than or equal to 16 A per phase and that is intended for connection to the PUBLIC MAINS NETWORK shall comply with the	Yes			

	requirements of IEC 61000-3-3. If ME EQUIPMENT or an ME SYSTEM has both long-time and momentary current ratings, the higher of the two ratings shall be used in determining the applicability of IEC 61000-3-3. NOTE Subclause 6.1 of IEC 61000-3-3 begins as follows: "Tests need not be made on equipment which is unlikely to produce significant voltage fluctuations or flicker… It may be necessary to determine, by examination of the circuit diagram and specification of the equipment and by a short functional test, whether significant voltage fluctuations are likely to be produced".				
7.3	Emissions requirements summary				Section Heading
	Emission limits per Environment	Yes			
8	**Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS**				
8.1	General				Section Heading
	The IMMUNITY test requirements for ME EQUIPMENT and ME SYSTEMS are specified by this collateral standard on a PORT-by-PORT basis.	Yes			
8.2	PATIENT physiological simulation				Section Heading
	During testing according to IEC 61000-4-4 and IEC 61000-4-6, PATIENT physiological simulation shall not provide additional conductive or capacitive connection to earth (other than needed to simulate the PATIENT or OPERATOR) except as specified in 4.3.2.	Yes			
8.3	Termination of PATIENT-COUPLED parts				Section Heading
	For testing according to IEC 61000-4-4 and IEC 61000-4-6, the conditions specified in 4.3.2 apply. These conditions may also be used in other tests, as specified by the MANUFACTURER.	N/A			
8.4	Hand-Held ME EQUIPMENT and parts intended to be HAND-HELD				Section Heading
	For testing according to IEC 61000-4-4 and IEC 61000-4-6 the following condition applies: *HAND-HELD ME EQUIPMENT and parts of ME EQUIPMENT intended to be HAND-HELD while providing its INTENDED USE shall be tested*	N/A	Not considered hand-held equipment		Body worn device, not hand-held

	with an artificial hand applied as specified in 8.3 of CISPR 16-1-2, sized and placed to simulate the approximate area and location of OPERATOR coupling while providing its INTENDED USE. The metal foil of the artificial hand is connected to terminal M of an RC element, as specified in 8.3 of CISPR 16-1-2 (see Figure 1), and the other terminal of the RC element shall be connected to the ground reference plane. These conditions may also be used in other tests, as specified by the MANUFACTURER. If HAND-HELD ME EQUIPMENT also has PATIENT-COUPLED parts, the PATIENT-COUPLED parts shall also have artificial hands applied as specified in 4.3.2, consistent with INTENDED USE.				
8.5	Subsystems				Section Heading
	Compliance with the requirements of this collateral standard may be demonstrated by testing each subsystem of an ME SYSTEM, provided that normal operating conditions are simulated. The RISK MANAGEMENT PROCESS shall be used to determine whether subsystem testing is allowed. Any simulator used instead of actual equipment shall properly represent the electrical and, if necessary, the mechanical characteristics of the interface, especially with respect to RF signals and impedances, as well as cable configuration and types.	N/A			No subsystems
8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS				Section Heading
	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS shall be TYPE TESTED by at least one of the following methods: – on a test site as a system; – on a test site on a subsystem basis; – *in situ* as a system at the premises of a RESPONSIBLE ORGANIZATION.	N/A			Not permanently installed
8.7	Operating modes				Section Heading
	During IMMUNITY testing, the BASIC SAFETY and ESSENTIAL	Yes			

	PERFORMANCE shall be tested in the modes and settings (e.g. gain) that are most likely to result in an unacceptable RISK, as determined by the MANUFACTURER.				
8.8	Non-ME Equipment				Section Heading
	Non-ME EQUIPMENT (e.g. ITE) that is a part of an ME SYSTEM shall fulfil the pass/fail criteria and IMMUNITY TEST LEVELS of Clause 8 if it has been determined, as a result of the RISK MANAGEMENT PROCESS, that the non-ME EQUIPMENT could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME SYSTEM.	Yes			
8.9	Immunity Test Levels				Section Heading
	IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS shall be according to the professional healthcare facility environment, HOME HEALTHCARE ENVIRONMENT, and SPECIAL ENVIRONMENT, based on the locations of INTENDED USE as shown in Figure 3 and specified in Table 4 through Table 9. If applicable, an INTENDED USE location not shown in Figure 3 shall be assigned to an environment with a similar location, as determined by the MANUFACTURER.	Yes			
8.10	Immunity to proximity fields from RF wireless communications equipment	Yes			
9	**Test report**				
	Minimum Test Report Contents	Yes			

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Extent of Standard Conformance: IEC 60601-2-47 Summary Report Table

NOTE: The general standard applies with exceptions noted here.

IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
201.4	**General Requirements**				
	Additional ESSENTIAL PERFORMANCE requirements				
201.4.3	**Essential Performance**				
201.4.101	**Additional ESSENTIAL PERFORMANCE requirements**				
	Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table201.101				
	Table 201.101 Distributed additional essential performance requirements Requirement / Subclause Heart rate / 201.12.1.101.3.1 Supraventricular ectopy / 201.12.1.101.3.2 Ventricular ectopy / 201.12.1.101.3.3 Bradycardia data / 201.12.1.101.3.4 PAUSES / 201.12.1.101.3.5 ST SEGMENT shifts / 201.12.1.101.3.6 ECG hard copy / 201.12.1.101.3.7	Yes	(b)(4)		
201.5	**General requirements for testing of ME EQUIPMENT**				
	Clause 5 of the general standard applies, except as follows:				
201.5.3	**Ambient temperature, humidity, atmospheric pressure**				
	In addition to item a) in the general standard: The AMBULATORY RECORDER shall fulfil the requirements of this standard under thefollowing ambient conditions: an ambient temperature range of 10 °C to 45 °C; a relative humidity of 10 % to 95 %, without condensation.	Yes	(b)(4)		022_Performance Testing – Bench, page 325
201.6.2	**Protection against electrical shock**				
	Applied parts shall be type BF APPLIED PARTS or TYPE CF APPLIED PARTS	Yes			(b)(4)
201.6.6	**Mode of operation**				
	ME EQUIPMENT shall be classified for CONTINUOUS OPERATION	Yes			
201.7	**ME EQUIPMENT identification, marking and documents**				
201.7.2.101	LEAD WIRE identification				

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Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	The LEAD WIRE(s) shall be permanently marked in such a manner that the proper LEAD WIRE can be directly determined at both the ELECTRODE attachment ends, and so constructed or marked as to avoid incorrect connection to the ME EQUIPMENT.	Yes			(b)(4)
201.7.9.2	**Instructions for Use**				
201.7.9.2.101	**Additional instructions for use**				
	a) Advice shall be given on the following: 1) the type of electrical installation to which the ME EQUIPMENT may be safely connected, including the connection to any POTENTIAL EQUALIZATION CONDUCTOR; 2) that conductive parts of ELECTRODES and associated connectors for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS, including the NEUTRAL ELECTRODE, should not contact other conductive parts including earth; b) Clear instructions shall be provided if a specific type of battery or battery chargingprocedure has to be used in order to fulfil the requirements of this particular standard. c) Clear instructions shall be provided for any use of the AMBULATORY RECORDER in wet environments. d) The ME EQUIPMENT labelling shall clearly indicate whether or not its use is intended for infants weighing less than 10 kg.	Yes	(b)(4)		

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IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	e) The manufacturer shall disclose the method for calculating the heart rate. f) The manufacturer shall disclose the method for determining a PAUSE. g) If the ME EQUIPMENT is designed to detect and/or measure ST SEGMENT shifts, the manufacturer shall disclose in the operating manual or physician's guide the following: whether the ST SEGMENT analysis is performed on all LEADS or only some LEADS, whether there are OPERATOR selectable detection criteria for ST SEGMENT shifts (such as displacement and slope parameters), how frequently ST SEGMENT shifts are summarized in the clinical report (e.g., hourly) and whether numbers of episodes, types of episodes (elevation or depression), and durations of episodes are reported, or whether the clinical report presents this information episode by episode, whether ranges of heart rates, ranges of displacements and/or slope values during each episode are reported.		(b)(4)		
201.8	**Protection against electrical HAZARDS from ME EQUIPMENT**				
	General Standard applies				
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**				
	General Standard applies				
201.10	**Protection against unwanted and excessive radiation HAZARDS**				
	General Standard applies				
201.11	**Protection against excessive temperatures and other HAZARDS**				
	General Standard applies				

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IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database; (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**				
201.12.1	**Accuracy of Controls and Instruments**				
201.12.1 .101	**Algorithm Testing [Testing by SmartCardia]**				
201.12.1 .101.1.1	Databases: Databases should be: • fully described (standard digital format); • clearly identifiable by name, version, date, etc.; and • annexed with utilities and instructions for use.				
201.12.1 .101.1.1. 1	- AHA: The American Heart Association Database for Evaluation of Ventricular Arrhythmia Detectors (80 records of 35 min each);	Yes			
	- MIT- BIH: The Massachusetts Institute of Technology - Beth Israel Hospital ArrhythmiaDatabase (48 records of 30 min each);	Yes			
	- ESC: The European Society of Cardiology ST-T Database(90 records of 2 h each);	N/A			(b)(4)
	- NST: The Noise Stress Test Database (12 ECG records of 30 min each plus 3 records of noise only supplied with the MIT- BIH database);	Yes			
	- CU: The Creighton University Sustained Ventricular Arrhythmia Database (35 records of 8 mins each - supplied with the MIT-BIH database with incomplete annotations).	Yes			
201.12.1 .101.1.1. 2	Excluded records during testing: • Records w/Pacemaker patients; • Records w/noise • Records w/VF	Yes			
201.12.1 .101.1.2	**Testing Requirements**				
201.12.1 .101.1.2. 1	The accuracy of QRS detection shall be tested using the AHA DB, the MIT- BIH DB, and the NST DB at a minimum	Yes			
201.12.1 .101.1.2. 2	The accuracy of heart rate measurements shall be tested using the AHA DB, the MIT-BIH DB, and the NST DB	Yes			

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IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
201.12.1 .101.1.2. 3	The accuracy of VEB detection shall be tested using the AHA DB, the MIT-BIH DB, and the NST DB at a minimum	Yes			
201.12.1 .101.1.2. 4	If the device is claimed to detect ventricular flutter or fibrillation (VF), its ability to do so shall be tested using the CU DB, the AHA DB, and the MIT-BIH DB at a minimum .	Yes	(b)(4)		
201.12.1 .101.1.2. 5	If the device is claimed to detect supraventricular ectopic beats, or atrialflutter or fibrillation (AF), its ability to do so shall be tested using the MIT-BIH DB and the NST DB at a minimum. If the device is claimed to measure ST SEGMENT deviations or to detect ST SEGMENT changes, its ability to do so shall be tested using the ESC DB at a minimum, unlessthe characteristics of the database conflict with the algorithm under test.	Yes			
201.12.1 .101.1.3	**Physician Report – Minimum Requirements**				
201.12.1 .101.1.3	**Test Environment**				
	Algorithm testing using standardized digital databases occurs, by definition, outside the context of the complete monitoring device's clinical setting. Yet, a correlation between algorithm performance and the device's actual clinical performance shall be ensured for the results to be meaningful. To conduct an evaluation that accurately reflects the capabilities of the algorithm as implemented in a monitoring device, it is preferable to perform the test using hardware comparable to the monitoring device although it is recognized that the nature of the algorithm testing process might require modifications of the hardware or software. Additionally, signals should be presented to the algorithm in a method comparable to the	N/A			(b)(4)

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Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database: (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	method employed in clinical settings. The computational environment used to perform algorithm testing shall be disclosed. When algorithm evaluations are conducted under conditions or constraints grossly different from those encountered by the monitoring device in an actual clinical setting, the algorithm results might not represent the true performance of the device. Actual devices can have limited processor speed, computational precision, filtering, etc. Testing or analysis shall be performed indicating that the algorithm performance in an actual monitoring device can reasonably be expected to correlate with performance in the simulated test environment. This validation shall be disclosed.				
201.12.1.101.1.4	**Multiple-lead Analysis**				
	Combination of channels used from each database	N/A			(b)(4)
201.12.1.101.1.5	**Requirements for the evaluation report**				
201.12.1.101.1.5.1	**Required Statistics**				
201.12.1.101.1.5.2	All arrhythmia algorithms: Statistics reported per table 201.103	Yes			
201.12.1.101.1.5.3	Algorithms with optional capabilities: Statistics reported per table 201.104	Yes			
201.12.1.101.1.6	**Simulated Test Patterns**				
	If the device is claimed to measure heart-rate variability (HRV) or RR interval variability (RRV), its ability to do so shall be tested using special simulated ECG patterns with predictable variability.	N/A			(b)(4)
201.12.1.101.2	**Automated Analysis**				
	Evaluations are performed without human intervention.	Yes			

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IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4), IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
201.12.1 .101.2.1	**Use of standard databases**				
	All DB records supplied to the algorithm continuously from beginning to end.	Yes			(b)(4)
201.12.1 .101..2.3	**Beat-by-beat comparison**				
201.12.1 .101.2.3. 1	**General Description**				
	Beat labels are matched by pairs.	Yes			
201.12.1 .101.2.3. 2	**Method for beat-by-beat comparison**				
	This paragraph describes how to perform beat-by-beat comparison	Yes			
201.12.1 .101.2.3. 3	**Heart rate, and heart rate or RR interval variability**				
201.12.1 .101.2.3. 3.1	Heart Rate measurement	Yes			
	Method of measurement is disclosed using the reference annotation files	Yes			
201.12.1 .101.2.3. 3.2.	Heart rate variability or RR interval variability measurement test patterns	N/A			(b)(4)
	HRV or RR interval variability using test patterns (see Annex D of this document)	N/A			
201.12.1 .101.2.4	**Run-by-run comparison**				
	Run Sensitivity (Annex E, table 201.108)	Yes			
	Run Positive Predictivity (Annex E, table 201.109)	Yes			
201.12.1 .101.2.4. 2	**Terms and Symbols**				
	Complies with terms and symbols used for run definitions Couplet (C) = a run of two consecutive V or F labels; Short run (S) = a run of three, four, or five consecutive V or F labels; Long run (L) = a run of six or more consecutive V or F labels.	Yes			

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Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database: (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	A segment of ventricular fibrillation or flutter marked by "[" and "]" labels is considered to be equivalent to a VE long run for the purposes of this subclause; any adjacent V or F labels are considered to be part of the same run. Similarly, a segment of atrial fibrillation or flutter marked by rhythm labels is considered to be equivalent to an SVE long run, and any adjacent S labels are considered to be part of the same run.				
201.12.1 .101.2.4. 3	**Run Sensitivity Summary Matrix**				
	This paragraph describes how to derive the VEB run sensitivity summary matrix.	Yes		(b)(4)	
201.12.1 .101.2.4. 4	**Run Positive Predictivity Summary Matrix**				
	This paragraph describes how to derive the VEB run positive predictivity summary matrix.	Yes		(b)(4)	
201.12.1 .101.2.5	**VF and AF Comparisons**				
	A separate VF and AF record are documented: a) the subclause of record used for testing; b) whether an alarm was generated for the test record; c) what the alarm was, if one occurred (e.g., asystole, ventricular tachycardia, or ventricular fibrillation); d) the gradation of alarms, if applicable; e) the interval between the onset of the arrhythmia to the time the alarm was activated, if one occurred. (This last requirement only applies to devices that perform real-time monitoring.) Any false positive detection is reported.	N/A			(b)(4)

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Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database; (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
201.12.1 .101.3	**Physicians Report – Minimum Requirements for report contents**				
201.12.1 .101.3.1	Heart Rate – Lowest, Mean, Highest HR	Yes			
201.12.1 .101.3.2	Supraventricular ectopy – Totals for: SVEBs, single SVEBs, paired SVEBs, runs of SVT, SVT duration (beat totals, or time duration)	Yes			
201.12.1 .101.3.3	Ventricular ectopy – Totals for: VEBs, single VEBs, paired VEBs, and runs of three or more VEBs, and duration of runs (beat totals, or time duration). For episodes of VT, the rate and duration (either beat totals or time duration). The number of minutes (and optionally seconds) that were analyzed shall be reported.	Yes			
201.12.1 .101.3.4	Bradycardia – Total of bradycardia episodes per hour with rate and duration of episodes (HR <50 bpm for 15 seconds, or manufacturer, or user defined parameters)	Yes			
201.12.1 .101.3.5	Pauses – Total number of pauses detected based on operator selectable absolute threshold or manufacturer selected parameter. Location and duration of longest pause.	Yes			
201.12.1 .101.3.6	ST Segment Shifts – Report with the manufacturer-claimed parameters and include definitions in accompanying documents	N/A			(b)(4)
201.12.1 .101.3.7	ECG Hard Copy – Operator selectable multichannel ECG strips (at 25 mm/sec) including: • Lead configuration on each channel • Time of strip • Heart rate on strip • Strip annotation • Patient ID on each page • Calibration signal	Yes			
201.12.4	**Protection against hazardous output**				
201.12.4 .4	Incorrect Output				
201.12.4 .4.101	Linearity and Dynamic range – Analog type = 6 mV peak-to-valley; Digital type = 10 mV peak-to-valley	Yes			

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IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
201.12.4.4.102	Input Impedance – >10 MΩ	Yes			
201.12.4.4.103	Common Mode Rejection - >60 dB with sine signal at mains frequency; >45 dB at two times the mains frequency	Yes			
201.12.4.4.104	Gain Accuracy – at all gain settings, ±10% of test signal referred to input	Yes			
201.12.4.4.105	Gain Stability - <3% change over 24 hours (in stable ambient conditions)	Yes			
201.12.4.4.106	System Noise - <50 µV p-v over any 10 second period	Yes			
201.12.4.4.107	Multichannel crosstalk – <5% referred to input	Yes			
201.12.4.4.108	Frequency response – test per a) and either b) or c) of the standard	Yes			
201.12.4.4.109	Pacemaker Pulses – no adverse effects from a pacemaker pulse if claimed by manufacturer to operate in the presence of pacemaker pulses – test per standard	Yes			
201.12.4.4.110	Timing accuracy - <30 seconds over 24 hours	Yes			
201.12.4.4.111	Gain settings and switching – GAIN used shall be printed out on the printout. Analogue systems shall provide a calibration pulse on the printout. At least GAINS of 10 mm/mV and 5 mm/mV shall be provided. If additional GAINS are provided, at least the GAIN of 20 mm/mV shall be provided	Yes			
201.12.4.4.112	Temporal Alignment – Channel to channel skew shall be less than ± 20 ms or ± 0,5 mm (at 25 mm/s time axis scale). This applies to the whole system	Yes			
201.13	Hazardous Situation and Fault Conditions				
	General standard applies				
201.14	Programmable Electrical Medical Systems (PEMS)				
	General standard applies				
201.15	Construction of ME Equipment				
	General Standard applies except:				
201.15.3.4.1	Ambulatory Recorders are not regarded as Hand-Held ME Equipment – subclause 15.3.4.1 of general standard does NOT apply	Yes			
201.15.3.4.2	Replacement for subclause 15.3.4.2 of the general standard with: Data	Yes	(b)(4)		022_Performance Testing – Bench, page 325-326

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IEC 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems					FDA Recognition No.: # 3-155
Conformance with Standards Sections Testing by: (b)(4) IEC 60601-2-47 C) Algorithm testing using standard databases and SmartCardia database, (b)(4) SCDB ECG Test Results					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	acquisition by the AMBULATORY RECORDER may be interrupted during shock but data acquired prior to the shock shall be unaffected and normal data acquisition shall resume within 60 s after the shock test				
201.15.4	**ME EQUIPMENT components and general assembly**				
201.15.4.3	Batteries				
201.15.4.3.101.1	Monitoring time shall be at least 24 hours or longer as specified in instructions for use	Yes			013_Instructions for Use, page 38 of 235
201.15.4.3.101.2	The ambulatory recorder shall retain stored information, without external power, for at least 72 hours after completion of monitoring time	Yes			013_Instructions for Use, page 156 of 235
201.16	ME Systems				
	General standard applies except:				
201.16.5	Addition: If the AMBULATORY RECORDER may be connected simultaneously to the PLAYBACK EQUIPMENT and the PATIENT, a SEPARATION DEVICE shall be provided.	N/A			Cannot connect to playback equipment. Data are transmitted wirelessly.
201.17	Electromagnetic Compatibility of ME Equipment and ME Systems				
	General standard applies				
202	**Electromagnetic compatibility - Requirements and tests**				
	IEC 60601-1-2:2007 applies, except as noted: Classified as Class 1, Class B per CISPR11 based on their intended use	Yes			
202.6.2	Immunity				
202.6.2.3	Radiated RF electromagnetic fields per the general standard plus: The AMBULATORY RECORDER (ME EQUIPMENT) shall continue to record the signal without loss of any stored data	Yes			

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Extent of Standard Conformance: IEC 60601-1-8 Summary Report Table

IEC 60601 1-8 Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral standard: General requirements, test and guidance for alarm systems in medical electrical equipment and medical electrical systems, Amendment 2					FDA Recognition No.: # 5-131
Conformance with Standards Sections Tested by SmartCardia: (b)(4) Verification Test Results - Notifications (Alerts/Alarms) Software; Software Section, Verification and Validation Testing, 016_Page 219					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
4	**General Requirements**				
	If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose.	Yes			
5	**ME EQUIPMENT identification marking and documents**				
5.1	Indicator Lights	Yes			
	Comply with indicator lights and meaning in 7.8.1 in the general standard (Table 2 in general standard) Table 2 – Colours and meanings of visual indicator lights and alarm indicator lights for ME EQUIPMENT [see also 6.3.2.2]	Yes			
5.2	**Accompanying Documents**				
5.2.1	**Instructions for Use**				
	Provide an overview of the ALARM SYSTEM, including a listing and description of every possible ALARM CONDITION and, as appropriate for the intended OPERATOR, a summary of how it is determined;	Yes			013_Instructions for Use, Page 60-62 of 235
	indicate any delay inherent in the determination of an ALARM CONDITION	Yes			013_Instructions for Use, Page 143 of 235
	disclose the OPERATOR'S POSITION;	Yes			013_Instructions for Use, Page 143 of 235
	include how and when to verify the functionality of the ALARM SYSTEM.	Yes			013_Instructions for Use, Page 60 of 235
	shall caution against setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless. See table B.3	Yes			013_Instructions for Use, Page 35 of 235
5.2.2	**Technical description**				

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Clause	Title	Conformance Yes/No/NA	Deviation or Option	Description	Justification/Comment
	Technical description of alarm system (see table B.3, end of this table) The requirements for general information to be included in the technical description are found in subclause 7.9.3 and in Table C.6 of the general standard. Additional requirements for general information to be included in the technical description are found in the subclauses listed in Table B.3.	Yes			013_Instructions for Use, Technical Manual, Pages 179-235 of 235
6	**Alarm Systems**				
6.1	**Alarm Condition**				
6.1.1	**General**				
	If ALARM CONDITIONS are grouped into PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS or other ALARM CONDITION groups by the MANUFACTURER, this shall be disclosed in the instructions for use.	Yes			
6.1.2	**Determination of Alarm Conditions and Assignment of Priority**				
	For each HAZARDOUS SITUATION where the MANUFACTURER has chosen to use an ALARM SYSTEM as a means of RISK CONTROL, the MANUFACTURER shall assign an ALARM CONDITION and its priority using Table 1.	Yes			
	For HAZARDOUS SITUATIONS where the onset of potential HARM is delayed and the potential result of a failure to respond is discomfort or minor reversible injury, the MANUFACTURER may determine that no ALARM CONDITION is required. In such cases, the MANUFACTURER may implement an INFORMATION SIGNAL.	Yes			
	The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.	Yes			
6.2	**Disclosures for Intelligent Alarm System**				
	If an INTELLIGENT ALARM SYSTEM is provided, the instructions for use shall include, as applicable, an overview of how the ALARM SYSTEM:	N/A			Intelligent alarm system not incorporated

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	a) determines an ALARM CONDITION on the basis of time, weightings, multiple variables, or other advanced processing (including, but not limited to, algorithms, neural networks, fuzzy logic, etc.);	N/A			Intelligent alarm system not incorporated
	b) generates ALARM SIGNALS for two or more ALARM CONDITIONS of equal priority (including, but not limited to, internal ranking, effect on generation of ALARM SIGNALS);	N/A			Intelligent alarm system not incorporated
	c) changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION (e.g., ESCALATION or DE-ESCALATION);	N/A			Intelligent alarm system not incorporated
	d) changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY; and	N/A			Intelligent alarm system not incorporated
	e) changes the characteristics of the generated ALARM SIGNALS (for example, volume, pitch, tempo, urgency, auditory Icon category).	N/A			Intelligent alarm system not incorporated
6.3	**Generation of Alarm Signals**				
6.3.1	**General**				
	Each ALARM CONDITION shall cause the generation of visual ALARM SIGNALS by a COMMUNICATOR as specified in this collateral standard. If deemed necessary by RISK ASSESSMENT regarding the environment in which the ALARM SYSTEM is intended to be used, additional ALARM SIGNALS by a COMMUNICATOR shall be generated. These additional ALARM SIGNALS by a COMMUNICATOR may be auditory, verbal, vibratory or produced by other means. **EXAMPLE** ALARM SYSTEMS with HIGH or MEDIUM PRIORITY ALARM CONDITIONS that are intended not to be continuously attended by an OPERATOR in NORMAL USE should generate additional auditory ALARM SIGNALS .	Yes			
6.3.2	**Visual Alarm Signals**				
6.3.2.1	**General**				
	ALARM SYSTEMS shall generate visual ALARM SIGNALS to indicate the presence of ALARM CONDITIONS, their priority and each specific ALARM CONDITION.	Yes			
6.3.2.2	**Characteristics of Visual Alarm Signals**				
6.3.2.2.1	4 m (distant) alarm signals				

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	If a visual indicator is necessary for the OPERATOR to identify the equipment or part of the equipment that requires	Yes			

Clause	Title	Conformance Yes/No/NA	Deviation or Option	Description	Justification/Comment
	OPERATOR response or awareness, at least one visual ALARM SIGNAL shall be provided that:				
	a) indicates the priority of the highest priority ALARM CONDITION; and	Yes			
	b) can be perceived correctly at a distance of 4 m from the ALARM SYSTEM.	Yes			
	If an alarm indicator light or graphical simulation of an indicator light is used for these purposes, it shall comply with the color and flashing requirements given in Table 2.	Yes			
	ALARM SYSTEMS that do not contain HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITIONS are exempt from this requirement if their visual indication cannot be confused with a HIGH PRIORITY or MEDIUM PRIORITY alarm indicator light complying with Table 2. NOTE 1 This visual indicator is necessary for ALARM SYSTEMS that are intended to be located in the proximity of other ALARM SYSTEMS. NOTE 2 This visual indicator is not necessary for ALARM SYSTEMS that are worn, e.g., a paging receiver. NOTE 3 An indicator light can be simulated, e.g. by a graphical display. See Table 2, Attachment 1.	N/A			System contains High and Medium priority alarm signals
6.3.2.2.2	**1 m (distant) alarm signals and information signals**				
	At least one visual ALARM SIGNAL that identifies the specific ALARM CONDITION and its priority shall be provided.	Yes			
	This signal shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION.	Yes			
	This visual indication may be text placed beside an indicator light or text on a display.	Yes			
	The presence of an ALARM CONDITION may be visually indicated (marked) with symbol IEC 60417-5307 (2002-10) (see Symbol 1 of Table C.1)	N/A	(b)(4)		Not a shall requirement

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	The priority may be indicated by adding one, two or three optional elements, (e.g., **!** for LOW PRIORITY, **!!** for MEDIUM PRIORITY, and **!!!** for HIGH PRIORITY)	N/A	(b)(4)		Not a shall requirement
	If multiple ALARM CONDITIONS occur at the same time, each individual ALARM CONDITION shall be visually indicated, either automatically or by OPERATOR action, unless an INTELLIGENT ALARM SYSTEM is provided that prevents a lower internal rank ALARM CONDITION from generating ALARM SIGNALS when a higher internal rank ALARM CONDITION is generating or has recently generated ALARM SIGNALS (see 6.2).	Yes			
6.3.3	**Auditory Alarm Signals**				
6.3.3.1	**Characteristics of Auditory Alarm Signals**				
	If a COMMUNICATOR of an ALARM SYSTEM is provided with auditory ALARM SIGNALS:				
	a) all auditory ALARM SIGNALS shall be priority encoded;	Yes			
	b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;	Yes			
	c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;	Yes			
	d) the COMMUNICATOR shall have at least one set of ALARM SIGNALS that:				
	1) complies with Annex G; or	Yes			

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	i) * A COMMUNICATOR with means to provide more than one set of auditory ALARM SIGNALS should be equipped with at least one set of auditory ALARM SIGNALS that complies with Annex G. 2) * is generated by means of different technology (e.g. voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g. by clinical or simulated clinical USABILITY testing); or 3) * meets the requirements of Table 3 and Table 4. (Attachment 1) *When the sound files of Annex G are utilized, only testing of tb is required and testing of the acoustic signal is permitted* NOTE 1 Figure 1 is intended to show the designation of temporal characteristics and does not illustrate any individual auditory ALARM SIGNAL. NOTE 2 See Figure G.1 and Figure G.2 for additional information.	Yes			
	If the ALARM SYSTEM is additionally provided with other sets of auditory ALARM SIGNALS, the following shall apply:	N/A			No other auditory signals
	e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;	N/A			No other auditory signals
	f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM	N/A			No other auditory signals
	PRESET; and				
	g) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.	N/A			No other auditory signals
	Any melody shall preclude the possibility of confusion with the auditory ALARM SIGNALS of Table 3, Table 4 and Annex F, unless their meaning is the same. If any of the melodies of Annex F is used to meet the requirements of Table 3 and Table 4, its meanings shall be as specified in Annex F.	N/A			No other melody/auditory signals

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	When a TECHNICAL ALARM CONDITION that precludes the generation of the usual ALARM SIGNALS occurs, e.g. power or ALARM SYSTEM failure, the ALARM SYSTEM may generate an auditory ALARM SIGNAL that does not comply with the above requirements.	N/A			Not a shall requirement
	If selection of auditory ALARM SIGNAL sets is provided, means shall be provided for the RESPONSIBLE ORGANIZATION to prevent the OPERATOR from unauthorized access to changing the auditory ALARM SIGNAL set in use (see 6.7).	N/A			Auditory alarm signal sets are not provided
6.3.3.2	**Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS**				
	The auditory HIGH PRIORITY and MEDIUM PRIORITY ALARM SIGNAL sound pressure level range and measurement radius, measured in accordance with the method of this subclause, shall be disclosed in the ACCOMPANYING DOCUMENTS.	No			Auditory signal is controlled by the user's personal computer where the volume can be turned off or muted. Mitigation is warning in IFU.
	If auditory INFORMATION SIGNALS are provided, they shall be distinguishable from those of auditory ALARM SIGNALS and their characteristics shall be disclosed in the instructions for use.	N/A			Auditory information signals are not provided
6.3.3.3	**Operator-adjustable sound pressure level**				
	If an ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION and an OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level, the instructions for use shall include a warning to the effect that auditory alarm signal sound pressure levels that are less than ambient levels can impede OPERATOR recognition of	Yes			

	ALARM CONDITIONS and the ALARM SYSTEM shall:				
	a) provide a restricted means for the RESPONSIBLE ORGANIZATION to configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level (see 6.7); or	No			Auditory signal is controlled by the user's personal computer where the volume can be turned off or muted. Mitigation is warning in IFU.
	b) provide a visual indication that the current sound pressure level might be inaudible when the auditory ALARM SIGNAL sound pressure level is below a threshold that is configured: – by a means restricted to the RESPONSIBLE ORGANIZATION (see 6.7); or – by the MANUFACTURER.	No			Auditory signal is controlled by the user's personal computer where the volume can be turned off or muted. The personal computer has an indication of sound level. Mitigation is warning in IFU.

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	This condition may be visually indicated (marked) with symbol IEC 60417-5576 (2002-11) (see Symbol 5 of Table C.1). If this symbol is used as that visual indication, an INFORMATION SIGNAL or other additional visual indication may be provided to distinguish this state from AUDIO OFF.	Yes			
	An ALARM SYSTEM may be equipped with a dynamically algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7) to enable and disable the algorithm adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the instructions for use shall describe the algorithm and the minimum and maximum levels. EXAMPLE 1 An algorithm that sets the minimum auditory ALARM SIGNAL sound pressure level in response to current ambient sound pressure levels, time of day, evidence of OPERATOR attendance or other variables. EXAMPLE 2 An algorithm that escalates unresolved active auditory ALARM SIGNALS by increasing their sound pressure level over time.	N/A			Not so equipped

6.3.4	**Characteristics of verbal ALARM SIGNALS**				
	When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with verbal ALARM SIGNALS.	N/A			Verbal alarm signals not used
6.4	**Disclosure of delays**				
6.4.1	**Alarm System Delays**				
	If the sum of the maximum ALARM CONDITION DELAY plus the maximum ALARM SIGNAL GENERATION DELAY is greater than 10 s, then the statistics of each distribution or statistics of the distribution of the sum shall be disclosed in the instructions for use.	Yes			013_Instructions for Use, Page 143 of 235
	If the sum of the mean ALARM CONDITION DELAY plus the mean ALARM SIGNAL GENERATION DELAY is greater than 5 s, then each delay or their sum shall be disclosed in the instructions for use.	Yes			013_Instructions for Use, Page 143 of 235

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6.4.2	**Delays to or from a DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)**				
	If an ALARM SYSTEM is provided with a means to send or receive ALARM CONDITIONS in a DIS or DAS:				
	a) the delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART shall be disclosed in the instructions for use; and	Yes			013_Instructions for Use, Page 143 of 235
	b) the maximum ALARM SIGNAL GENERATION DELAY of the COMMUNICATOR, including the method used to determine the maximum ALARM SIGNAL GENERATION DELAY, or the time to determine the generation of the TECHNICAL ALARM CONDITION (see 6.11.2.2.1 b)) shall be disclosed in the instructions for use.	N/A			Reference to 6.11.2.2.1 b) is for a DAS with confirmed delivery of alarm conditions.
	The following methods may be used to determine the ALARM SIGNAL GENERATION DELAY contribution for each component of a DIS or DAS, as applicable:				Informative
	c) from:				
	1) the onset of the ALARM CONDITION; 2) the time of the ALARM SIGNAL generation at the SOURCE; 3) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR; or 4) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR;				(b)(4)
	) to: 1) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR; 2) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR; or 3) the time of the ALARM SIGNAL generation at the COMMUNICATOR.				
6.5	**Alarm Presets**				
6.5.1	**General Requirements**				

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	Any ALARM PRESET that uses mechanical adjustment is exempt from the requirements of 6.5. Example 1 A switch that indicates the value of a set point.	N/A			(b)(4)
	An ALARM SYSTEM is exempt from the requirements of 6.5 if in NORMAL USE it: a) can only retain current ALARM SETTINGS, and b) does not otherwise provide ALARM PRESETS, and) displays each adjustable ALARM SETTINGS continuously.	N/A			
	ALARM PRESETS shall include the ALARM LIMIT used to trigger each ALARM CONDITION and its priority, or they shall be determined from information available to the ALARM SYSTEM concerning the current PATIENT. ALARM PRESETS may include other parameters that	Yes			
	affect or modify performance of the ALARM SYSTEM.				
	The instructions for use shall contain a warning statement to the effect that a HAZARD can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.	N/A			(b)(4)
6.5.2	**Manufacturer-configured alarm presets**				
	An ALARM SYSTEM shall be provided with at least one MANUFACTURER-configured ALARM PRESET.	Yes			
	The ALARM LIMITS and a summary of any algorithms used in any MANUFACTURER-configured ALARM PRESETS shall be disclosed in the instructions for use.	Yes			013_Instructions for Use, Page 60 of 235
6.5.3	**RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS**				
6.5.3.1	**ALARM SYSTEMS with one ALARM PRESET**				
	If the ALARM SYSTEM can store only one ALARM PRESET:	Yes			
	a) means shall be provided to prevent the OPERATOR from saving changes to this ALARM PRESET. Saving changes to this ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); **and**	Yes			
	b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the ALARM PRESET to its MANUFACTURER-configured state.	Yes			
6.5.3.2	**ALARM SYSTEMS with more than one ALARM PRESET**				

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	If the ALARM SYSTEM provides means to store or activate one or more RESPONSIBLE ORGANIZATION configured or OPERATOR-configured ALARM PRESETS in addition to any MANUFACTURER-configured ALARM PRESETS:	N/A			Does not have this function
	a) means shall be provided for the OPERATOR to choose between the available ALARM PRESETS;	N/A			Does not have this function
	b) means shall be provided for the OPERATOR to readily identify which ALARM PRESET is in use;	N/A			Does not have this function
	c) the instructions for use shall contain a warning statement to the effect that the OPERATOR should check that the current ALARM PRESET is appropriate prior to use on each PATIENT;	N/A			Does not have this function
	d) the means for configuration and storage of ALARM PRESETS shall be disclosed in the ACCOMPANYING DOCUMENTS;	N/A			Does not have this function
	e) means shall be provided to prevent the OPERATOR from saving changes to any RESPONSIBLE ORGANIZATION configured or MANUFACTURER configured ALARM PRESET. Saving changes to any RESPONSIBLE ORGANIZATION configured or MANUFACTURER configured ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);	N/A			Does not have this function
	f) means shall be provided to prevent an individual OPERATOR from saving changes to ALARM PRESETS that were stored by any other OPERATOR (see 6.7); and	N/A			Does not have this function
	g) the ALARM SYSTEM may store the current ALARM SETTINGS for later recall.	N/A			Does not have this function
6.5.4	**Default Alarm Preset**				
6.5.4.1	**General requirements**				
	If the DEFAULT ALARM PRESET can be set to values that differ from the MANUFACTURER-configured values:				
	a) means shall be provided to prevent any OPERATOR from storing changes to the DEFAULT ALARM PRESET. Storing changes to the DEFAULT ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); **and**	Yes			

	b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the DEFAULT ALARM PRESET to its MANUFACTURER-configured values.	Yes			
6.5.4.2	**Selection of DEFAULT ALARM PRESET**				
	Whenever: a) the OPERATOR switches the ALARM SYSTEM on after an interval specified by the MANUFACTURER as being longer than might be considered unintentional; **or** b) the ALARM SYSTEM is enabled; **or** c) the OPERATOR indicates to the ALARM SYSTEM, preferably through an "admit new PATIENT" function,	N/A			Stated Requirement, see e) below
	that a different PATIENT has been connected to the ALARM SYSTEM; **or** d) power is restored to the ALARM SYSTEM after it has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) beyond the time that it automatically restores the ALARM SETTINGS (see 6.5.5);				
	then: e) the DEFAULT ALARM PRESET shall be automatically selected; **or** f) means shall be provided for the OPERATOR to select an ALARM PRESET; **or** g) means may be provided for the OPERATOR to select the retained ALARM SETTINGS from the previous use. NOTE Care is needed to ensure that the OPERATOR is aware of which previously retained ALARM SETTINGS are being restored when the OPERATOR selects the retained ALARM SETTINGS.	Yes	**(b)(4)**		
	The MANUFACTURER shall disclose in the instructions for use an estimate of the duration of the power interruption after which the ALARM SYSTEM is unable to restore the ALARM SETTINGS and the subsequent behavior of the ALARM SYSTEM.	Yes			
6.5.5	**Interruptions of less than or equal to 30 s**				

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	When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss shall be restored automatically. This behavior shall be described in the instructions for use. NOTE Power refers to external SUPPLY MAINS, any INTERNAL ELECTRICAL POWER SOURCE exchangeable in NORMAL USE, or external batteries.	Yes			
6.6	**Alarm Limit**				
6.6.1	**General Requirements**				
	An ALARM LIMIT may be non-adjustable, a simple OPERATOR-adjustable setpoint or an algorithmically determined criterion.	Yes			
6.6.2	**Adjustable ALARM LIMIT**				
6.6.2.1	**Indication of OPERATOR-adjustable ALARM LIMIT**				
	If an OPERATOR-adjustable ALARM LIMIT is provided, the ALARM LIMIT shall be indicated continuously or by OPERATOR action. The means of control to display the ALARM LIMITS may be visually indicated (marked) with symbol IEC 60417-5649 (2002-10) (see symbol 10 of Table C.1), IEC 60417-5650 (2002-10) (see symbol 11 of Table C.1) or IEC 60417-5651 (2002-10) (see symbol 12 of Table C.1), as appropriate.	Yes			(b)(4)
6.6.2.2	**Indication of automatically set ALARM LIMIT**				
	An ALARM LIMIT may be automatically set, with or without OPERATOR action, to ranges or percentages above or below:				
	a) the value of a monitored variable at a point in time; **or**	N/A			Does not have this function
	b) recent values of a monitored variable; **or**	N/A			Does not have this function
	c) a current control setting.	Yes			(b)(4)
	If such an automatically set ALARM LIMIT is provided, its value shall be indicated continuously or by OPERATOR action, unless:	Yes			
	d) this ALARM LIMIT is obvious from the associated control setting and the behavior is described in the instructions for use; **or**	N/A			Does not have this function
	e) the ALARM LIMIT is determined by an INTELLIGENT ALARM SYSTEM (see 6.2).	N/A			Does not have this function
6.6.2.3	**ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET**				
	During adjustment of any ALARM LIMIT or OPERATOR-adjustable ALARM PRESET, the ALARM SYSTEM shall continue to operate normally.	Yes			

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6.7	**ALARM SYSTEM security**				
	Means of restricting access to changing or to the storage of changes shall be described in the technical description (see 6.3.3.1, 6.3.3.3, 6.5.3.1, 6.5.3.2, 6.5.4.1, 6.8.2 b) and c), 6.8.3 b), 6.8.5, 6.10, 6.11.2.2.1 and 6.12.3):	Yes			013_Instructions for Use, page 44 of 235
	EXAMPLE 1 Access controlled by a tool.				
	EXAMPLE 2 Access controlled by RESPONSIBLE ORGANIZATION password and a technical description that is separate from the instructions for use. EXAMPLE 3 Access controlled by individual OPERATOR password. NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password. EXAMPLE 4 Access controlled by voice recognition. EXAMPLE 5 Access controlled by fingerprints. NOTE 2 Multiple means of restriction can be needed, e.g., one for the RESPONSIBLE ORGANIZATION and one for each OPERATOR.				
6.8	**Alarm signal inactivation states**				
6.8.1	**General**				
	Means shall be provided for the OPERATOR to inactivate the auditory, or the visual and auditory, generation of ALARM SIGNALS. Means may be provided to inactivate the generation of other ALARM SIGNALS. Inactivation may apply to an individual ALARM CONDITION, to a group of ALARM CONDITIONS, to the entire ALARM SYSTEM or to any part of a DISTRIBUTED ALARM SYSTEM. The inactivation of the generation of ALARM SIGNALS may be indefinite (i.e., ALARM OFF, AUDIO OFF) or indeterminate (indefinite ACKNOWLEDGED) or timed (i.e., ALARM PAUSED, AUDIO PAUSED or timed ACKNOWLEDGED).	Yes	(b)(4)		

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	Means shall be provided for the OPERATOR to determine the ALARM CONDITIONS for which ALARM SIGNALS are inactivated. NOTE 1 A group can be predetermined or not.	Yes			(b)(4)

	EXAMPLE 1 All ventilation ALARM CONDITIONS. EXAMPLE 2 An ALARM SYSTEM that has not received valid data since it was enabled (e.g. after power-up or before a PATIENT has been connected). NOTE 2 Additional requirements regarding global ALARM OFF or AUDIO OFF are found in 6.8.3.				
	If ALARM SIGNAL inactivation applies to an individual ALARM CONDITION or a group of ALARM CONDITIONS, the generation of ALARM SIGNALS from other ALARM CONDITIONS shall be unaffected.	Yes			
	During the ALARM OFF or ALARM PAUSED ALARM SIGNAL inactivation states, the ALARM SYSTEM may discontinue the processing of signals used to generate the inactivated ALARM CONDITIONS. NOTE 3 If the ALARM SYSTEM discontinues the processing of a signal used to generate an ALARM CONDITION, the ALARM SYSTEM log cannot log that ALARM CONDITION.	Yes			
	AUDIO PAUSED or AUDIO OFF shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.	Yes			

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	AUDIO PAUSED or AUDIO OFF may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1 or may cause DE-ESCALATION of the ALARM CONDITION priority. NOTE 4 An INTELLIGENT ALARM SYSTEM can use the OPERATOR'S activation of AUDIO PAUSED or AUDIO OFF to cause DEESCALATION or to re-evaluate the need for an ALARM CONDITION.	N/A			Does not have this function
	ACKNOWLEDGED, if provided, shall inactivate the auditory ALARM SIGNALS of currently active ALARM CONDITIONS and shall not affect the ALARM SIGNALS of inactive ALARM	N/A			Does not have this function

	CONDITIONS. ACKNOWLEDGED shall terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists. See also 6.8.4.				
	A timed ACKNOWLEDGED shall terminate after a defined duration. An indefinite ACKNOWLEDGED shall not terminate after a defined duration.	N/A			Does not have this function
	ACKNOWLEDGED shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.	N/A			Does not have this function
	ACKNOWLEDGED may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1.	N/A			Does not have this function
	ACKNOWLEDGED may cause the DE-ESCALATION of the ALARM CONDITION priority, including DEESCALATION of the ALARM SIGNALS of a LOW PRIORITY ALARM CONDITION into an INFORMATION SIGNAL.	N/A			Does not have this function
6.8.2	**REMINDER SIGNALS**				
	The ALARM SYSTEM may be provided with a REMINDER SIGNAL. If an ALARM SYSTEM is provided with a REMINDER SIGNAL:	N/A			Does not have this function
	a) the nature of the REMINDER SIGNAL and the intervals between REMINDER SIGNALS shall be disclosed in the instructions for use;	N/A			Does not have this function
	b) the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7): – to enable and disable the REMINDER SIGNAL; **and** – to configure the maximum REMINDER SIGNAL interval, if adjustment is provided.	N/A			Does not have this function

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	c) the ALARM SYSTEM may include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7): – to permit designated (see 6.7) OPERATORS to enable and disable the REMINDER SIGNAL; – to permit any OPERATOR to enable and disable the REMINDER SIGNAL.	N/A			Does not have this function
6.8.3	**Global indefinite ALARM SIGNAL inactivation states**				
	If deemed acceptable by RISK ASSESSMENT with regard to the intended environment of use of the ALARM SYSTEM, a global ALARM OFF or AUDIO OFF may be provided. If an ALARM SYSTEM is provided with a global ALARM OFF or AUDIO OFF, the ALARM SYSTEM shall be provided with:	N/A			Does not have global ALARM OFF or AUDIO OFF function.
	a) a REMINDER SIGNAL; **and**	N/A			Does not have global ALARM OFF or AUDIO OFF function
	b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF. Such means shall be restricted to the RESPONSIBLE ORGANIZATION and shall prevent the clinical OPERATOR from changing the configuration in NORMAL USE (see 6.7). NOTE 1 For the purposes of this standard, a global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state can affect all ALARM CONDITIONS or all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM. NOTE 2 See also 6.8.2 for requirements for REMINDER SIGNALS.	N/A			Does not have global ALARM OFF or AUDIO OFF function
6.8.4	**Termination of inactivation of ALARM SIGNALS**				
	Means shall be provided for the OPERATOR to terminate any ALARM SIGNAL inactivation state.	Yes			

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	An ALARM SIGNAL inactivation state may terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists. EXAMPLE 1 A non-latching PHYSIOLOGICAL ALARM CONDITION automatically terminates when the monitored parameter returns within its ALARM LIMITS. EXAMPLE 2 When an ALARM CONDITION has been ACKNOWLEDGED, the resulting state automatically terminates when the underlying ALARM CONDITION no longer exists.	Yes			

6.8.5	**Indication and access**				
	The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, ALARM OFF and ACKNOWLEDGED shall be visually indicated (marked) with the appropriate symbol referenced in Table 5. This indication shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION.	Yes			
	The means of control used to enter one of the ALARM SIGNAL inactivation states may be marked with a symbol referenced in Table 5. If a symbol that is referenced in Table 5 is used, it shall initiate the associated ALARM SIGNAL inactivation state.	N/A			(b)(4)
	The duration of AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED, if provided, shall be disclosed in the instructions for use.	Yes			
	If the AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED interval is OPERATOR adjustable, means to adjust the maximum interval shall only be provided to the RESPONSIBLE ORGANIZATION (see 6.7) and means may be provided for the OPERATOR to adjust the interval up to the maximum interval.	N/A			(b)(4)
6.9	**Alarm Reset**				
	The means of ALARM RESET may be marked with symbol IEC 60417-5309 (DB-2002-10) (see symbol 2 of Table C.1) or marking 5 of Table C.2.	N/A			Does not have this function
6.10	**NON-LATCHING and LATCHING ALARM SIGNALS**				

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	A NON-LATCHING ALARM SIGNAL shall automatically cease being generated when its triggering event no longer exists. A LATCHING ALARM SIGNAL shall continue to be generated after its triggering event no longer exists. An ALARM SYSTEM may consist of a mixture of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS.	Yes			(b)(4)

	NOTE 1 An INTELLIGENT ALARM SYSTEM can decrease the priority of a LATCHING ALARM SIGNAL.				
	In the case of an ALARM CONDITION of short duration, a MEDIUM PRIORITY auditory ALARM SIGNAL shall complete at least one full BURST and a HIGH PRIORITY auditory ALARM SIGNAL shall complete one half of one full BURST, unless inactivated by the OPERATOR.	Yes			
	Auditory ALARM SIGNALS shall cease being generated when:				
	a) an OPERATOR has initiated the AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF state; **or**	Yes			
	b) an OPERATOR has ALARM RESET the ALARM CONDITION.	N/A			Does not have ALARM RESET
	Means shall be provided to prevent the OPERATORS from selecting between LATCHING and ONLATCHING ALARM SIGNALS. The selection between LATCHING and NON-LATCHING ALARM SIGNALS shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7).	N/A			No selection is available
6.11	**DISTRIBUTED ALARM SYSTEMS (DAS) and DISTRIBUTED INFORMATION SYSTEMS (DIS) ABOUT ALARM CONDITIONS**				
6.11.1	**Existence of a DIS or DAS**				
	The details necessary for the safe use of a DIS or a DAS shall be disclosed in the technical description. A DIS or a DAS is a permitted form of an ALARM SYSTEM.	Yes			

	An ALARM SYSTEM is permitted to send or receive data, including the indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of a DIS or a DAS. A DIS or a DAS is permitted to be located outside of the PATIENT ENVIRONMENT. Part(s) of a DIS or a DAS are permitted to be located outside of the PATIENT ENVIRONMENT. Data are permitted to be transmitted between different parts of a DIS or a DAS by wire, by telemetry or by other means. EXAMPLE 1 A central station. EXAMPLE 2 An electronic record-keeping device.	Yes			
	EXAMPLE 3 Remote viewing from home or office. EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g., one nurse for two beds). EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell phones, hand-held computers, etc.				
6.11.2	**Requirements for communication of ALARM CONDITIONS**				
6.11.2.1	**SOURCE and identification of ALARM CONDITIONS**				
	In a DAS or DIS, means shall be provided to identify the SOURCE of the ALARM CONDITION at every COMMUNICATOR that generates ALARM SIGNALS for that ALARM CONDITION.	Yes			
	ALARM SIGNALS that indicate the urgency of the response required, categorization of the cause of the ALARM CONDITION and identification of the PATIENT, equipment or PATIENT's location should also be generated by the DISTRIBUTED ALARM SYSTEM.	Yes			System is DIS
6.11.2.2	**Failure of remote communication of ALARM CONDITIONS**				
6.11.2.2.1	**DAS or CDAS**				
	A DAS or CDAS shall be so designed that a communications failure or failure in any remote component of the DAS or CDAS:	N/A			System is DIS, not DAS or CDAS
	a) shall not adversely affect any part of the DAS or CDAS other than the loss of the distributed functionality; **and**	N/A			System is DIS, not DAS or CDAS
	b) shall initiate a TECHNICAL ALARM CONDITION for all relevant COMMUNICATORS of the DAS or CDAS.	N/A			System is DIS, not DAS or CDAS

	1) The ALARM SYSTEM should provide a means for the OPERATOR to inactivate any auditory ALARM SIGNALS of this TECHNICAL ALARM CONDITION.	N/A			System is DIS, not DAS or CDAS
	MANUFACTURERS should take care in the design of ME EQUIPMENT to ensure that it reverts to a safe mode of operation, which can include ESCALATION of the volume of auditory ALARM SIGNALS or utilization of a redundant communication pathway.	N/A			System is DIS, not DAS or CDAS
6.11.2.2.2	**DIS**				
	A DIS shall be so designed that a communications failure or failure in any remote component of the DIS:				
	a) shall not adversely affect any part of the DIS other than the loss of the distributed functionality; **and**	Yes			
	b) any remote COMMUNICATOR of a DIS that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS. EXAMPLE A one-way paging system requires such a warning. NOTE Inability to successfully send or receive ALARM CONDITIONS or INFORMATION SIGNALS is considered a failure.	Yes			
6.11.2.2.3	**Source with a global audio off in a DISTRIBUTED ALARM SYSTEM**				
	If there is a communications failure between a SOURCE with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM, the affected SOURCE shall terminate the global AUDIO OFF state, if active.	N/A			No global AUDIO OFF. AUDIO OFF is patient centric. AUDIO OFF is not part of the SOURCE
	If the OPERATOR subsequently activates AUDIO OFF or a global AUDIO OFF in the SOURCE, continuing failure of the link need not cause additional auditory ALARM SIGNALS.	N/A			No global AUDIO OFF. AUDIO OFF is patient centric. AUDIO OFF is not part of the SOURCE
6.11.2.3	**Remote ALARM SYSTEM controls**				
	A DAS or CDAS may provide remote OPERATOR access to some, or all ALARM SYSTEM controls. If provided:	N/A			System is DIS, not DAS or CDAS
	a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; **and**	N/A			System is DIS, not DAS or CDAS

	b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).	N/A			System is DIS, not DAS or CDAS
6.11.2.4	**CDAS**				
	In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION shall have means to create the OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) and transfer them to the INTEGRATOR.	N/A			System is DIS, not CDAS

	a) In a CDAS, the communicator that receives an alarm condition and initiates an operator response (responsibility accepted or responsibility rejected) shall indicate the operator response state (responsibility accepted or responsibility rejected).	N/A			System is DIS, not CDAS
	The means of control used to initiate an OPERATOR response or indication of state may be marked with:	N/A			System is DIS, not CDAS
	b) symbol ISO 7000-6334A (2015-06) (see Symbol 13 of Table C.1) for RESPONSIBILITY ACCEPTED; **or**	N/A			System is DIS, not CDAS
	c) symbol ISO 7000-6335A (2015-06) (see Symbol 16 of Table C.1) for RESPONSIBILITY REJECTED.	N/A			System is DIS, not CDAS
	Means shall be provided for the OPERATOR to terminate RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED while the related ALARM CONDITION is active. Initiating RESPONSIBILITY REJECTED may be used to terminate RESPONSIBILITY ACCEPTED. Initiating RESPONSIBILITY ACCEPTED may be used to terminate RESPONSIBILITY REJECTED.	N/A			System is DIS, not CDAS
	In a CDAS, RESPONSIBILITY ACCEPTED may initiate an ALARM SIGNAL inactivation state. (this is different than an alarm inactivation state)	N/A			System is DIS, not CDAS
	In a CDAS, the INTEGRATOR shall have means to accept OPERATOR responses from the COMMUNICATOR.	N/A			System is DIS, not CDAS
	In a CDAS, the SOURCE may receive OPERATOR responses from the INTEGRATOR.	N/A			System is DIS, not CDAS
6.12	**Alarm System Logging**				
6.12.1	**General**				
	An alarm system may be equipped with an operator alarm system log or a responsible organization alarm system log	Yes			

	An OPERATOR ALARM SYSTEM log is intended to be utilized while the ALARM SYSTEM is being used for a PATIENT. A RESPONSIBLE ORGANIZATION ALARM SYSTEM log is intended to be utilized after PATIENT use has been concluded.	N/A			Responsible Organization alarm system log only

	An operator alarm system log is typically a subset of the responsible organization alarm system log.	N/A			Responsible Organization alarm system log only
6.12.2	**OPERATOR ALARM SYSTEM logging**				
	If an ALARM SYSTEM is provided with an operator alarm system log:				
	a) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS for that ALARM CONDITION, if OPERATOR-adjustable and, where feasible, the data that caused the ALARM CONDITION;	Yes			
	b) the ALARM SYSTEM shall log the occurrence and identity of all HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS;	Yes			
	c) for each logged ALARM CONDITION, the ALARM SYSTEM shall log: – the date and time of the occurrence; **or** – the elapsed time since the occurrence of the ALARM CONDITION; **or** – the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;	Yes			
	d) the ALARM SYSTEM should log the occurrence and identity of all ALARM SIGNAL inactivation states and, for a CDAS, OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED);	Yes			

	1) for each logged ALARM SIGNAL inactivation state, the ALARM SYSTEM shall log: – the date and time of the occurrence, **or** – the elapsed time since the occurrence of the ALARM CONDITION or ALARM SIGNAL inactivation state, **or**	Yes			
	– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;				
	e) if a means is provided for the OPERATOR to indicate to the ALARM SYSTEM that a different PATIENT has been connected, then that event should be logged in the OPERATOR ALARM SYSTEM log;	Yes			
	f) means may be provided for the logging of changes to the OPERATOR-adjustable ALARM SETTINGS in the OPERATOR ALARM SYSTEM log;	N/A			Responsible Organization alarm system log only. Alarm settings are logged
	g) means may be provided for the OPERATOR to add explanatory notes or comments to the OPERATOR ALARM SYSTEM log, and if provided: – means should be provided to record the identity of the annotator and the date and time of the annotation;	N/A			In the Responsible Organization alarm system log only
	h) means shall not be provided for the OPERATOR to edit or delete entries in the OPERATOR ALARM SYSTEM log, unless a new PATIENT is admitted, or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log is provided;	N/A			In the Responsible Organization alarm system log only
	i) the log may be provided either within the equipment or remotely through a communications interface; **and**	Yes			
	j) the instructions for use shall indicate:				
	1) the means for the OPERATOR to access the OPERATOR ALARM SYSTEM log;	N/A			Responsible Organization alarm system log only
	2) whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log;	N/A			Responsible Organization alarm system log only

	3) what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;	N/A			Responsible Organization alarm system log only
	4) the capacity of the log; **and**	N/A			Responsible Organization alarm system log only
	5) what happens to the contents of the log as it reaches capacity.	N/A			Responsible Organization alarm system log only

6.12.3	**RESPONSIBLE ORGANIZATION ALARM SYSTEM logging**				
	If an alarm system is provided with a responsible organization alarm system log:				
	a) viewing the responsible organization alarm system log shall be restricted to the responsible organization (see 6.7);	Yes			
	b) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain all of the information contained in the OPERATOR ALARM SYSTEM log;	Yes			
	c) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain the ALARM SETTINGS and each change of those settings;	Yes			
	d) means shall not be provided for the OPERATOR or RESPONSIBLE ORGANIZATION to edit or delete entries in the RESPONSIBLE ORGANIZATION ALARM SYSTEM log;	Yes			
	e) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be retained when the ALARM SYSTEM is powered down;	Yes			
	f) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;	Yes			
	g) the instructions for use shall indicate:				
	1) the responsible organization alarm system log capacity, **and**	Yes			
	2) what happens to the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as it reaches capacity;	Yes			
	h) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR ACTION; **and**	Yes			
	i) the log may be provided either within the equipment or remotely through a communications interface.	Yes			

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6.13	**Alarm System Functions**				
6.13.1	**General**				
	An ALARM SYSTEM shall have at least one:				
	a) SOURCE;	Yes			
	b) INTEGRATOR; **and**	Yes			
	c) COMMUNICATOR.	Yes			
6.13.2	**Source (SRC)**				
	An ME EQUIPMENT, a DIS or a DAS may have more than one SOURCE.	Yes			
	An ALARM CONDITION shall only originate from a SOURCE.	Yes			
	A source may receive an indication of responsibility accepted, responsibility rejected or responsibility undefined originating at a communicator (from an operator) that was transferred from an integrator.	N/A			
6.13.3	**Integrator (INT)**				
	An INTEGRATOR shall map SOURCES and their ALARM CONDITIONS to one or more specific COMMUNICATORS.	Yes			
	An integrator may receive an indication of responsibility accepted, responsibility rejected or responsibility undefined originating at a communicator (from an operator) and may transfer it to a source.	N/A			
	An INTEGRATOR may provide REDIRECTION to additional or different COMMUNICATORS based on the response or lack of response from COMMUNICATORS. The MANUFACTURER should consider a means for the RESPONSIBLE ORGANIZATION to manage the REDIRECTION to assure an appropriate OPERATOR response.	N/A			
	An integrator may:				
	contain a SOURCE that performs the functions of an INTELLIGENT ALARM SYSTEM (see 6.2); EXAMPLE 1 Removing redundant ALARM CONDITIONS. EXAMPLE 2 Creating an ALARM CONDITION from multiple inputs. EXAMPLE 3 Suppressing superfluous ALARM SIGNALS.	N/A			
	b) generate the RESPONSIBILITY UNDEFINED state;	N/A			
	c) generate an ALARM SIGNAL inactivation state.	N/A			
	The ME EQUIPMENT, a DIS or a DAS may have more than one INTEGRATOR.	Yes			Each patient has a SmartCardia Phone as an INTEGRATOR

(b)(4)

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6.13.4	**Communicator (COM)**				
	A communicator receives alarm conditions from one or more integrators. A communicator may also process or direct an operator response (responsibility accepted or responsibility rejected) to the integrator.	N/A			This requirement is a 'may', not a 'shall'
	An OPERATOR response need not be limited to direct OPERATOR action and can be achieved by other means (e.g., an OPERATOR locator system).	N/A			System is a DIS, not DAS or CDAS. There is no OPERATOR response back to the system
	If OPERATOR response is achieved by other means than direct OPERATOR action, the ALARM SYSTEM shall provide means to indicate to the corresponding OPERATOR that RESPONSIBILITY ACCEPTED is active for the affected COMMUNICATOR.	N/A			System is a DIS, not DAS or CDAS. There is no OPERATOR response back to the system
	An ME EQUIPMENT, a DIS or a DAS may have more than one COMMUNICATOR.	Yes			

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Attachment 1 – Tables and Figures

Table 1 – Determination of Alarm Conditions and Assignment of Priorities

(b)(4)

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Extent of Standard Conformance (b)(4) **Summary Report Table**

ANSI/AAM (b)(4) 2000/(R)2020 Disposable ECG Electrodes					FDA Recognition No.: # 3-52
Conformance with Standards Sections Tested by: A) (b)(4) file 022_Performance Testing – Bench, page 364 B) (b)(4) Biocompatibility Test Reports, file 015_ISO 10993 Biocompatibility Test Reports					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
4	**Requirements**				
4.1	Labeling Requirements				
4.1 (a)	a statement indicating the date beyond which conformance of the device with the requirements of this standard cannot be assured (for example, "use before _____") and the lot number, or a statement indicating the date of manufacture, shelf life, and lot number;	Yes			
4.1 (b)	appropriate precautions and warnings, including limits of duration of electrode application and an indication of the useful out-of-pouch shelf life of the product; if the electrode should be used immediately upon opening the pouch, then an appropriate caution shall be indicated;	Yes			
4.1 (c)	appropriate instructions for use, including procedures for skin preparation, and for electrode preparation if the electrode is not pre-gelled (for example, gel type and gel amount);	Yes			
4.1 (d)	instructions concerning storage requirements, if applicable.	Yes			
4.2	Performance Requirements				
4.2.1	Packaging and shelf life				
	The device shall be manufactured and packaged in such a way that all requirements of this standard will be met up to the "use before" date specified by the manufacturer according to 4.1 a), under the storage conditions recommended by the manufacturer according to 4.1 d).	Yes			
4.2.2	Electrical Performance (b)(4)				
4.2.2.1	AC Impedance				
	The average value of 10-hertz (Hz) impedance for at least 12 electrode pairs connected gel-to-gel, at a level of impressed current not exceeding 100 microamperes (μA) peak-to-peak (p-p), shall not exceed 2 kilohms (kΩ). None of the individual pair impedances shall exceed 3 kΩ.	Yes			
4.2.2.2	DC Offset Voltage				
	After a 1-minute (min) stabilization period, a pair of electrodes connected	Yes			

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ANSI/AAMI (b)(4) 2000/(R)2020 Disposable ECG Electrodes					FDA Recognition No.: # 3-52
Conformance with Standards Sections Tested by: A) (b)(4) file 022_Performance Testing – Bench, page 364 B) (b)(4) Biocompatibility Test Reports, file 015_ISO 10993 Biocompatibility Test Reports					
Clause	**Title**	**Conformance Yes/No/NA**	**Deviation or Option**	**Description**	**Justification/Comment**
	gel-to-gel shall not exhibit an offset voltage greater than 100 millivolts (mV).				
4.2.2.3	Combined Offset Instability and Internal Noise				
	After a 1-min stabilization period, a pair of electrodes connected gel-to-gel shall not generate a voltage greater than 150 microvolts (μV) p-p in the passband (first-order frequency response) of 0.15 to 100 Hz, for a period of 5 min following the stabilization period.	Yes			
4.2.2.4	Defibrillation Overload Recovery				
	Five sec after each of four capacitor discharges, the absolute value of polarization potential of a pair of electrodes connected gel-to-gel shall not exceed 100 mV.	N/A			Not Defibrillation Proof, complies with defibrillator energy reduction test, 022_Performance Testing – Bench, Page 334
4.2.2.5	Bias Current Tolerance				
	The observed DC voltage offset change across a pair of electrodes connected gel-to-gel shall not exceed 100 mV when the electrode pair is subjected to a continuous 200-nanoampere (nA) DC current over the period recommended by the manufacturer for the clinical use of the electrodes. In no case shall this period be less than 8 hours.	Yes			
4.3	**Safety Requirements**				
4.3.1	Biological Response				
	The device shall be biocompatible. For this application (i.e., an electrode in contact with the skin) biocompatibility requires evaluation of cytotoxicity, skin irritation, and either skin sensitization or intracutaneous reactivity.	Yes			
4.3.2	Pre-attached lead wire safety				
	Electrodes with pre-attached (permanently attached) lead wires shall be constructed in such a manner that the lead wire connector used to mate with the instrument trunk cable cannot contact ground or a possibly hazardous potential. In particular, this connector shall be constructed to prevent conductive contact with a mains outlet or a detachable power cord.	N/A			No pre-attached lead wires, body worn patch
4.4	Adhesive Performance (Duration of Use)				
	The electrode's adhesive performance, as it impacts the duration of use, should meet the claims or applications that the manufacturer has indicated.	Yes			

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Extent of Standard Conformance: **IEC 60601-1-11 Summary Report Table**

IEC 60601-1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	FDA Recognition No.: # 19-14
Conformance with Standards Sections Tested by: A) (b)(4) Test Report; File 022_Performance Testing – Bench, page 312 B) SmartCardia Internal Tests (b)(4) Device Specifications Test Report, Shock and Vibration Summary Test Report, File 022_Performance Testing – Bench, page 437	

Clause	Title	Conformance Yes/No/NA	Deviation or Option	Description	Justification/Comment
4	**General Requirements**				
4.1	**Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**				Section Heading
	SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT shall be assumed to have the following characteristics: no voltage in excess of 110 % or lower than 85 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth.	N/A			Applied parts do not have AC MAINS
	For ME EQUIPMENT or ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT, SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT shall be assumed to have the following characteristics: no voltage in excess of 110 % or lower than 80 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth.	N/A			Not intended to actively keep alive or resuscitate a patient
	The RATED range of NOMINAL voltage of the ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT shall include at least 12,4 V to 15,1 V for operation from 12 V d.c. SUPPLY MAINS and at least 24,8 V to 30,3 V for operation from 24 V d.c. SUPPLY MAINS.	N/A			Does not have AC MAINS, battery operated, body worn senso (b)(4) (b)(4)
	ME EQUIPMENT and ME SYSTEMS in the HOME HEALTHCARE ENVIRONMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V from a 12 V d.c. SUPPLY MAINS and during and following a 30 s dip to 20 V for operation from a 24 V d.c. SUPPLY MAINS.	N/A			Does not have AC MAINS, battery operated, body worn sensor.
4.2	**Environmental conditions for ME EQUIPMENT**				Section Heading
4.2.1	General				Section Heading

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	All environmental tests at temperatures below +5 °C need not be performed with humidity control of the test chamber. NOTE In IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, the MANUFACTURER specifies the				Informative
	permissible conditions of use, including conditions for transport and storage in the technical description (see 7.9.3.1, second dash). These conditions are referenced in requirements for testing throughout the general standard, (e.g. 5.3 and 11.1.1).				
4.2.1	Environmental conditions of transport and storage between uses				Section Heading
	The instructions for use shall indicate the permissible environmental conditions of transport and storage of ME EQUIPMENT after the ME EQUIPMENT has been removed from its protective packaging and subsequently between uses.	Yes			
	Unless otherwise indicated in the instructions for use or if the ME EQUIPMENT is STATIONARY, the ME EQUIPMENT shall remain operational in NORMAL USE within its specification and the requirements of this standard after transport or storage in the following environmental range: • – 25 °C to + 5 °C, and • + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing; • >35 °C to 70 °C at a water vapor pressure up to 50 hPa after having been removed from its protective packaging and subsequently between uses.	Yes			Indicated in Patient IFU, File 013_Instructions for Use, Page 22 of 235.

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	If the instructions for use state a more restricted range of environmental transport and storage conditions between uses, these environmental conditions shall be: – justified in the RISK MANAGEMENT FILE; – marked on the ME EQUIPMENT, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and – marked on the carrying case, if the instructions for use indicate that the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses.	N/A			IFU does not state a more restricted use other than normal environment.

4.2.3	Environmental operating conditions				Section Heading
4.2.3.1	Continuous Operating Conditions				Section Heading
	The instructions for use shall indicate the permissible environmental operating conditions of the ME EQUIPMENT.	Yes			
	Unless otherwise indicated in the instructions for use, the ME EQUIPMENT shall comply with its specifications and all the requirements of this standard when operated in NORMAL USE under the following environmental operating conditions: – a temperature range of + 5 to + 40 °C; – a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa; and – an atmospheric pressure range of 700 hPa to 1 060 hPa	Yes			(b)(4) test report
	If the instructions for use state a more restricted range of environmental transport and storage conditions between uses, these environmental conditions shall be: – justified in the RISK MANAGEMENT FILE; – marked on the ME EQUIPMENT, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and – marked on the carrying case, if the instructions for use indicate that the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses.	N/A			Instructions for Use do not state a more restricted range
4.2.3.2	Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT				Section Heading

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	If the instructions for use state a wider range of continuous environmental operating conditions than those indicated in 4.2.3.1, the TRANSIT-OPERABLE ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock resulting from rapid changes in environmental temperature and humidity during INTENDED USE.	N/A			Instructions for Use do not state a wider environmental operating conditions
5	**General requirements for testing ME EQUIPMENT**				
	In addition to the requirements of 5.9.2.1 of the general standard, parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and, where necessary, by testing. In case of doubt, a part of ME EQUIPMENT that is to be regarded as an ACCESSIBLE PART is determined by a test with the small finger probe shown in Figure 1, applied in a bent or straight position: – for all positions of the ME EQUIPMENT when operated as in NORMAL USE; and – after opening ACCESS COVERS and removal of parts, including lamps, fuses and fuse holders, when: i) the ACCESS COVERS can be opened without the use of a TOOL, or ii) the instructions for use instruct a LAY OPERATOR to open the relevant ACCESS COVER.	N/A			(b)(4)
6	**Classification of ME EQUIPMENT and ME SYSTEMS**				
	In addition to the requirements in 6.2 of the general standard, unless the ME EQUIPMENT intended for the HOME HEALTHCARE ENVIRONMENT is PERMANENTLY INSTALLED, it: – shall be CLASS II or INTERNALLY POWERED; – shall not have a FUNCTIONAL EARTH TERMINAL; and – if equipped with APPLIED PARTS, shall have either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.	Yes			
7	**ME EQUIPMENT identification, marking and documents**				
7.1	USABILITY of the ACCOMPANYING DOCUMENTS				Section Heading

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	In addition to the requirements of 7.1.1 of the general standard, the USABILITY of the identification, marking and ACCOMPANYING DOCUMENTS intended for the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION shall be evaluated based on an OPERATOR PROFILE that includes a minimum of eight years of education.	Yes			(b)(4)

7.2	Additional requirements for marking of IP classification				Section Heading
	In addition to the requirements of 7.2.9 of the general standard, the ME EQUIPMENT or its parts and, when appropriate, a carrying case shall be marked with the appropriate IP classification as tested in 8.3.1.	Yes			IPX7 label on patch
	If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then: a) the ENCLOSURE of the ME EQUIPMENT shall be marked with its degree of protection and SAFETY SIGN ISO 7010-W001 (see IEC 60601-1:2005, Table D.2, SAFETY SIGN 2), – as well as with 'keep dry', or – the symbol ISO 15223-1:2016, 5.3.4 (ISO 7000-0626 (2004-01)) (see Table C.1, symbol 1); and b) the carrying case shall be marked with its degree of protection. If the ENCLOSURE of the ME EQUIPMENT is classified IPXX, IP00, IPX0 or IP0X then it need not be marked as such. However, the other marking requirements in a) still apply.	N/A			No carrying case
7.3	ACCOMPANYING DOCUMENTS				Section Heading
7.3.1	Contact Information				Section Heading
	In addition to the requirements of 7.9.1 and 16.2 of the general standard, the ACCOMPANYING DOCUMENTS for ME EQUIPMENT that is intended for use by a LAY OPERATOR shall indicate that the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or the MANUFACTURER'S representative: – for assistance, if needed, in setting up, using or maintaining the ME EQUIPMENT or ME SYSTEM; or – to report unexpected operation or events.	Yes			

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	The ACCOMPANYING DOCUMENTS shall include a postal address and either a telephone number or web address through which the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION can contact the MANUFACTURER or the MANUFACTURER'S representative.	Yes			

7.3.2	LAY OPERATOR briefing information				Section Heading
	When appropriate in addition to the requirements of 7.9.1 and 16.2 of the general standard, the ACCOMPANYING DOCUMENTS shall include the details necessary for the healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of the ME EQUIPMENT or ME SYSTEM and any precautions to be taken. This shall include: – precautions to be taken in the event of changes in the performance of the ME EQUIPMENT or ME SYSTEM; – precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions (e.g. to magnetic fields, electromagnetic fields, external electrical influences, ELECTROSTATIC DISCHARGE, pressure or variations in pressure, acceleration, thermal ignition sources); – adequate information regarding any medicinal substances that the ME EQUIPMENT is designed to administer, including any limitations in the choice of substances to be delivered; – information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and – the degree of accuracy claimed for ME EQUIPMENT with a measuring function.	Yes			
7.4	Instructions for use				Section Heading
7.4.1	Additional requirements for warning and safety notices				
	In addition to the requirements of 7.9.2.2 and 16.2 c) of the general standard for each warning and SAFETY SIGN, the instructions for use shall describe the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK.				

	If applicable, the instructions for use shall address the issues of: – strangulation due to cables and hoses, particularly due to excessive length; EXAMPLE 1 Strangulation resulting from baby or child entanglement in monitoring cables. EXAMPLE 2 Strangulation resulting from breathing system hoses. – small parts being inhaled or swallowed; EXAMPLE 3 Choking resulting from a child swallowing a small part that has become detached from the ME EQUIPMENT. – potential allergic reactions to accessible materials used in the ME EQUIPMENT; EXAMPLE 4 Natural rubber latex sensitivity. – contact injuries. EXAMPLE 5 Skin irritation due to prolonged exposure to APPLIED PARTS or other ACCESSORIES.	Yes			
	If applicable, the instructions for use shall include warnings to the effect that it can be unsafe to: – use ACCESSORIES, detachable parts and materials not described in the instructions for use (see 7.9.2.14 of the general standard); – interconnect this equipment with other equipment not described in the instructions for use (see 16.2 c) indent 9) of the general standard); – modify the equipment; – use the ME EQUIPMENT outside its carrying case if some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1).	N/A			No accessories, no interconnects, no carrying case
7.4.2	Additional requirements for an electrical power source				Section Heading

	In addition to the requirements of 7.9.2.4 of the general standard, if ME EQUIPMENT is equipped with an INTERNAL ELECTRICAL POWER SOURCE and the BASIC SAFETY or ESSENTIAL PERFORMANCE is dependent on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use shall describe: – the typical operation time or number of PROCEDURES; – the typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and – for a rechargeable INTERNAL ELECTRICAL POWER SOURCE, the behaviour of the ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging. EXAMPLE 1 Number of years after which a rechargeable battery needs to be replaced. EXAMPLE 2 Number of discharge cycles after which a rechargeable battery needs to be replaced.	Yes			IFU states up to 14 days.; batteries are not rechargeable.
7.4.3	Additional requirements for ME EQUIPMENT description				Section Heading
	In addition to the requirements of 7.9.2.5 of the general standard, the instructions for use for ME EQUIPMENT that is intended for use by a LAY OPERATOR shall include easily understood diagrams, illustrations or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided with the ME EQUIPMENT (see 7.1).	Yes			
7.4.4	Additional requirements for ME EQUIPMENT start-up PROCEDURE				Section Heading
	In addition to the requirements of 7.9.2.8 of the general standard, the instructions for use shall include: – easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1); and – the time from switching "ON" until the ME EQUIPMENT is ready for	Yes			

	NORMAL USE, if that time exceeds 15 s (see 15.4.4 of the general standard). – the time required for the ME EQUIPMENT to warm from the minimum storage temperature between uses (4.2.2) until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C; and – the time required for the ME EQUIPMENT to cool from the maximum storage temperature between uses (4.2.2) until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C.				
7.4.5	Additional requirements for operating instructions				Section Heading
	In addition to the requirements of 7.9.2.9 of the general standard, the instructions for use for ME EQUIPMENT that is intended for use by a LAY OPERATOR shall include a description of generally known conditions in the HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the LAY OPERATOR to identify and resolve these conditions, and shall include, where applicable, at least the following issues: – the effects of lint, dust, light (including sunlight), etc.; – a list of known devices or other sources that can potentially cause interference problems; EXAMPLE 1 Heat from a fireplace or radiant heater. EXAMPLE 2 Moisture from a nebulizer or steam kettle. – the effects of degraded sensors and electrodes, or loosened electrodes, which can degrade performance or cause other problems; – the effects caused by pets, pests, or children.	Yes			
	The instructions for use shall explain the meaning of the IP classification marked on the ME EQUIPMENT and, if applicable, on any carrying case provided with the ME EQUIPMENT.	Yes			
7.4.6	Additional requirements for ME EQUIPMENT messages				Section Heading

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	In addition to the requirements of 7.9.2.10 of the general standard, the instructions for use shall include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation. The troubleshooting guide shall disclose the necessary steps to be taken in the event of each TECHNICAL ALARM CONDITION.	Yes			
7.4.7	Additional requirements for cleaning, disinfection and sterilization				Section Heading
	In addition to the requirements of 7.9.2.12 and 16.2 c), indent 3 of the general standard, for ME EQUIPMENT, ME SYSTEMS, their parts or ACCESSORIES that are intended for other than single use and that can become contaminated through contact with the PATIENT or with body fluids or expired gases during INTENDED USE, the instructions for use shall: Either,				(b)(4)
	– indicate the frequency of cleaning, cleaning and disinfection or cleaning and sterilization, as appropriate, of the ME EQUIPMENT, ME SYSTEMS, parts or ACCESSORIES used on the same PATIENT including methods for rinsing, drying, handling and storage between uses (see 8.1 and 8.2); and EXAMPLE 1 Periodic cleaning and disinfection of a breathing system to prevent infection of a PATIENT during chronic care. – if intended for multiple PATIENT use, indicate that it is necessary to clean and disinfect or clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts or ACCESSORIES between uses on different PATIENTS, including methods for rinsing, drying, handling and storage until re-use (see 8.1 and 8.2); EXAMPLE 2 Cleaning and disinfection of a thermometer following use to prevent PATIENT cross infection. **OR,** – indicate that the ME EQUIPMENT, ME SYSTEMS or ACCESSORIES require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2).	Yes N/A			Cleaning and disinfection instruction in 013_Instructions for Use, page 18 of 235 – system does not require professional hygienic maintenance prior to use.

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7.4.8	Additional requirements for maintenance				Section Heading
	In addition to the requirements of 7.9.2.13 of the general standard the instructions for use shall include: – the EXPECTED SERVICE LIFE of the ME EQUIPMENT; – the EXPECTED SERVICE LIFE of parts or ACCESSORIES shipped with the ME EQUIPMENT; and – where the SHELF LIFE is less than the EXPECTED SERVICE LIFE, the SHELF LIFE of parts or ACCESSORIES shipped with the ME EQUIPMENT.	Yes			
7.4.9	Additional requirements for environmental protection				Section Heading
	In addition to the requirements of 7.9.2.15 of the general standard, the instructions for use shall include, where applicable, a statement to the effect that the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio-hazardous parts and ACCESSORIES.	N/A			No biohazardous parts or accessories for the lay person to dispose of.
7.4.10	Additional requirements for ME EQUIPMENT and ME SYSTEMS				Section Heading
	For ME EQUIPMENT or an ME SYSTEM utilizing a DISTRIBUTED ALARM SYSTEM the instructions for use shall include the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM to ensure that an OPERATOR can be notified at all times by an appropriate element of the DISTRIBUTED ALARM SYSTEM within its specified range.	N/A			No alarm function on the mobile app
7.5	Technical Description				
7.5.1	PERMANENTLY INSTALLED CLASS I ME EQUIPMENT				
	In addition to the requirements of 7.9.3.1 of the general standard to ensure that PERMANENTLY INSTALLED CLASS I ME EQUIPMENT is PROPERLY	N/A			Not permanently installed

	INSTALLED, the technical description shall include: – a warning to the effect that the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL; – the specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR; – a warning to verify the integrity of the external protective earthing system; – a warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system.				
7.5.2	Additional requirements for professional hygienic maintenance				Section Heading
	For ME EQUIPMENT or ACCESSORIES that require professional hygienic maintenance prior to re-use (see 7.4.7), the technical description shall include methods for cleaning and disinfection or cleaning and sterilization: – before and after any type of service PROCEDURE; – when the ME EQUIPMENT is transferred to another PATIENT.	N/A			Cleaning and disinfection instruction in 013_Instructions for Use, page 18 of 235 – system does not require professional hygienic maintenance prior to use.
8	**Protection against excessive temperatures and other HAZARDS**				
8.1	Additional requirements for cleaning, disinfection of ME EQUIPMENT and ME SYSTEMS				Section Heading
	In addition to the requirements of 11.6.6 of the general standard, the cleaning or cleaning and disinfection PROCESSES intended to be performed in the HOME HEALTHCARE ENVIRONMENT by a LAY OPERATOR shall be capable of being performed by a LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT (see 7.4.7). The USABILITY of each such PROCESS as it pertains to a LAY OPERATOR shall be investigated by the USABILITY ENGINEERING PROCESS.	Yes			
8.2	Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS				Section Heading

	In addition to the requirements of 11.6.7 of the general standard, the cleaning and sterilization PROCESSES intended to be performed in the HOME HEALTHCARE ENVIRONMENT by a LAY OPERATOR shall be capable of being performed by a LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT (see 7.4.7). The USABILITY of each such PROCESS as it pertains to a LAY OPERATOR shall be investigated by the USABILITY ENGINEERING PROCESS.	N/A			Sterilization is not required
8.3	Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS				Section Heading
8.3.1	Ingress of water or particulate matter into ME EQUIPMENT				Section Heading
	In addition to the requirements of 11.6.5 of the general standard, TRANSIT-OPERABLE, HAND-HELD, and BODY-WORN ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013 for at least IP22. All other ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 and IEC 60529:1989/AMD2:2013 for at least IP21. For PORTABLE ME EQUIPMENT that is only intended to be used while inside a carrying case, this requirement may be met while the ME EQUIPMENT is inside the carrying case. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the ME EQUIPMENT shall be tested while inside the carrying case.	Yes			
8.3.2	Ingress of water or particulate matter into ME SYSTEMS				Section Heading
	In addition to the requirements for ENCLOSURES in 16.4 of the general standard, the ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS shall provide the degree of protection against harmful ingress of water or particulate matter equivalent	Yes			

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	to equipment complying with their respective IEC or ISO safety standards. Compliance is checked by the tests of IEC 60529:1989 with the equipment placed in the least favorable position of NORMAL USE and by inspection. Ingress tests that have already been performed on individual equipment of an ME SYSTEM according to relevant standards need not be repeated. See also 5.1 of the general standard.				
8.4	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM				Section Heading
	In addition to the requirements of 11.8 and 16.8 of the general standard, ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall maintain its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES, when loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE occurs. The time or number of PROCEDURES remaining shall allow alternative life-supporting methods to be employed.	N/A			Not intended to actively keep alive or resuscitate a patient.
	An INTERNAL ELECTRICAL POWER SOURCE may be utilized to maintain ESSENTIAL PERFORMANCE. Independent means may also be utilized to provide ESSENTIAL PERFORMANCE.	N/A			Not intended to actively keep alive or resuscitate a patient.
	The instructions for use shall disclose the time or number of PROCEDURES available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE. The instructions for use shall describe the alternative life-supporting methods to be employed. The technical description shall describe methods that can be employed for longer periods.	N/A			Not intended to actively keep alive or resuscitate a patient.
	If an INTERNAL ELECTRICAL POWER SOURCE is not used, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION that indicates a power supply failure.	N/A			Not intended to actively keep alive or resuscitate a patient.

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	If an INTERNAL ELECTRICAL POWER SOURCE is used, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an automatic switchover to the INTERNAL ELECTRICAL POWER SOURCE.	N/A			Not intended to actively keep alive or resuscitate a patient.
	If an INTERNAL ELECTRICAL POWER SOURCE is used, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION that indicates that the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for ME EQUIPMENT operation. This TECHNICAL ALARM CONDITION shall provide for a sufficient time or for a sufficient number of PROCEDURES for a LAY OPERATOR to act. A TECHNICAL ALARM CONDITION of at least LOW PRIORITY shall remain active until the INTERNAL ELECTRICAL POWER SOURCE is returned to a level that is above the ALARM LIMIT or until it is depleted. It shall not be possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION.	N/A			Not intended to actively keep alive or resuscitate a patient.
8.5	Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE				Section Heading
8.5.1	Indication of State				Section Heading
	If the INTERNAL ELECTRICAL POWER SOURCE is essential to maintain BASIC SAFETY or to maintain ESSENTIAL PERFORMANCE or control the RISKS associated with the loss of ESSENTIAL PERFORMANCE, the ME EQUIPMENT shall be equipped with a means for the OPERATOR to determine the state of the INTERNAL ELECTRICAL POWER SOURCE. The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated as: – a number of PROCEDURES remaining; – the remaining operating time; – the percentage of the remaining operating time or energy; or a "fuel" gauge.	Yes			

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	The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated continuously or by OPERATOR action.	Yes			
	The instructions for use shall describe how to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.	Yes			
8.5.2	Accessibility of small INTERNAL ELECTRICAL POWER SOURCEs				Section Heading
	Means other than labelling shall be provided to prevent the RISK of swallowing coin/button cells. A replaceable button cell shall require the use of a TOOL for replacement.	N/A			(b)(4)
8.5.3	Additional requirements for separation of parts				Section Heading
	In addition to the requirements of 8.5 of the general standard for ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE, if: – simultaneous connection of the ME EQUIPMENT to the PATIENT during INTENDED USE and to an SUPPLY MAINS is possible, then – APPLIED PARTS and parts that likely come in contact with the PATIENT, according to 4.6 of the general standard, shall have two MOPP from the SUPPLY MAINS.	Yes			(b)(4)
	However, parts, which the PATIENT intentionally handles as the intended OPERATOR according to 7.9.2.1 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:— (e.g. touch keys, ENCLOSURE) while the ME EQUIPMENT is not being used for its intended medical function, may be insulated with two MOOP from SUPPLY MAINS.	Yes			
9	**Accuracy of controls and instruments and protection against hazardous outputs**				
	In addition to the requirements of 12.2 of the general standard, when performing the USABILITY ENGINEERING PROCESS, the RISKS associated with USABILITY in the HOME HEALTHCARE ENVIRONMENT for OPERATOR PROFILES including a LAY OPERATOR shall include consideration of at least:				Informative for requirement

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	– changes of controls; – unexpected movement; – potential for misconnection; – potential for improper operation, or unsafe use; – potential for confusion as to current operational mode; – change in the transfer of energy or substance; – exposure to environmental conditions specified in this standard; – exposure to biological materials; and – small parts being inhaled or swallowed.	Yes			
	Particular emphasis shall be placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE. The MANUFACTURER shall include the least capable intended LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION in the USABILITY ENGINEERING PROCESS. EXAMPLES LAY OPERATORS with sensory, cognitive, physical limitations or comorbidities.	Yes			
10	**Construction of ME EQUIPMENT**				
10.1	Additional requirements for mechanical strength				Section Heading
10.1.1	General requirements for mechanical strength				Section Heading
	Additions to the mechanical strength applicability of Table 28 of the general standard are indicated in Table 1 and Table 2. Attachment 1	Yes			
10.1.2	Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT				Section Heading
	In addition to the requirements of 15.3 of the general standard, ME EQUIPMENT and its parts, including mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling. FIXED and STATIONARY ME EQUIPMENT are exempt from the requirements of this subclause.	N/A			No mounting accessories are required or used

	After the following tests, ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE. OPERATOR-resettable protective devices that can be reset without the use of a TOOL may be reset prior to the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE.				Shock and vibration testing performed by (b)(4) and SmartCardia, 022_Performance Testing – Bench
	a) Shock test in accordance with IEC 60068-2-27:2008, using the following conditions: NOTE 1 This represents Class 7M1 as described in IEC TR 60721-4-7:2001 [7]. *– peak acceleration: 150 m/s2 (15 g);* – duration: 11 ms; *– pulse shape: half-sine;* – number of shocks: 3 shocks per direction per axis (18 total).	Yes			
	b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions: NOTE 2 This represents Class 7M1 and 7M2 as described in IEC TR 60721-4-7:2001. – acceleration amplitude: *• 10 Hz to 100 Hz: 1,0 (m/s2)2/Hz;* *• 100 Hz to 200 Hz: – 3 db per octave;* *• 200 Hz to 2 000 Hz: 0,5 (m/s2)2/Hz;* *– duration: 30 min per perpendicular axis (3 total).*	Yes			
10.1.3	Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT				Section Heading
	In addition to the requirements of 15.3 of the general standard, ME EQUIPMENT and its parts, including mounting ACCESSORIES, intended for TRANSIT-OPERABLE use, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping, and rough handling and by rigorous conditions of PATIENT movement as well as transportation by trolleys, carts, road vehicles, trains, ships and aircraft.				
	a) For other than HAND-HELD ME EQUIPMENT and its parts, including	Yes			

	mounting ACCESSORIES, shock test in accordance with IEC 60068-2-27:2008, using the following conditions: NOTE 3 This represents Class 7M2 as described in IEC TR 60721-4-7:2001 [7]. *1) test type: Type 1;* *– peak acceleration: 150 m/s2 (15 g),* – duration: 11 ms, *– pulse shape: half-sine,* – number of shocks: 3 shocks per direction per axis (18 total); ***OR*** *2) test type: Type 2;* *– peak acceleration: 300 m/s2 (30 g),* *– duration: 6 ms,* *– pulse shape: half-sine,* – number of shocks: 3 shocks per direction per axis (18 total).				
	b) For HAND-HELD ME EQUIPMENT and its parts, including mounting ACCESSORIES, shock test in accordance with IEC 60068-2-27:2008, using the following conditions: NOTE 4 This represents Class 7M3 as described in IEC TR 60721-4-7:2001. *1) test type: Type 1;* *– peak acceleration: 300 m/s2 (30 g),* *– duration: 11 ms,* *– pulse shape: half-sine,* *– number of shocks: 3 shocks per direction per axis (18 total);* **OR** *2) test type: Type 2;* *– peak acceleration: 1 000 m/s2 (100 g),* *– duration: 6 ms,* *– pulse shape: half-sine,* – number of shocks: 3 shocks per direction per axis (18 total).	Yes			
	c) For ME EQUIPMENT and its parts, including mounting ACCESSORIES, broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:	Yes			

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	NOTE 5 This represents Class 7M1 and 7M2 as described in IEC TR 60721-4-7:2001. • acceleration amplitude: *– 10 Hz to 100 Hz: 1,0 (m/s2)2/Hz,* *– 100 Hz to 200 Hz: -3 db per octave,* *– 200 Hz to 2 000 Hz: 0,5 (m/s2)2/Hz,* *• duration: 30 min per perpendicular axis (3 total).*				
	• d) For PORTABLE and MOBILE ME EQUIPMENT and its parts, including mounting ACCESSORIES, free fall to IEC 60068-2-31:2008, using PROCEDURE 1 and the following conditions: NOTE 6 This represents Class 7M2 as described in IEC TR 60721-4-7:2001. • fall height: *– for mass ≤ 1 kg, 0,25 m,* *– for mass > 1 kg and ≤ 10 kg, 0,1 m,* *– for mass > 10 kg and ≤ 50 kg, 0,05 m,* *– for mass > 50 kg, 0,01 m,* • number of falls: 2 in each specified attitude. *For PORTABLE ME EQUIPMENT that is intended to be used only with a carrying case, that case may be applied to the equipment during this test.*	Yes			
10.2	Additional requirements for actuating parts of controls of ME EQUIPMENT				Section Heading
	In addition to the requirements of 15.4.6.2 of the general standard for ME EQUIPMENT that is intended for use by a LAY OPERATOR, controls that can affect BASIC SAFETY or ESSENTIAL PERFORMANCE shall be protected from accidental or unauthorized changes or adjustments.	Yes			
11	**Protection against strangulation or asphyxiation**				
	Means shall be provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level. EXAMPLE 1 By routing wires or tubing. EXAMPLE 2 Using retention devices. EXAMPLE 3 Providing the option of multiple length ACCESSORIES.	N/A			**(b)(4)**
	EXAMPLE 4 Not providing removable small parts for ME EQUIPMENT.				
12	**Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS**				

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	In addition to the requirements of 7.1.1 of IEC 60601-1-2:2014, ME EQUIPMENT and ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT shall be classified as Class B according to CISPR 11:2009. NOTE Use in the HOME HEALTHCARE ENVIRONMENT includes use 'in domestic establishments'.	Yes			
13	**Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS**				
13.1	Additional requirement for generation of ALARM SIGNALS				Section Heading
	In addition to the requirements of 6.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/ AMD1:2012 for the ALARM SYSTEM of ME EQUIPMENT and ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT, unless they are connected to a DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS (6.11.2.2.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) that includes the generation of auditory ALARM SIGNALS as specified in IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION shall cause the generation of auditory or verbal ALARM SIGNALS as specified in IEC 60601-1-8:2006 and IEC 60601-1-8:2006/ AMD1:2012.	N/A			(b)(4)
13.2	Additional requirement for ALARM SIGNAL volume				Section Heading
	In addition to the requirements of 6.3.3.3 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 for the ALARM SYSTEM of ME EQUIPMENT and ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT and intended for the HOME HEALTHCARE ENVIRONMENT, reducing the auditory ALARM SIGNAL volume below audible levels shall not be possible unless the ALARM SYSTEM is connected to a DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS (6.11.2.2.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) that includes the generation of auditory ALARM SIGNALS as specified in IEC 60601-1-8:2006+IEC 60601-1-8:2006/AMD1:2012. NOTE Guidance on suitable auditory ALARM SIGNAL volumes is found in the rationale IEC 60601-1-8:2006.	N/A			Not intended to actively keep alive or resuscitate a patient

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Attachment 1

Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE

ME EQUIPMENT usage and type	Test from the general standard	Test from this standard
(b)(4)		

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Software Design Specifications

(b)(4) Software Internal Design, Physiologic Parameters

(b)(4) Software Internal Design, Mobile Application

(b)(4) Software Internal Design, Server Backend / Frontend

(b)(4) Software Internal Design, SCMarkTool with arrhythmia analysis

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(b)(4) Software Internal Design, Physiologic Parameters

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(b)(4) Software Internal Design, Mobile Application

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(b)(4) Software Internal Design, Server Backend / Frontend

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(b)(4) Software Internal Design, SCMarkTool with Arrhythmia Analysis

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General Summary of Submission/Executive Summary

Device Description

(b)(4)

The SmartCardia 7L Platform has the following characteristics:

a. It is non-invasive and has no significant safety issues
b. It uses electrode and ECG technology that is the same as that of the predicate device K192757,
c. It includes additional monitoring of a patient's skin temperature, and
d. It is used in conjunction with other symptoms and tests to aid the physician in the diagnosis or monitoring of patients with cardiac arrhythmia.

The SmartCardia 7L Platform provides monitoring of physiological vital signs and includes automatic notifications if the vital sign for heart rate value exceeds pre-set alarm limit settings. In addition, the SmartCardia 7L Platform performs analysis and automatic notifications for Atrial Fibrillation. The

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analysis is done on one of the ECG channels. The clinician can set criteria for notifications via email for atrial fibrillation new onset, high heart rate atrial fibrillation, bradycardia new onset, pause, and tachycardia new onset in the analysis component on the back end server. These events do not provide alarm notifications in real-time, but the clinician can enable notifications to be sent via email and mark the event in the database for review and take appropriate action. Ventricular tachycardia and ventricular fibrillation events also do not automatically provide alarm notifications and these events must be reviewed by the clinician or technician who must then take appropriate action after verification. These are not real-time analysis or alarm notifications. They must be reviewed and accepted or rejected by the clinician for inclusion in the patients Holter report.

The SmartCardia 7L Patch, like the name indicates, is an adhesive patch that is placed on the patient's chest. The 7L Patch contains four electrodes to measure ECG. The four electrodes transmit three independent vectors of ECG. From these three vectors, the system displays up to 7 channels of electrocardiogram that are labeled as Leads A, B, C, D, E, F, and G. The patch and electrode identifications along with the channels of ECG presented are shown in Figures 1 and 2.

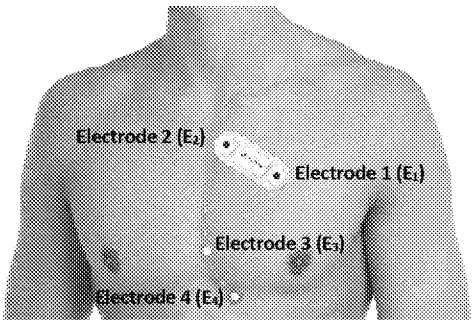

Figure 1 ECG Electrode Identification

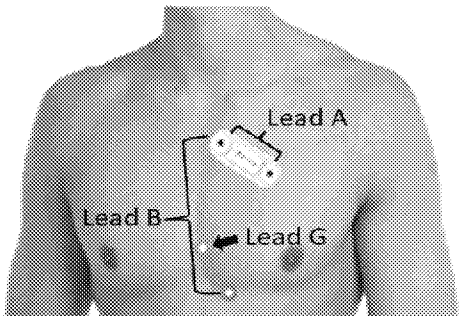

Figure 2 ECG channels transmitted

ECG Leads Available for Analysis and Display

Lead A = E_1 - E_2

Lead B = E_4 - E_2

Lead C = ECG A - ECG B

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$$\text{Lead D} = \frac{\text{ECG A} - \text{ECG C}}{2}$$

$$\text{Lead E} = \frac{\text{ECG A} + \text{ECG B}}{2}$$

$$\text{Lead F} = \frac{\text{ECG B} + \text{ECG C}}{2}$$

$$\text{Lead G} = E_3 - \frac{(\text{ECG A} + \text{ECG B} + \text{ECG C})}{3}$$

As shown in the above figures, the 7L Patch with 7L Sensor contains the ECG electrodes, the sensor for skin temperature, and the wireless BLE component. Skin temperature is done via an infrared sensor.

Analysis is performed on ECG Lead A only.

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Intended Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.

2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation).

3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).

4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.

5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports. Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.

2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

Patient or Clinician User Interaction

Patient interaction consists of the following:

1) A clinician or healthcare professional applies the 7L Sensor to the patient's chest. This may be done by the patient as well, without clinician supervision,
2) The clinician or healthcare professional admits the patient to the SmartCardia application which couples the sensor, phone, and patient identification. The service begins when the patient correctly identifies their name on the SmartCardia phone and correctly enters their date of birth (patient name and date of birth provide authentication). They also set up or verify the account (with proper patient information) with the SmartCardia backend server for remote monitoring.
3) The patient can enter an event by pressing a button on the 7L Sensor or on the SmartCardia Phone to tag the event for review. This will present a list of symptoms to attach to the event,
4) The patient may be directed to replace the disposable 7L Patch if needed during monitoring (example. Low battery indicated during longer term monitoring),
5) The patient is directed to remove the 7L Sensor component after remote monitoring is no

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longer needed

6) The patient may be directed to send the 7L Sensor and the SmartCardia Phone to the physician, or the patient may be directed to return to the physician location for return of the 7L Sensor and SmartCardia Phone.

Variants

The SmartCardia 7L Platform (part number (b)(4) is offered in a single variant that includes the following components:

(b)(4)

*The 7L Patch is a disposable single-patient-use accessory that can be provided separately and contains the batteries for the system. It may require replacement if longer term monitoring is required.

Accessories

The SmartCardia 7L Platform has the following accessories:

(b)(4) 7L Patch, an adhesive chest patch with 4 electrodes

Labeling Accessories:
PL-08, SmartCardia 7L Instructions for use – Patient
PL-09, SmartCardia 7L Instructions for use – Clinician
PL-10, SmartCardia 7L Quick Start Guide – Clinician
PL-17, SmartCardia 7L Technical Manual

Device Background

The SmartCardia 7L Platform has been created as a wearable wireless physiological monitoring system to continuously stream ECG data in near real time. Data are transmitted from ECG sensors via Bluetooth Low Energy (BLE) to a mobile phone (Android operating system) which in turn communicates this data to the SmartCardia backend. The SmartCardia 7L Platform is the second generation of the SmartCardia platform and has been re-designed to improve physiological monitoring performance, enhance the ergonomic design for comfort, and provide increased functionality.

There are no changes to the patient contact materials.

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Substantial Equivalence Comparison Technological Characteristics Table Attachment

Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
Indications for Use	The VitalConnect Platform is a wireless remote monitoring system intended for use by healthcare professionals for continuous collection of physiological data in home and healthcare settings. This can include heart rate, electrocardiography (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, skin temperature, activity (including step count), and posture (body position relative to gravity including fall). Data are transmitted wirelessly from the VitalConnect Sensor for storage and analysis. The VitalConnect Platform can include the ability to notify healthcare professionals when physiological data fall	MoMe® Kardia is intended to be used for: 1.Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2.Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation) 3.Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath) 4.Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring. 5.ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.	The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for: 1. Patients who experience transient symptoms that may suggest cardiac arrhythmia. 2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g. atrial fibrillation). 3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath). 4. Patients recovering from cardiac surgery or	The indications for use of the predicate and predicate/reference devices are substantially equivalent to the SmartCardia SA 7L Platform.

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Characteristic	Predicate Device VitalConnect Biosensor (K192757)	Predicate/Reference MoMe Kardia (K160064)	SmartCardia 7L Platform	Discussion of Major Differences
	outside selected parameters. The device is intended for use on general care patients who are 18 years of age or older as a general patient monitor, to provide physiological information. The data from the VitalConnect Platform are intended for use by healthcare professionals as an aid to diagnosis and treatment. VitalPatch device can be used on patients with pacemakers that comply with ISO 14117:2012 and ANSI/AAMI PC69:2000 without deviations. Heart rate, electrocardiography (ECG), heart rate variability, R-R interval, and respiratory rate are not intended for patients with pacemakers. The device is not intended for use on critical care patients.	MoMe® Kardia is contraindicated for: 1. MoMe® Kardia is contraindicated for those patients requiring attended, in-hospital monitoring for life threatening arrhythmias. Note: MoMe® Kardia does not provide interpretive statements. Interpretation and diagnosis is the responsibility of a physician.	interventional procedures who are indicated for outpatient arrhythmia monitoring. 5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports Measurements include: electrocardiogram (ECG signal), R-R interval, Heart Rate. Notification alerts can be set for one or more of these measures. The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home. SmartCardia 7L Platform contraindications: 1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening	

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
			conditions such as lethal arrhythmias is required. 2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation. 2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.	
Intended Use	For monitoring and collection of physiological data in home and healthcare settings for patients 18 years or older and can include a notification of vital sign data outside selected parameters	For monitoring of physiological data in home and healthcare settings, for ECG reporting and arrhythmia detection in patients with non-life-threatening arrhythmias	For monitoring and collection of physiological data in home and healthcare settings, for patients 18 years or older and can include notification of vital sign data outside selected parameters; and for ECG reporting and arrhythmia detection in patients with non-life-threatening arrhythmias	Same
Number of ECG electrodes	2 electrodes, single lead ECG	3 electrodes	4 electrodes	Using multiple electrodes and deriving additional ECG vectors provides additional information for the clinician. This does not affect safety or effectiveness.

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
Number of channels transmitted	1 channel	2 channels	3 channels	Same.
Parameters Monitored	Heart rate, electrocardiogram (ECG), heart rate variability, R-R interval, respiratory rate, body temperature, activity (including step count), and posture (body position relative to gravity including fall)	Heart rate, electrocardiogram (ECG)	Heart Rate, electrocardiogram (ECG signal),	Same as predicate /reference device
Heart Rate Accuracy	<±5 or 10% Beats per Minute, whichever is greater	Not available	± 3 BPM	Same
Function in the presence of Pacemaker Pulse	No, Heart Rate values (including heart rate variability and R-R interval) is not available for patients with pacemakers	Yes	Yes	Same as predicate/reference device
Analysis Channels	1	1	1	Same
Arrhythmia detection	Proprietary, Located on Server	Proprietary, Located on Server	Proprietary, Located on Server	Same
Arrhythmia Types Detected	Atrial Fibrillation, Pause, Sinus Arrhythmia, Sinus Bradycardia, Sinus Tachycardia, Supraventricular Tachycardia, 2nd Degree	Atrial Fibrillation, Atrial Fibrillation (new onset and High HR AFib), Pause, Bradycardia (low heart rate), Tachycardia (high heart rate), 2nd Degree AV Block, Complete Heart Block,	Atrial Fibrillation, Bradycardia, Tachycardia, Pauses, Presence of VEB, Ventricular Couplets, Ventricular Short Runs, Ventricular Long Runs,	Same. The SmartCardia 7L Platform detects the same arrhythmia types and does detect non-life-threatening arrhythmia in the same

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
	AV Block, Ventricular Bigeminy, Ventricular Trigeminy, Prolonged PR, Wide QRS, Prolonged QT Interval	Ventricular Fibrillation, Ventricular Tachycardia	Ventricular Tachycardia, Presence of SVEB, Supraventricular Couplets, Supraventricular Short Runs, Supraventricular Long runs, Ventricular / Supraventricular Bigeminy / Trigeminy.	manner as the predicate/reference devices. Heart Rate and Atrial Fibrillation are real-time notifications which is the same as the VitalConnect Platform. All other arrhythmias are detected and triggered as an event in the stored retrospective Holter data for later verification and report compilation.
Battery Type	Disposable zinc air	Li Ion Rechargeable	Disposable Manganese Oxide-lithium	Substantially equivalent.
Data Acquisition	Body worn sensor plus VistaTablet gateway	Body worn sensor / transmitter (MoMe) with cellular communication gateway included	Body worn sensor plus SmartCardia Phone gateway	Same
Data Transmission	BLE to VistaTablet, WiFi to cloud server	Cellular from MoMe to cloud server	BLE to phone, Cellular or WiFi to cloud server	Same
User Event Trigger	Yes, push button on sensor	Yes, push button on sensor	Yes, event button on phone	Same
Use Environment	Physician practice, clinics, healthcare settings, sensor use in home	Physician practice, clinics, healthcare settings, sensor use in home	Physician practice, clinics, healthcare settings, sensor use in home	Same
Data Storage and Report Generation Environment	Remote cloud based	Remote cloud based	Remote cloud based	Same
Prescription Use	Yes	Yes	Yes	Same

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Characteristic	Predicate Device	Predicate/Reference	SmartCardia 7L Platform	Discussion of Major Differences
	VitalConnect Biosensor (K192757)	MoMe Kardia (K160064)		
Clinician access to patient data	Yes	Yes	Yes	Same
Operating	Temperature: 10 – 40 ^{0}C	Temperature: 5 – 40 ^{0}C	Temperature: Operating: +5	Similar, operating
(b)(4)				
Water Ingress	Waterproof with adhesive overlay	Not Available	Waterproof – tested to IPX7	Same
Defibrillator Protection	Yes	No	No. Passes energy reduction test	Similar to predicate
Electrode type	Hydrogel	Not Available	Hydrogel	Same
Patch Adhesive	Hydrocolloid	Not Available	Hydrocolloid	Same

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022_Performance Testing - Bench

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SmartCardia
EPFL Innovation Park
Building
1015, Lausanne, Switzerland
contact@smartcardia.com

May 1, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation Document
Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Notification

Dear Sir or Madam:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act and 21 CFR §807, SmartCardia SA, hereby submits this 510(k) Premarket Notification for the ***SmartCardia 7L Platform***. This 510(k) is submitted to obtain clearance from FDA to commercially distribute this device.

(b)(4)

Attachment 1 to this cover letter is the Administrative Information content recommended by Appendix A of the FDA guidance document "*Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, 13 September 2019*".

This submission is provided as an electronic eSTAR copy.

SmartCardia trusts the contents of this submission completes the requirements for the 510(k) and looks forward to a favorable response from FDA. If any additional information is required, please contact the Application Correspondent, Mr. Robert Steurer, directly at (425) 358-1072, or via email at steurerbob@gmail.com.

Kindest regards,

(b)(6)

Srinivasan Murali, CEO
SmartCardia SA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Attachment 1: Administrative Information

Confidentiality:	SmartCardia SA considers the existence of this submittal confidential
Type of submission:	**Traditional 510(k)**
Submitter Correspondent:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland Mr. Srinivasan Murali Phone: +41 7887 50864 Email: srinivasan.murali@smartcardia.com
Application Correspondent:	Steurer Consulting Group 800 Blue Quail Rd Keller, TX 76248 Mr. Robert Steurer Phone: (425) 358-1072 Email: steurerbob@gmail.com
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Common Name:	SmartCardia 7LPlatform
Primary Classification Regulation:	21 CFR ¶870.2910
Primary Product Code:	DRG
Secondary Classification Regulation:	(b)(4)
Secondary Product Code:	DSI
Secondary Classification Name:	(b)(4)
Product Class:	Class II
Classification Panel:	Cardiovascular Devices (OHT2)
Predicate Device	VitalConnect Biosensor (K192757)
Predicate/Reference Device	InfoBionic MoMe Kardia (K60064)

Basis for Submission:

Submission:	New Device
Prior FDA Documents:	(b)(4)

Design and Use of the Device:

Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	No
Is the device intended for single use?	No
If yes, does this device type require reprocessed validation data?	No
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	Yes
Does the submission include clinical information?	No
Is the device implanted?	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2: Pre-Submission Correspondence & Previous Regulator Interaction

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0511 Expiration Date: October 31, 2024. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

SmartCardia SA
Building C
EPFL Innovation Park
Lausanne
CH
1015
CH

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Srinivasan Murali
2.1 E-MAIL ADDRESS
srinivasan.murali@smartcardia.com
2.2 TELEPHONE NUMBER (include Area code)
7887-50864
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: (b)(4)

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

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the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 01-May-2023

Form FDA 3601 (07/22)

"Close Window" Print Cover sheet

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2564
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4584

Premarket Notification 510(k) Review

Post-Review Reminders

- ☐ Final Check: Ensure your documentation accurately reflects the final recommendation prior to signature (e.g., Review Summary, data in the Device Description section, the Labeling section, etc)
- ☐ Complete CTS: Procode, Clinical Trials, Combo Product, MR compatibility
- ☐ Ensure the content of the 510(k) Summary is accurate (N/A if a 510(k) Statement was provided instead).
- ☐ For SE Decisions: Upload SE Letter, and PDFs of IFU form and 510(k) Summary (if included) in DocMan.

To add reminders, type the reminder in the text field to the left then press the Tab key.

Date: June 29, 2023

Reviewer: Vincent Do

510(k)# K231276 Subject: Traditional

Applicant: SmartCardia SA	**Device Trade Name:** SmartCardia 7L Platform
Contact Name: Robert Steurer	**Contact Title:** Consultant
Correspondent Firm: Steurer Consulting Group LLC	**Phone:** (425) 358-1072 **Email:** steurerbob@gmail.com
Received Date: May 2, 2023	**Due Date:** August 1, 2023
Pro Code(s): DRG **Class:** II **Reg #:** 870.2910	**Reg Name:** Radiofrequency Physiological Signal Transmitter And Receiver
Pro Code(s): DSI Class: II Reg #: 870.1025	Reg Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192757	DRG, DSI, MHX	VitalPatch 5D Biosensor - single, VitalPatch 7D Biosensor - single, VitalPatch 5D Biosensor – bag of 20, VitalPatch 7D Biosensor – bag of 20	VitalConnect, Inc.
K160064	DSI	MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System	Infobionic, Inc.

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.16.00)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
For each of the specific issues identified in the recommended requests to the applicant above, I and/or if applicable contributing consulting reviewer(s) (and or supervisors), have provided a statement of basis for the request(s); and either cited as part of it an available, applicable, and relevant final rule, statute, final guidance, or FDA-recognized consensus standard, or confirmed to the best of my ability for requests: 8-12 and 1, 2, 4 in minor deficiencies that there is no final rule, statute, final guidance, or FDA-recognized consensus standard available, applicable, and relevant to the request(s). I also confirm, if applicable, that contributing consulting reviewers (and or supervisors) have provided the above attestation.	
Reviewer Sign-Off	Vincent N. Do -S Digitally signed by Vincent N. Do -S Date: 2023.06.29 14:40:49 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: steurerbob@gmail.com <steurerbob@gmail.com>

Sent: Monday, August 28, 2023 6:19 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov>

Cc: 'Srini Murali' <srinivasan.murali@smartcardia.com>; 'Francisco Rincon' <francisco.rincon@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; 'James Welch' <jwelch@arcbiomed.com>

Subject: RE: [EXTERNAL] Interactive Response 3

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Thank you for your response. This time is OK but I haven't heard from the team in Switzerland but those of us in the US are available. Go ahead and schedule and send us the invite. I will let you know if there are any issues.

Best Regards,

Bob Steurer

[cid:image001.png@01D9D9D3.B1F412F0]Steurer Consulting Group

http://www.scgconsulting.net<http://secure-web.cisco.com/1ALNwxB0hu_d3rTIdT5BRo2eStaHKnNJKtOO-EaE5G-VyrK7W9nKy6sCS4rl6FzWDozELRLhb37ZcAtOhdTpKhXbN9D4w6wqKKPnMY-onI4niHd7GmjEsgCYkVbU4ZmNdJehxcAt4ITrG9AM6-k2a-SHL0I8oO3IPRMI17_6AHFba912KJkKiRXh-i55kef5GE3sWUJVg9kL7mwRnH5Exlg/http%3A%2F%2Fwww.scgconsulting.net%2F>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Monday, August 28, 2023 5:09 PM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Cc: Srini Murali <srinivasan.murali@smartcardia.com<mailto:srinivasan.murali@smartcardia.com>>; Francisco Rincon <francisco.rincon@smartcardia.com<mailto:francisco.rincon@smartcardia.com>>; 'Brodie Pedersen' <brodiecp@borderlessmd.com<mailto:brodiecp@borderlessmd.com>>; James Welch <jwelch@arcbiomed.com<mailto:jwelch@arcbiomed.com>>

Subject: RE: [EXTERNAL] Interactive Response 3

Hi Bob,

Thank you so much for your email. (b)(4) (b)(4) (b)(4) I found a potential slot to hold a teleconference with you and your team tomorrow (I have sent out invites to the review team and have not received confirmation yet, but it should be okay). I will keep you and your team updated. Please check if the following date/time is okay with your team:

* Tuesday 08/29/2023 at 1PM E.T.

Please let me know if there is anything.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Thank you,

Vincent

From: steurerbob@gmail.com<mailto:steurerbob@gmail.com>
<steurerbob@gmail.com<mailto:steurerbob@gmail.com>>

Sent: Monday, August 28, 2023 2:57 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Cc: Srini Murali
<srinivasan.murali@smartcardia.com<mailto:srinivasan.murali@smartcardia.com>>;
Francisco Rincon
<francisco.rincon@smartcardia.com<mailto:francisco.rincon@smartcardia.com>>; 'Brodie
Pedersen' <brodiecp@borderlessmd.com<mailto:brodiecp@borderlessmd.com>>; James Welch
<jwelch@arcbiomed.com<mailto:jwelch@arcbiomed.com>>

Subject: [EXTERNAL] Interactive Response 3

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Attached is the SmartCardia response to Interactive Request 3 you sent on Friday, August 25, 2023, along with the updated IFUs.

FDA Request: After reviewing the information provided, we have the following comment:

(b)(4)

If you need anything else, please don't hesitate to contact me.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Best Regards,

Bob Steurer

[cid:image001.png@01D9D9D3.B1F412F0]Steurer Consulting Group

http://www.scgconsulting.net<http://secure-web.cisco.com/1ALNwxB0hu_d3rTIdT5BRo2eStaHKnNJKtOO-EaE5G-VyrK7W9nKy6sCS4rl6FzWDozELRLhb37ZcAtOhdTpKhXbN9D4w6wqKKPnMY-onI4niHd7GmjEsgCYkVbU4ZmNdJehxcAt4ITrG9AM6-k2a-SHL0I8oO3IPRMI17_6AHFba912KJkKiRXh-i55kef5GE3sWUJVg9kL7mwRnH5Exlg/http%3A%2F%2Fwww.scgconsulting.net%2F>

m: +1 425-358-1072

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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013_Instructions for Use K231276_ (b)(4)

- PL-08 SmartCardia 7L Patient Guide
- PL-09 SmartCardia 7L Clinician User Guide
- PL-10 SmartCardia 7L Clinician QRG
- PL-17 SmartCardia 7L Platform Technical Manual

Questions? Contact FDA/CDRH/OCE/DIP at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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· PL-08 SmartCardia 7L Patient Guide

Questions? Contact FOIA_CDRH_HQ_EDM at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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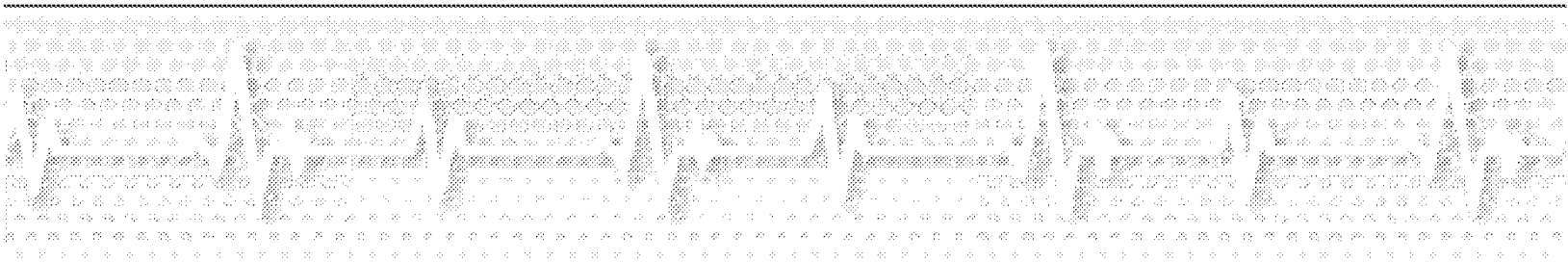

SmartCardia 7L™ – Patient Guide

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Welcome!

Your doctor has prescribed this device so they can remotely view your vital signs.

We are here to help you.

So feel free to give us a call anytime at 800-363-8151.

SmartCardia 7L
monitoring the fabric of life®

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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About This Manual

This Patient Guide describes how to use the SmartCardia 7L™ Platform.
For more information about SmartCardia 7L, visit www.SmartCardia.com.

Safety Precautions

This manual contains safety precautions as shown below.

	WARNING
	Indicates a hazard or unsafe use that could cause death or serious injury.

	CAUTION
	Indicates a hazard or unsafe use that could cause minor injury or product damage.

Note	A note shows more information about using the product.

Note: *The information contained in this document is subject to change without notice.*

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Warnings and Cautions

WARNING

- **The SmartCardia 7L system is not an emergency response service. If you experience symptoms that are cause for concern, immediately seek medical help.**
- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**
- **If you have severe skin irritation or burning feeling, remove 7L Patch right away and contact your doctor.**
- **Do not use this device in an MRI**

CAUTION

- Do not try to service the SmartCardia 7L system. The SmartCardia 7L system is not field reparable and there are no replaceable components.
- Do not use in a hospital operating room.
- To avoid the risk of fire, do not use the SmartCardia 7L system around anything flammable. Do not try to take apart the *7L Patch* or *7L Sensor*.
- Do not try to change the battery in the *7L Patch*.
- Stay away from heavy electrical equipment or other sources of interference.
- The SmartCardia 7L system is used for adults over the age of 18 years.
- Take care if showering. Caution should always be taken when wearing in a wet location.
- Install and use the SmartCardia 7L system as instructed. Do not attempt to connect it to another piece of equipment.
- Only use the charger provided with the Phone.
- Place the *7L Sensor* and *7L Patch* on the body as instructed.
- Keep the SmartCardia *Phone* closer than 10 feet at all times.

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	• The SmartCardia 7L Platform should not be used in an aircraft.

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Intended Use/Indications for Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

Measurements include: electrocardiogram (ECG signal), R-R interval, and Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

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Getting Started

Product Description

The SmartCardia 7L Platform is used to monitor your heart using the SmartCardia *7L Sensor* and *7L Patch*. This is worn on the body and monitors and saves your vital signals and sends this data to your doctor using the SmartCardia *Phone*.

SmartCardia 7L Components

SmartCardia 7L Sensor (the *7L Sensor*)

A reusable Sensor **(do not throw away)**

- Inserts into the *7L Patch*
- Monitors ECG
- Sends your data to the SmartCardia *Phone*
- Is waterproof when used with the 7L Patch

SmartCardia 7L Patch (the *7L Patch*)

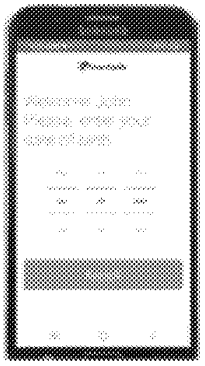
A single-use patch **(you can throw away)**

- Includes batteries
- Holds the reusable *7L Sensor*
- Sticks to your skin
- Expected shelf life up to 14 days

	WARNING
	The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.

SmartCardia Phone (the *Phone*)

Sends your data to the doctor



- Always keep it close to the SmartCardia *7L Sensor* (within 10 ft.)
- Charge daily (or more often)

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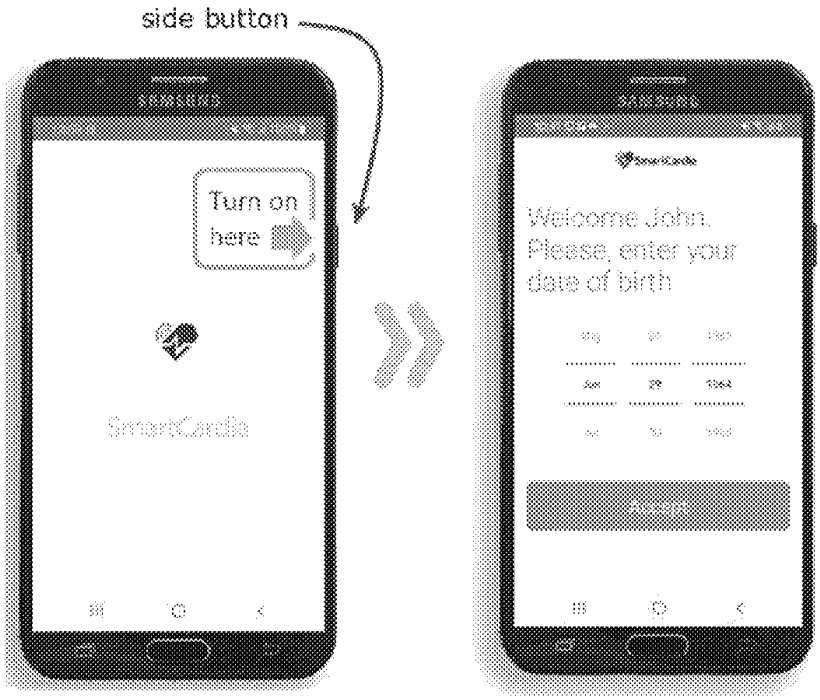
Start the Phone

Step 1
Push the side button on the *Phone* to turn on. (This may take several minutes) Swipe up to unlock *Phone*

Step 2
Enter your date of birth on the screen display.



Note: *You cannot make personal phone calls on this phone. This phone will not make calls or send emails. It is for SmartCardia use only.*

Note: *After you attach the 7L Patch, your heart rhythm will appear on the screen. See page 12 for more details.*

⚠	**CAUTION**
	Keep the SmartCardia *Phone* closer than 10 feet at all times.

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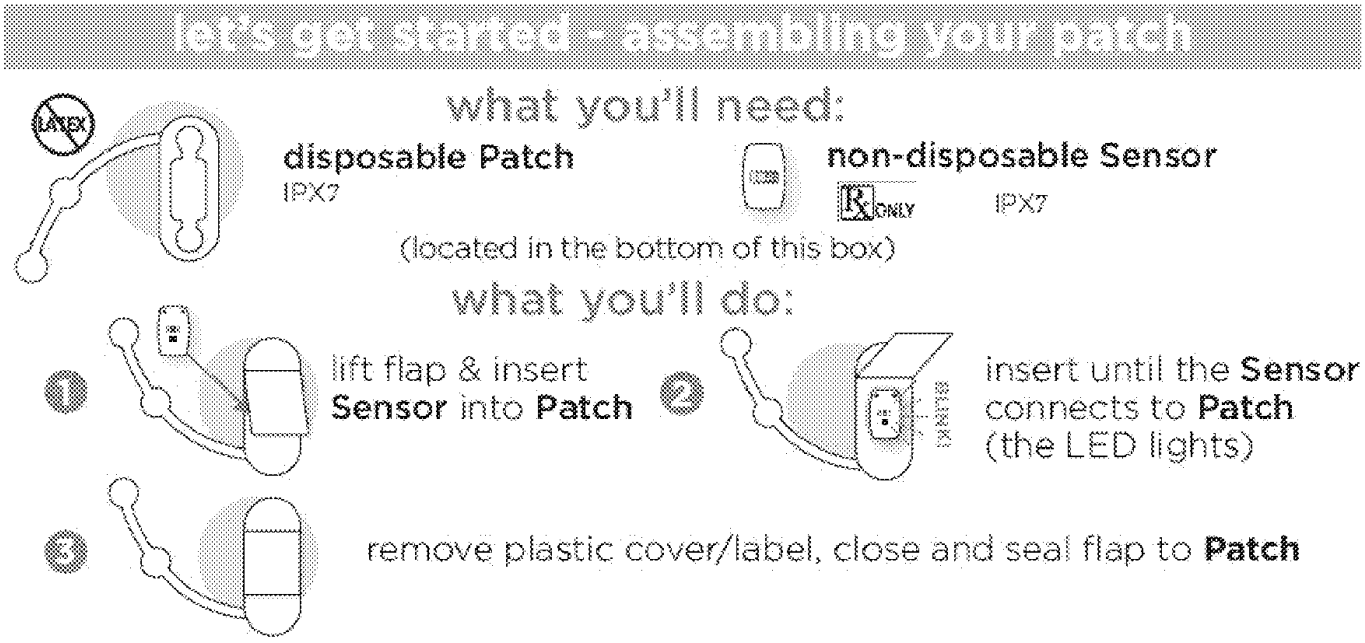
Attach Patch with Sensor

The *7L Patch* is placed on your skin to monitor your heart (shown in the diagrams below).

Step 1

The *7L Sensor* (**not disposable**) is inserted into the disposable *7L Patch*.

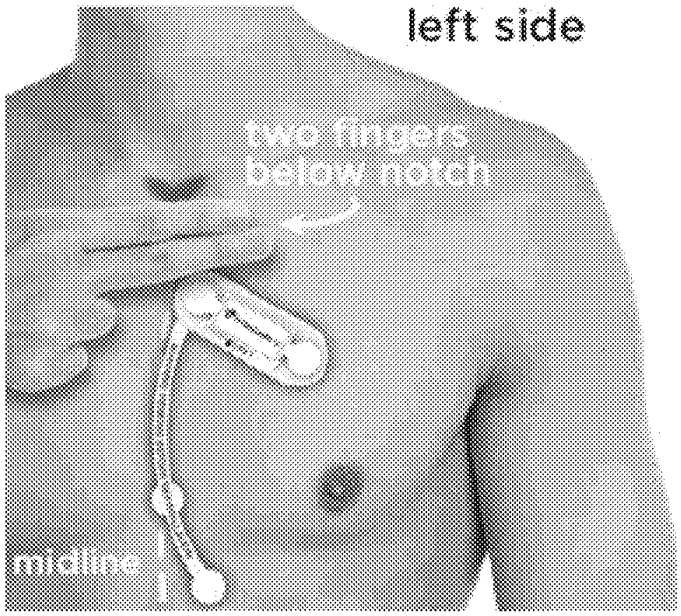
Note: *The 7L Sensor will fit into the 7L Patch in only one direction. Make sure to align the 'marks' on the 7L Sensor to those on the 7L Patch.*



Step 2

Clean and dry your skin before the *7L Patch* is placed on your body.

For men, chest hair should be shaved or clipped where the *7L Patch* will be placed.



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	WARNING **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**

	CAUTION The 7L Patch should be applied immediately after the pouch is opened. Dispose of the patch and do not use if the pouch has been opened before.

Note: *The 7L Patch should never be placed on injured areas of skin or on open wounds.*

Note: *Failure to prepare the skin area can make removal of the 7L Patch difficult.*

	WARNING **If you have severe skin irritation or burning feeling, remove *7L Patch* right away and contact your doctor.**

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Monitoring

Once finished you are free to go about your normal daily activities, unless told otherwise.

Note: *Once you start, do not remove the 7L Patch and 7L Sensor. It must be worn all the time, even when you sleep.*

- Your doctor will tell you how long you should wear the *7L Patch* and *7L Sensor*. You must change the patch if you have to wear the patch for longer than 14 days. Refer to page 15.
- When you are finished, you will return the *7L Sensor*, the *Phone*, and phone charger in the enclosed prepaid package.
- Your doctor will review your data.

IMPORTANT

- Always keep the SmartCardia *Phone* closer than 10 feet from you.
- You may shower.

Note: *The body worn system is waterproof, but the Phone is not.*

CAUTION

Do not get the SmartCardia *Phone* wet or in water.

CAUTION

If water seeps into the *7L Patch* or the *7L Patch* falls off, replace the *7L Patch*.

Note: *If the Patch peels or lifts at the edges, try to press, and hold along the edges to re-apply.*

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	CAUTION
	Continue to wear the *7L Patch* for the length of time prescribed by your doctor.

SmartCardia Phone

The *Phone* is used to:

- Send your data from the *7L Sensor*
- Mark events when you press the EVENT button
- Show your heart rate

Note: *The Phone is for use only with the SmartCardia 7L Platform. It will not work as a cell phone.*

Note: *Do not drop the Phone and always keep it in a dry and safe place.*

Note: *Do not worry if you are in an area where the Phone has no cell service. The 7L Sensor and 7L Patch saves the data. When cell service comes back, the saved data is sent to your doctor.*

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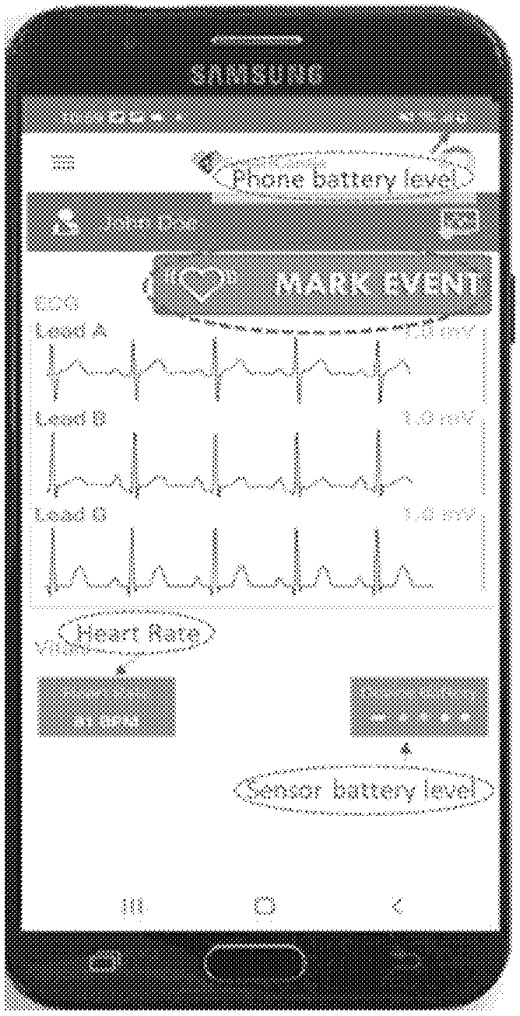
Phone Screen Display

The *Phone* allows you to see your data. When the *Phone* is turned on it shows:

- Your name
- Phone battery level (always keep charged)
- MARK EVENT button to press when you do not feel well
- Your ECG waveform
- Your heart rate
- The *7L Sensor* battery level (device battery)
  - The battery level of the *7L Sensor* is shown when it is connected to the *Phone*
  - The battery level is shown by four dots. When the dots are green that is the battery life remaining
  - A low battery level alert will be shown in red



Using the MARK EVENT Button on SmartCardia Phone

If you feel dizzy, short of breath, or have chest pain, press the MARK EVENT button, and select event duration then select what you are feeling.

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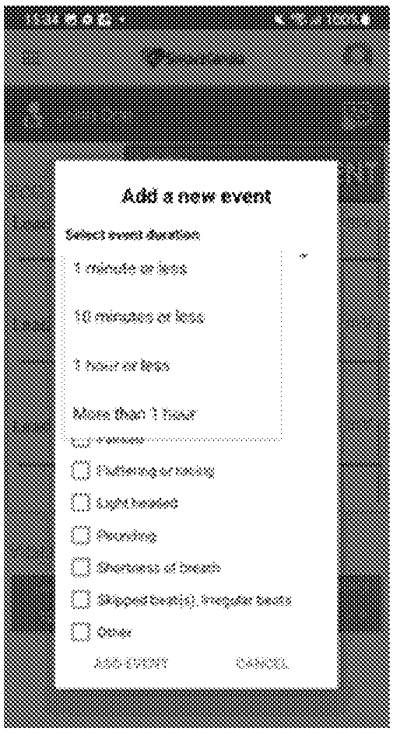

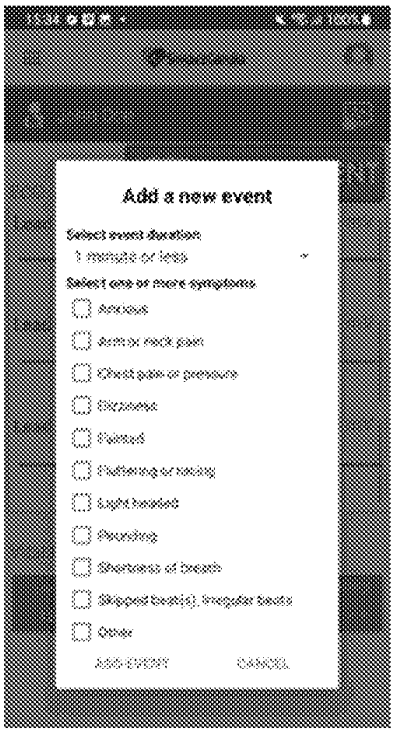

	WARNING
⚠	**The SmartCardia 7L Platform is not an emergency response system. If you experience a symptom that you feel is a medical emergency, call 911 immediately for emergency medical attention.**

Charging the *Phone*

The *Phone* must be charged all the time. It is best to do this every day when you are resting or sleeping.

When to Change the *7L Patch*

Do not remove the *7L Sensor* and *7L Patch* unless:

- The *7L Sensor* and *7L Patch* become damaged.
- Your skin under the *7L Sensor* and *7L Patch* has a rash.
- The *7L Sensor* and *7L Patch* begins to come off.
- You are told to do so by your doctor or caregiver.

How to Change the *7L Patch*

Step 1

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Carefully remove the *7L Sensor* and *7L Patch*. Use of baby oil to loosen the adhesive may make it easier to remove.

Step 2

Gently take out the *7L Sensor* from the *7L Patch.*

Get the new *7L Patch* and repeat the Set-Up Process (refer to pages 9/10).

Cleaning and Disinfecting the *7L Sensor*

Step 1

Clean the *7L Sensor* with warm water and dish soap using a cloth or sponge to remove surface dirt.

Step 2

Disinfect the *7L Sensor* with PDI Super Sani-Cloth® Germicidal Disposable Wipe for five minutes following the instructions on the package.

When You Are Finished

- Remove the *7L Sensor* and the *7L Patch* from your body.
- Take out the *7L Sensor* from inside the *7L Patch* and place it into the SmartCardia large pre-addressed shipping envelope for return.
- Place the *Phone* in the small envelope and put into larger pre-addressed shipping envelope along with the 7L Sensor, phone charger and cable for return.
- Discard the used *7L Patch*.

Note: *If you have difficulty removing the 7L Sensor from the 7L Patch, return both.*

Return to SmartCardia

- Seal pre-addressed shipping envelope tightly.
- Drop the shipping package off at the specified carrier shipping location.
- Document the tracking number from the carrier for your records.

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Troubleshooting

What to do if you get skin irritation

The *7L Patch* uses a medical adhesive that can be worn for a long time.

- Mild itching, irritation or rash on the skin may occur. This is normal and usually temporary.
- If you have severe itching or redness, contact your doctor.

WARNING

If you have severe skin irritation or burning feeling, remove *7L Patch* right away and contact your doctor.

Problem	What is the Cause	What to Do
7L Sensor will not go into *7L Patch*	*7L Sensor* is put in backward	• Check the instructions on the *7L Patch* for correct alignment • Make sure the connector (green side) on the *7L Sensor* is facing the *7L Patch* • Align the marks on the *7L Sensor* with the marks on the *7L Patch*
Phone will not turn ON	The *Phone* is out of battery	Plug in phone charger and check to see if phone is charging
ECG is not shown on *Phone*	• *7L Sensor* and *7L Patch* are not sending ECG to *Phone* • *Phone* is out of battery • *7L Sensor* and *7L Patch* are out of battery	• Make sure the *Phone* is closer than 10 feet from you at all times • Plug in the phone charger and check to see if it is charging • Check the battery level on the *Phone* and if it does not indicate“Device Battery” remaining, replace the *7L Patch* as instructed

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Warranty and Services

For help at any time, call 1-800-363-8151.

The *7L Sensor* requires no calibration.

In the event the *7L Sensor* is not working properly, use the troubleshooting steps outlined above. If the *7L Sensor* is still not working properly, contact SmartCardia SA for technical and service support by calling 1-800-363-8151 or email info@smartcardia.com.

SmartCardia SA warrants the *7L Sensor* hardware against defects in materials and workmanship when used normally per the *7L Sensor* instructions for a period of Two (2) Years from the date of original retail purchase by the end- user purchaser (“Warranty Period”).

SmartCardia does not warrant that the operation of the *7L Sensor* will be uninterrupted or error-free.

SmartCardia SA is not responsible for the damage arising from the failure to follow instructions relating to the *7L Sensor* device.

The *7L Patch* has a shelf life of Two (2) Years when handled properly and stored within its stated environmental conditions (see *Specifications*).

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Symbols Used

Symbol	Title of Symbol	Symbol Description
	Manufacturer	Shows who manufactured the product
	European Conformity	The product meets the standards for Medical Device in the European Union
	Batch code	Indicates the manufacturer's Lot code
	Catalog number	Indicates the manufacturer's catalogue number
	Serial number	Indicates the serial number of the medical device
	Non-sterile	The product is not sterile
	Do not use if package is damaged	Do not use if package has been damaged or opened
	Fragile, handle with care	Indicates you should handle the product with care
	Not made with natural rubber latex	There is no natural rubber latex in the product or its package
	Do not use in MRI	Do not use the product in a magnetic resonance imaging instrument
	Keep dry	The product needs to be kept dry
	Temperature limits	Indicates the high and low temperatures for storage and use
	Humidity limits	Indicates the high and low humidity for storage and operation
	Do not re-use	Product is for single use only and not to use on another patient
	Consult instructions for use	For more information, read the operation manual or instructions for use
	Caution or Warning	Consult the instructions for use of important warnings and cautions that are printed on the product
	Use-by-date	The date after which the product or accessories should not be used
	Crossed-off wheeled bin	The product contains electrical parts and must be disposed of properly, not into any bin, but must be placed in an electrical equipment bin
	Non-ionizing radiation	The product does radiate RF, but it is non-ionizing
	BF applied part	To identify a type BF applied part complying with IEC 60601-1

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Specifications

Physical and Environmental	
Size (approximate)	*7L Sensor*: 1.97 x 1.18 x .39 inch; (50 x 30 x 10 mm) *7L Patch* (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14 mm)
Weight (approximate)	*7L Sensor and 7L Patch*: Less than 3.52 oz. (100 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C) Operating: +41 to +104°F (+5 to + 45°C)
Humidity	0 to 90% at +41 to 95°F (+5 to +35°C) (non-condensing) / 70 – 106 kPa
Safety	Type BF
Water Ingress	IPX7 (Waterproof)
Battery Life	Up to 14 days depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993-5, ISO 10993-10, ISO 10993-12 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30-200	Beats per minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

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Unique Device Identifier(s)

7L Sensor 7640375610058
7L Patch 7640375610041

SmartCardia SA
EPFL Innovation Park, Building C 1015Lausanne, Switzerland
Customer Support: 800-363-8151

PL-08 SmartCardia 7L™ Platform – Patient Guide

Prescription Only

Consult Instructions for Use or User Manual

Type BF

See Warnings and Cautions

SmartCardia SA
EPFL Innovation Park,
Building C
1015 Lausanne, Switzerland

FCC

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:

1. These devices may not cause harmful interference, and
2. These devices must accept any interference received, including interference that may cause undesired operation.

FCC ID: XPYNINAAB30

Non-ionizing electromagnetic radiation

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SmartCardia 7L™
monitoring the fabric of life™

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EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

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· PL-09 SmartCardia 7L Clinician User Guide

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SmartCardia 7L Platform™
Clinician User Guide

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About SmartCardia

SmartCardia, SA is a Swiss medical device company that focuses on clinical quality data and validation. The company works with key opinion leaders across a variety of clinical fields; from cardiology, vascular medicine, sleep, and COPD to validate the unique insights our systems provide.

SmartCardia is an ISO 13485 certified medical device manufacturer that meets the strict quality control standards for our solutions. The company is also ISO 27001 certified for data security and privacy.

Through rigorous clinical testing and validation, the 7L Patch, cloud and software are CE-marked as a Class IIa medical device.

CE 2803 ISO 13485:2016 HTCert Health Technology Certification

This *Clinician User Guide* describes the features of this product, main structure, function, specifications, correct method for transportation, installation, usage, operation, repair, maintenance, and storage, as well as safety procedures to protect both the user and the equipment.

EPFL Innovation Park, Building C

1015 Lausanne, Switzerland

Email: contact@smartcardia.com

Customer Support (800) 363-8151

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About this User Guide

User Guide Use and Audience

This user guide is a key part of the SmartCardia 7L Platform™ and describes the use of the system.

This user guide is for use by clinical professionals. They should have the appropriate training to observe and interpret patients' heart condition and check for abnormalities of heart rate and arrhythmias. It is important for the clinician to recognize and respond appropriately to changes in patient's heart rate and any abnormal conditions in patients' heart rhythm. In addition, analysis and creation of reports is necessary to provide a complete and accurate record of time that patients are monitored. Using the SmartCardia 7L Platform should not replace using sound clinical judgment when monitoring patients.

User Guide Style

The following styles and naming are used in the user guide to emphasize text or indicate an action.

Bold	Important information
Italic	References the components of the SmartCardia 7L Platform
Bold italic	Used for emphasis
Bold red text	Most important information, used to bring attention to a warning or caution
Select	The word select means to choose and confirm
“ ”	Quotation marks indicates this is an option to select on the 7L Web Browser screen
NOTE	Provides additional helpful information

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SmartCardia 7L Platform Naming Convention

Component Name	Name	Part Number	Brief Description
SmartCardia 7L Sensor	*7L Sensor*	DS-36	Electronic unit collects ECG data
SmartCardia 7L Patch	*7L Patch*	DS-33	Connects to skin and holds and powers the *7L Sensor*
SmartCardia Phone	*Phone*	DS-39	Android phone configured in kiosk mode, uses cellular service to transmit ECG using the *7L Mobile Application* to Cloud, viewed on *7L Web Browser*
SmartCardia 7L Web Browser	*7L Web Browser*	DS-41	Chrome web browser for clinicians to manage ECG data

Illustrations and Names

This user guide uses illustrations to show examples. They may not include all possible configurations available in the SmartCardia 7L Platform.

Reference Materials

- PL-10 Clinician Quick Reference Guide (QRG)
- PL-13 Clinician training video
- PL-08 Patient User Guide
- SmartCardia Customer Support (800) 363-8151

Safety

Warnings and Cautions

To ensure safe use of the equipment, please read the following statements. This user guide contains safety precautions that are explained below.

	WARNING
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

	CAUTION
	Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

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WARNINGS:

- **The 7L Platform™ is not an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.**

CAUTIONS:

- The 7L Platform is used for adults over the age of 18 years.
- Install the 7L Platform and use as instructed. Do **not** attempt to connect it to another piece of equipment.
- Do **not** try to service the 7L Platform. It is **not** field repairable and there are no replaceable components.
- The 7L Platform is to be used by adequately trained personnel.
- Do not use with other devices, which have high-level electromagnetic radiation.
- The 7L Platform is not designated for use in the operating room or operating theater.
- Make sure to have a good internet connection and sufficient bandwidth.
- The SmartCardia 7L Platform should not be used in an aircraft.

7L Sensor, 7L Patch, and SmartCardia Phone

WARNINGS:

- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia *7L Patch* and *7L Sensor* before external defibrillation.**
- **If a patient has severe skin irritation or burning feeling, they should remove the 7L Patch right away and contact their doctor.**
- **Do not use this device in an MRI.**

CAUTIONS:

- The 7L Platform is not intended to record the activity of an implanted pacemaker onto the ECG waveform. The 7L Platform is designed to operate in the presence of pacemaker pulses. Caution should be used to not locate the *7L Patch* with the *7L Sensor* on top of a pacemaker.
- The SmartCardia *Phone* should not be placed over a pacemaker.
- Do not try to take apart the *7L Patch* or *7L Sensor*.
- Do not try to change the battery in the *7L Patch*.
- Do not use the device if the *7L Sensor* or *7L Patch* is damaged.
- The *7L Patch* is single use for a single patient. Do not reuse.
- Follow the instructions to use correctly.
- Make sure the *7L Sensor* is installed correctly and is firmly sealed in the *7L Patch*.
- The *7L Sensor* and *7L Patch* should be placed on the patient's body as instructed.
- Care should be taken by the patient if showering. Caution should always be taken when wearing in a wet location.

Questions? Contact FDA/CDRH/OHT5/DHT5 at CDRH-PMISTATUS@fda.hhs.gov or 301-796-8118

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- The SmartCardia Phone cannot get wet.
- Avoid extreme high or low temperature and humidity.
- Follow the instructions for the correct cleaning solution and process.
- Do not use the device if the battery is depleted**.** Refer to the SmartCardia documentation for the battery life expectancy.
- Do not place the *7L Patch* on open wounds.
- The patient must keep the SmartCardia *Phone* within 10 ft of the *7L Sensor* at all times.
- Make sure the SmartCardia *Phone* is fully charged. It is best to charge the phone each night.
- If the Bluetooth on the SmartCardia *Phone* Is OFF, contact SmartCardia Customer Support.
- Only use the charger provided with the SmartCardia *Phone*.
- It is very important to have a good internet connection.
- For best results, the patient's skin where the *7L Patch* is applied should be cleaned and hair clipped or shaved to reduce artifact and prevent a noisy signal.
- Do not use the *7L Patch* if date of manufacture is more than two years. Refer to the *7L Patch* labeling.
- The patient must stay away from heavy electrical equipment or other sources of interference. For additional information regarding Electromagnetic Compatibility (EMC), see Attachment B.

SmartCardia 7L Web Browser

CAUTIONS:

- Keep username and login in a safe place and do not share them with anyone.
- Do not leave your session open if you leave the device unattended. Always log out.
- Do not access the cloud platform from a shared computer.
- Make sure to set the correct mode of monitoring operation for the patient (Holter, Extended Holter, Event.
- Measured vital sign values should be reviewed and verified by alternate means if measurements are suspected to be inaccurate.

Alarms

WARNINGS:

- **Alarm conditions must be set to ON for a notification to be presented at the remote viewing station.**
- **Make sure that parameter limit settings are appropriate for the clinical condition of the patient being monitored - do not set parameter limit settings outside the physiological range for the patient.**
- **When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.**
- **Alarm limits are patient or facility specific. The clinician must set and verify alarm limits appropriate for each patient. Failure to set alarm limits properly can lead to false alarms or failure to alarm.**

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- **No computerized interpretation of patient data can correctly detect and classify a medical condition 100% of the time. Use sound clinical judgment when monitoring your patients.**
- **Audio on the PC used to view the *7L Web Browser* must be ON and sufficiently loud enough.**
- **When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**
- **Do not turn OFF the audible notifications without providing continuous observation of the patient.**
- **Check notification volume periodically! If the volume is too low, it could result in the inability to hear a notification.**
- **In certain circumstances the pacemaker pulse may be detected as a heartbeat. Verify heartbeat with an alternative method such as auscultation, radial artery palpation, or viewing ECG.**
- **Make sure that proper patient preparation and settings are in place to avoid sensitivity to excessive artifact which can result in inaccurate notifications.**
- **Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a clinician views these events, they should follow their practice guidelines and manually document the event in the patient record.**
- **The alarms provided on the SmartCardia 7L Platform should be properly assessed by medically trained or relevant qualified and accredited personnel.**
- **It is the responsibility of the clinician or care provider to respond to alarms consistent with their practice license.**

CAUTIONS:

- When remote monitoring a patient, remember they may not have a caregiver or helper nearby and they may not be able to respond to communications. Always know how to provide aid for each patient.
- Receipt of alarm signals is not confirmed.
- Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.
- If the wireless connection from the *7L Sensor* and *7L Patch* to the SmartCardia *Phone* or the *Phone* to the internet/cloud application is disconnected, a notification will show on the display. Periodically check to make sure the connection is intact.

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Indications for Use

The SmartCardia 7L Platform is a prescribed device used for the purpose of identifying non-lethal arrhythmias. The SmartCardia 7L Platform is intended for:

1. Patients who experience transient symptoms that may suggest cardiac arrhythmia.
2. Patients who require monitoring of effect of drugs to control ventricular rate in various atrial arrhythmias (e.g., atrial fibrillation).
3. Patients with symptoms that may be due to cardiac arrhythmias. These may include but are not limited to symptoms such as: a) dizziness or lightheadedness; b) syncope of unknown etiology in which arrhythmias are suspected or need to be excluded; and c) dyspnea (shortness of breath).
4. Patients recovering from cardiac surgery or interventional procedures who are indicated for outpatient arrhythmia monitoring.
5. ECG data recorded by the device can be analyzed by other processing systems to provide Holter style reports.

Measurements include: electrocardiogram (ECG signal), R-R interval, and Heart Rate. Notification alerts can be set for one or more of these measures.

The SmartCardia 7L Platform is indicated for use on patients who are 18 years of age or older to provide monitoring of physiological information. It is intended for use in a physician office, outpatient facility, or in the patient's home.

SmartCardia 7L Platform contraindications:

1. The SmartCardia 7L Platform is contraindicated for use in a critical care setting where an immediate response to life threatening conditions such as lethal arrhythmias is required.
2. The SmartCardia 7L Platform is contraindicated for use during external defibrillation.

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SmartCardia 7L Platform™ Introduction

System Description

The SmartCardia, Inc. 7L Platform™ is a system comprising a wireless sensor component (the *7L Sensor*), an adhesive patch (the *7L Patch*) which the *7L Sensor* connects to, a mobile component (the SmartCardia *Phone*), and a backend server component (*SmartCardia 7L Web Browser*) to access the patient database. The SmartCardia *Phone* is an Android OS mobile phone that is configured by SmartCardia in a kiosk mode so it can only be used by the SmartCardia *7L Mobile Application* (it does not function as a usable phone, only as a mobile gateway for the SmartCardia data). The data are viewed on the SmartCardia *Phone* and via a SmartCardia *7L Web Browser* application.

The *7L Sensor* and *7L Patch* make up a body worn applied device consisting of the ***reusable*** electronic *7L Sensor* and a ***disposable*** adhesive *7L Patch* into which the *7L Sensor* is inserted and connection is made. The accessory *7L Patch* has four electrodes. The sensor and patch assembly adheres to the chest and contains the batteries to power the connected reusable *7L Sensor* to wirelessly monitor electrocardiogram (ECG) and heart rate of the patient.

The SmartCardia 7L Platform provides monitoring for Holter applications and supports three monitoring service modes:

- Holter Monitoring (up to 48 hours) and Extended Holter Monitoring (greater than 48 hours)
- Event Monitoring

The SmartCardia 7L Platform has the following characteristics:

- It provides monitoring for any operation mode,
- It is non-invasive and has no significant safety issues, and
- It uses electrode and ECG technology that is in use today.

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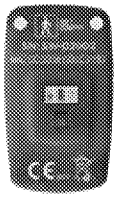
SmartCardia 7L Platform Components

SmartCardia 7L Sensor (the *7L Sensor*)
A reusable Sensor (do **not** throw away)

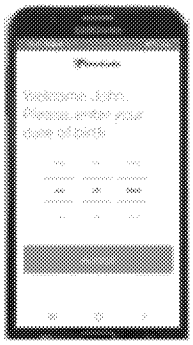


- Inserts into the *7L Patch*
- Monitors ECG
- Sends patient data to the SmartCardia *Phone*
- Is waterproof when used with the *7L Patch*

SmartCardia 7L Patch (the *7L Patch*)
A single-use patch (disposable)

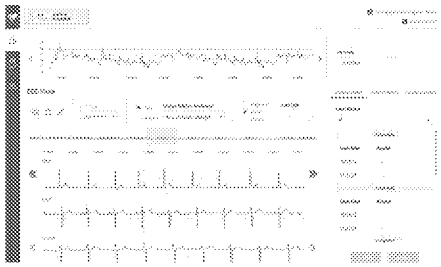
- Includes batteries
- Holds the reusable *7L Sensor*
- Includes ECG Electrodes
- Medical adhesive used to apply to the skin

SmartCardia Phone (the *Phone*)



- Is a gateway to send patient data to the provider viewed on the *7L Web Browser*
- Always kept close within 10 feet of the SmartCardia *7L Sensor*
- Charged daily (or more often as needed)
- Uses the *7L Mobile Application*
- Provided and configured by SmartCardia

SmartCardia 7L Web Browser (the *7L Web Browser*)



- Application is validated on Google Chrome browser only
- Service mode choices (Holter, Extended Holter, Event Recording)
- View patient data, manage alarms, analyze ECG, and create reports

Responsibilities

Clinician responsibility

- Patient registration in the system
- Provide remote support for the patient

Responsibility of SmartCardia

- Remote clinical support
- Remote technical support

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Abbreviations

ECG: Electrocardiogram
HR: Heart Rate
BPM: Beats per minute

Icon & Symbol Table

Symbols on the Product and Packaging

Symbol	Title of Symbol	Symbol Description
	SmartCardia	Represents the SmartCardia logo
	European Conformity	The product meets the standards for Medical Device in the European Union and Subscript text next to the symbol indicates the code of the notified body
	Manufacturer	Indicates the medical device manufacturer
	Authorized Representative in the European Community	Indicates the Authorized representative in the European Community
	Date of manufacture	Indicates the date when the medical device was manufactured
	Use-by-date	The date after which the product or the accessories should not be used
	FCC Compliance Mark	Meets FCC requirements per 21 CFR Part 15
	Serial number	Indicates the serial number of the medical device
	Catalog number	Indicates the manufacturer's catalogue number so the medical device can be identified
	Batch code	Indicates the manufacturer's Lot code
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information
	Temperature limits	Indicates the high and low temperatures for storage and use
	Humidity limits	Indicates the high and low humidity for storage and operation

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Symbol	Title of Symbol	Symbol Description
	Do not re-use	Product is for single use only and not to use on another patient
	Keep dry	The product needs to be kept dry
	Non-ionizing electromagnetic radiation	This product does radiate RF, but it is non-ionizing
	Restriction of hazardous substances	Product is in accordance with the requirements restricting the use of specific hazardous materials
	BF applied part	To identify a type BF applied part complying with IEC 60601-1
	Do not use in MRI	Do not use the product in a magnetic resonance imaging instrument
	Not made with natural rubber latex	There is no natural rubber latex in the product or its package
	Non-sterile	The product is not sterile
	Crossed-off wheeled bin	The product contains electrical parts and must be disposed of properly, not into any bin, but must be placed in an electrical equipment bin
	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner
	Consult instructions for use	For more information, read the operation manual or instructions for use
	Do not use if package is damaged	Do not use if the package has been damaged or opened
IPX7	Ingress protection (IP) rating	Indicates the assembled 7L Sensor and 7L Patch can withstand ingress of water in harmful quantity when immersed in water under defined conditions of pressure and time (up to 1 meter (3 ft 3 in) of submersion)
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully
	Warning	Consult the instructions for use for important warning information that cannot be presented on the medical device itself
	Caution	Consult the instructions for use for important cautionary information that cannot be presented on the medical device itself

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Symbols on the User Interface

Symbol	Title of Symbol	Symbol Description
	Mail	Refers to email
	Phone	Refers to phone number
	Password	Refers to password
	Clinician	Refers to clinician
	Patient	Refers to patient
	Multi-Patient	Refers to the display of 12 or more patient tiles
	Device	Refers to the SmartCardia *7L Sensor*
	Chest device location	Represents the *7L Patch* with *7L Sensor* on the patient's chest
	Bell cancel	To identify the control where an audio alarm sound may be switched off or to indicate the operating status of the alarm audio.
	Edit	Represents that data can be edited
	Delete	Represents that data can be deleted
	Calendar	Refers to a calendar where date can be selected
	Clock	Refers to the time
	Time zone	Refers to the time zone
	Add	Refers to adding or seeing more information
	Heart	Represents the patient's heartbeat

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Symbol	Title of Symbol	Symbol Description
	Import Records / Upload File	Refers to the action of importing a record (upload a SmartCardia file)
	Clipboard	Represents information
	Return	Represents the action of coming back to the initial state
	Zoom	Represents the zoom action
	Undo	Represents that the action can be undone
	Search	Represents the action of searching
	Sort	Represents the action of sorting
	Logout	Refers to logout action
	Stop	Refers to stopping an action
	Measure	Represents ECG chart measurement
	Close	The tab can be closed
	Arrow	Clinicians use the arrows to scroll through the graph
	File	The report created by the clinician can be downloaded
	Link	Refers to the association between one patient and a device
	Unlink	There is no patient-device association
	Battery	Refers to the battery of the *7L Patch*
	Battery critically low	Battery of the *7L Patch,* less than 10% remains

Questions? Contact FDAAccessCDRH@fda.hhs.gov or 301-796-8118

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7L Web Browser Navigation

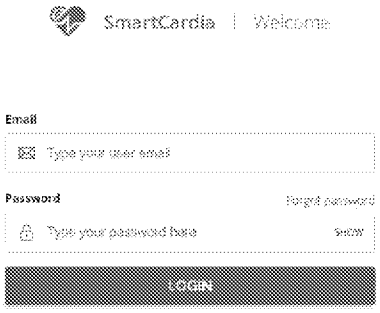
Clinician Login

General Recommendations

- The cloud platform known as the *7L Web Browser* should always be accessed using Google Chrome from an authorized and secured device with at least 4 GB of RAM.
- The *7L Web Browser* must only be used by clinical personnel who have been properly trained on the safe and efficacious use of the product.

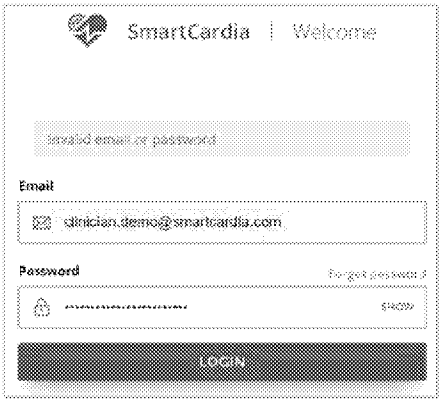
The first view accessed by the clinician when opening the application is the Login window. The user must enter his/her email address (email@example.com), which has been previously registered in the SmartCardia 7L Platform and their corresponding password.

- Enter your user Email and Password
- Click "LOGIN" to show a list of patients



NOTE: If there is a problem when entering your password without displaying it, you can press the "SHOW" button to the right side in the Password box to display it.

- If the email or password is entered incorrectly, an error message box is displayed.
- Re-enter the Email, Password, and LOGIN.



Questions? Contact FDAACDRHDOCSTAR at CDRH-FOISTAT@fda.hhs.gov or 301-796-8118

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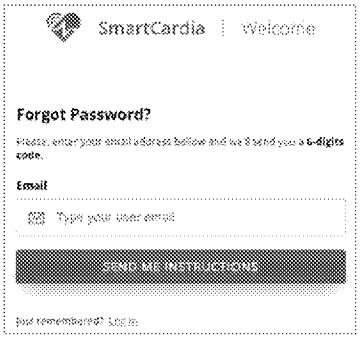
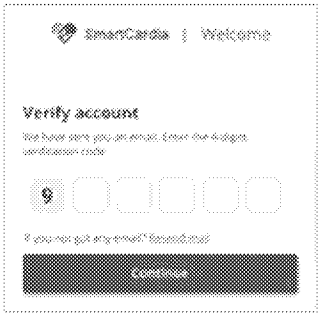
Forgot your password?



- Select the “Forgot password?” button located to the right of the Password box just above it. This new window opens to retrieve your password
- In the new window, in case the password is remembered, at the lower left corner of the box, the “Log in” hyperlink can be selected to return to the log in page
- In the event you do not remember your password, enter your email, and press the “Send me instructions” button



- You will then receive a message with a six-digit code to enter in the new window to verify your account
- In case you do not receive any message, you can request a new code again by pressing the “Resend mail” button.
- After entering the six-digit verification code, press the “Continue” button and if the verification code is correct, a new window will appear.

- In the reset password new window, you enter a new password according to the following rules:
  - Minimum length of 10 characters
  - At least 1 uppercase
  - At least 1 lowercase
  - At least 1 digit
- After pressing the “Update password” button, you will be redirected to the Login page

NOTE: In case of error, the user has three more attempts before being locked out. Contact SmartCardia Customer Support.

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Main Menu: Navigation Bar

The *7L Web Browser* has a main navigation menu that allows the user to move through the application. The main navigation bar can be used showing symbols and item names or showing only the symbols. The main navigation, which always appears on the left side of the web application and consists of the following symbols that appear from top to bottom:

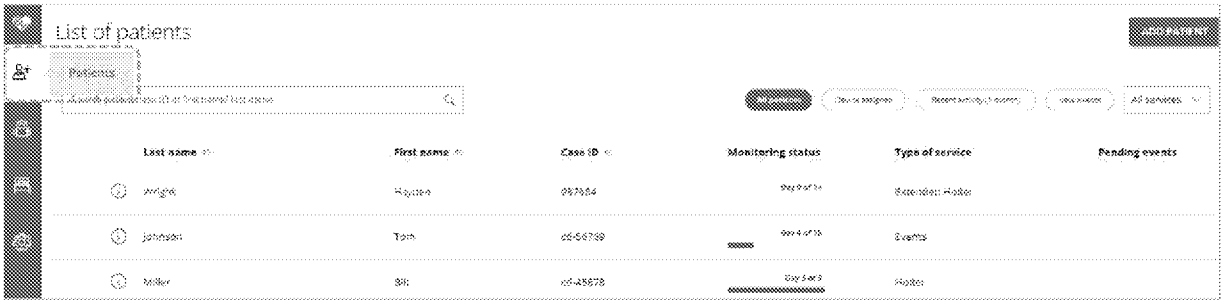
	SmartCardia logo
	Patients- press the button to access the list of patients
	Devices- press to access the list of devices
	Multi-Patient- press to access the view of multiple patient tiles
	Settings- access for clinician administrative information and settings
	Clinician- allows you to log out of the application

Patient Management

Main Page: List of Patients

Navigation Menu

The main page of the application is the “List of patients”, as shown below.

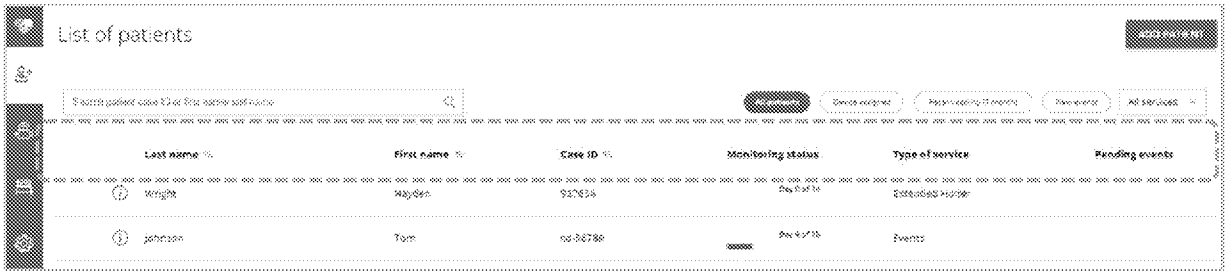


Questions? Contact FDAACDRHDOCSTAR at CDRH-FOISTAR@fda.hhs.gov or 301-796-8118

Functions to select across the top include:

- The search bar box can be used to search for a patient using the patient case ID, first name, or last name
- "All patients" provides the list of all patients ever added to the system
- "Device assigned" shows the list of patients that currently have a device assigned (the *7L Sensor*) presented in alphabetical and numerical order
- "Recent activity (1 month)" lists activity for the past one month
- "New events" displays the list of patients with pending events (all new events triggered based on the alarm and notification settings)
- "All services" provides a drop-down menu list of service types to sort list of patients (All services, Holter, Extended Holter, Events)

The column headers below provide navigation and information about the list of patients.



- Patients can be sorted by last name, first name, or case ID by clicking on the "Sort" icon on the right side of the column headers
- Monitoring status shows the current number of days that have been monitored and the number of days remaining
- Type of service displays the type of service currently in use for each patient
- Pending events lists pending events, the number of events is listed inside the red circle

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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List of Patients

One of the important functionalities for the clinician on the main page is to view additional information about a patient.

Clinicians can see detailed information for each patient by selecting the information sign to the left of the patient's name.

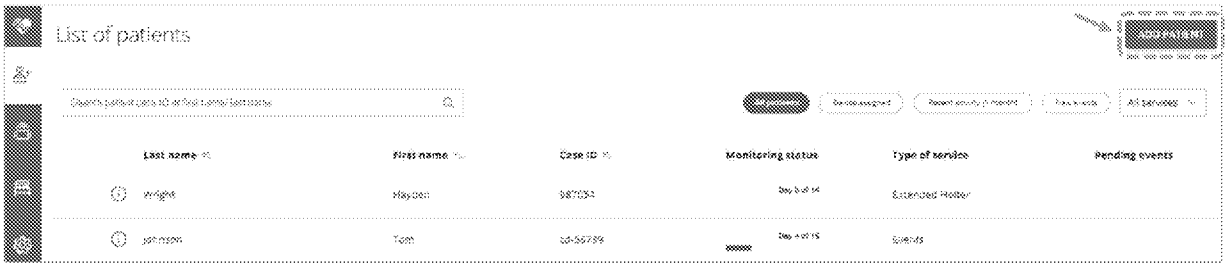
The detailed information includes:

- Last name, first name
- Age: patient's age
- Sex: patient's sex
- Multi-Patient Tile #: viewing location of patient tile assigned to the patient

  Note: The patient is automatically assigned to a Multi-Patient Tile when admitted
- Chest device: the device is attached to the chest and a green solid circle with the device name is listed

Add a Patient

The other important functionality for the clinician that appears on the main page is the addition of a new patient, this happens when the user selects the "ADD PATIENT" button located in the upper right corner.



The patient onboarding screen opens, and you are on the add new patient screen.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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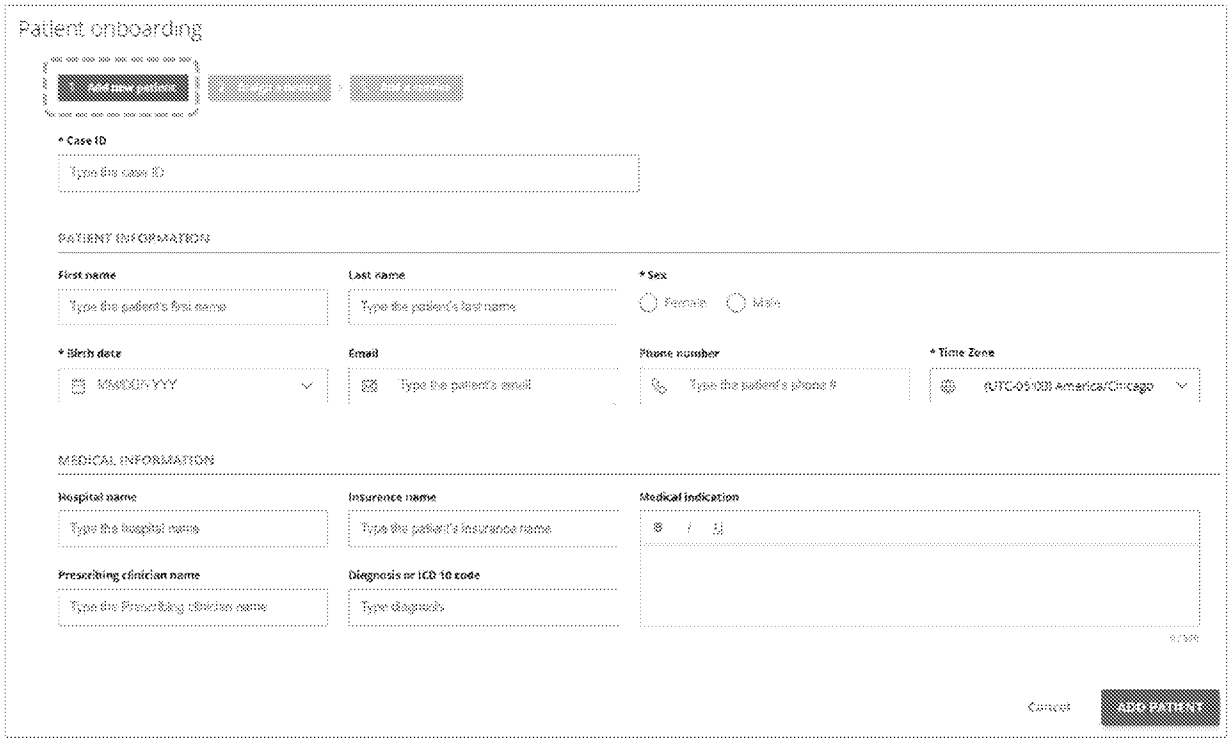
Patient Onboarding- Step 1: Add a new patient

Enter the patient and medical information on the form.



To exit the form without filling it out, press the “Cancel” button.

In the form, complete the following fields (* indicates required field):

- Case ID*- identifier associated with each patient (must be a unique number)
- Name- patient's first and last name
- Sex*- select the sex of the patient (female or male)
- Birth date*- use the calendar to enter the birth date of the patient (to enter the year, select the year displayed then scroll to the one desired and select it. To enter the month, select the month displayed, then scroll to the appropriate one and select it.)
- Time zone*- if not filled with the correct time zone, using the drop-down list select the time zone of the patient’s location

When finished filling out the form without errors, at the lower area of the patient onboarding screen, select the “ADD PATIENT” button. The screen then wraps to the next step in the process.

NOTE: If an error occurs when inserting the new patient information, the fields where errors are detected will be highlighted in red, indicating that there has been a problem and the new patient cannot be added until those errors are corrected.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-EDISTATUS@fda.hhs.gov or 301-796-8118

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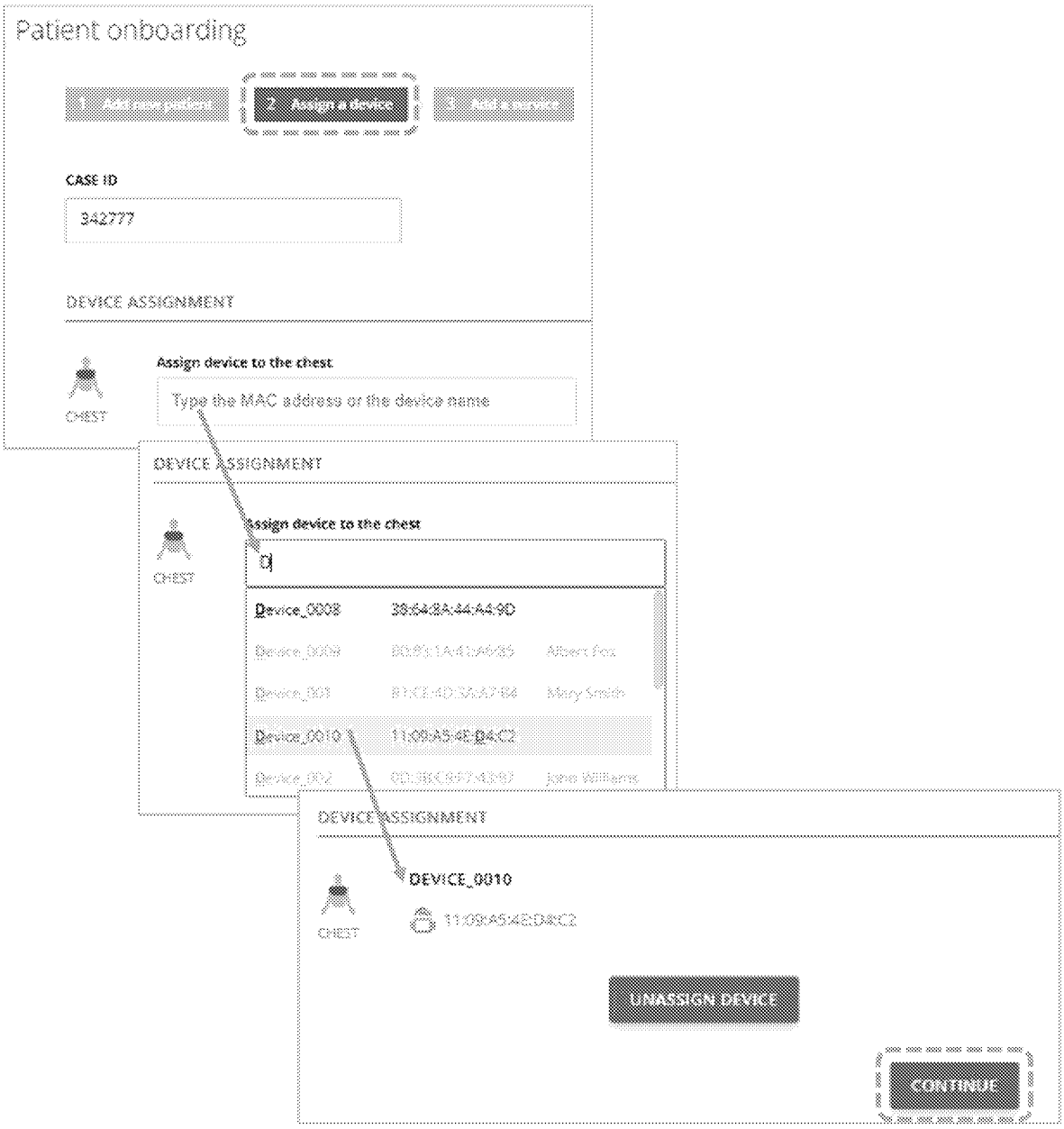
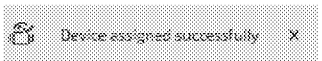
Patient Onboarding Step 2: Assign a device for the patient

- On the screen "ASSIGN A DEVICE"
- Type the MAC address or device name. As the information is typed, a box below begins to populate with the device, then select it from the list of options, next select "CONTINUE" to associate the *7L Sensor* to the patient.

NOTE: The MAC address is found on the surface of the *7L Sensor* that is inserted into the *7L Patch.*



After selection of "CONTINUE" a confirmation message 

is displayed and you advance to the next step in the onboarding process.

Questions? Contact FDAACDRHDOCSPDS at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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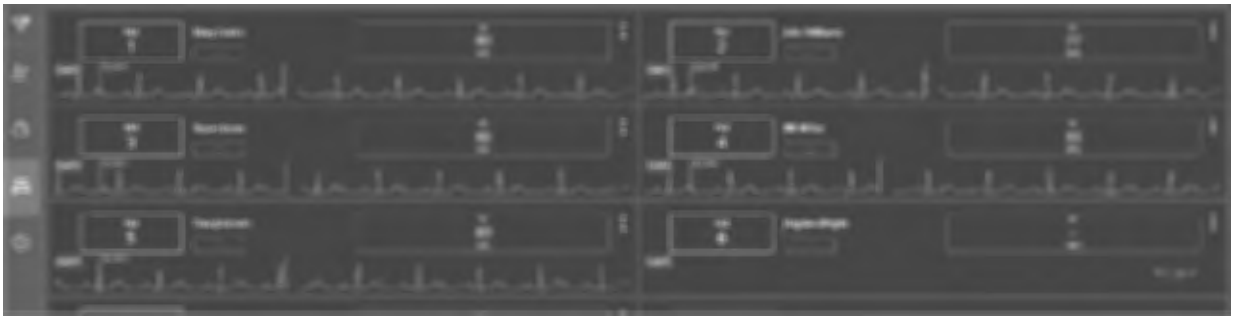
Patient Onboarding Step 3: Choose the monitoring service type for the patient

- From the drop-down menu, select the service type (No service, Holter, Extended Holter, Events)
- Enter the number of days for the duration of service
- Select "FINISH" this new patient is now added to the patient list
- Once "FINISH" is selected you are taken to the Alarm Settings screen to review and customize alarms for the patient just added (see *Alarms and Alarm Management* section on *page 35* for detailed information)

NOTE: Once admission is finished the new patient is added to the Multi-Patient view screen as shown below. No signal is displayed until service begins once the *7L Sensor* is on the patient's body and connected to the *7L Mobile Application*.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display. Consult the *PL-17 SmartCardia 7L PlatformTechnical Manual.*



Service type options and features:

	Features				
Service Type	Measurements	Event Capture	Real Time View	Duration	Report Editing and Creation
Holter	7 lead ECG, Atrial Fibrillation	Yes	Optional	<48 hrs	Yes
Extended Holter	7 lead ECG, Atrial Fibrillation	Yes	Optional	>48 hrs	Yes
Event	7 lead ECG, Atrial Fibrillation	Yes	Optional	As ordered	Yes

Note: the maximum duration for a single SmartCardia 7L Patch is 14 days.

Questions? Contact FDA/CDRH/OCE/DAB at CDRH-PDISTATE3@fda.hhs.gov or 301-796-8118
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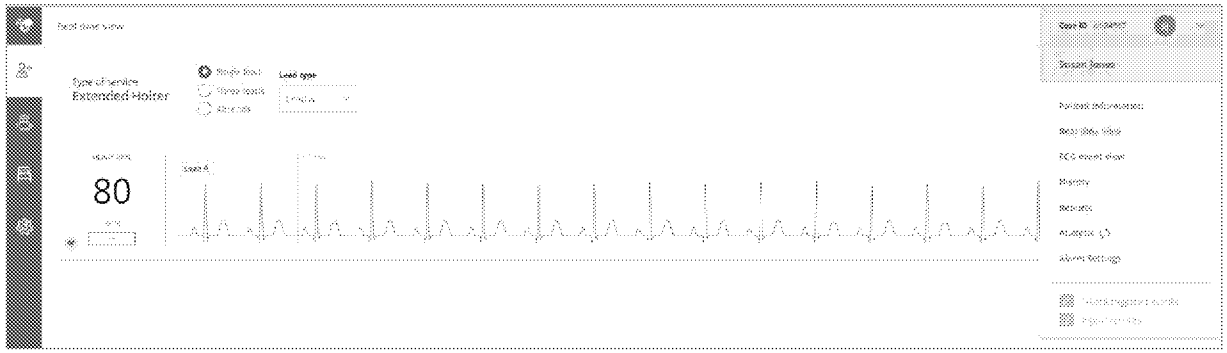
Individual Patient Page

Select “PATIENTS” on the left navigation menu, which displays the list of patients. Once the desired patient name is selected, the “real time” view for the patient is displayed. In the upper right corner, select the arrow on the right of the patient’s Case ID and blue circle with patient initials.

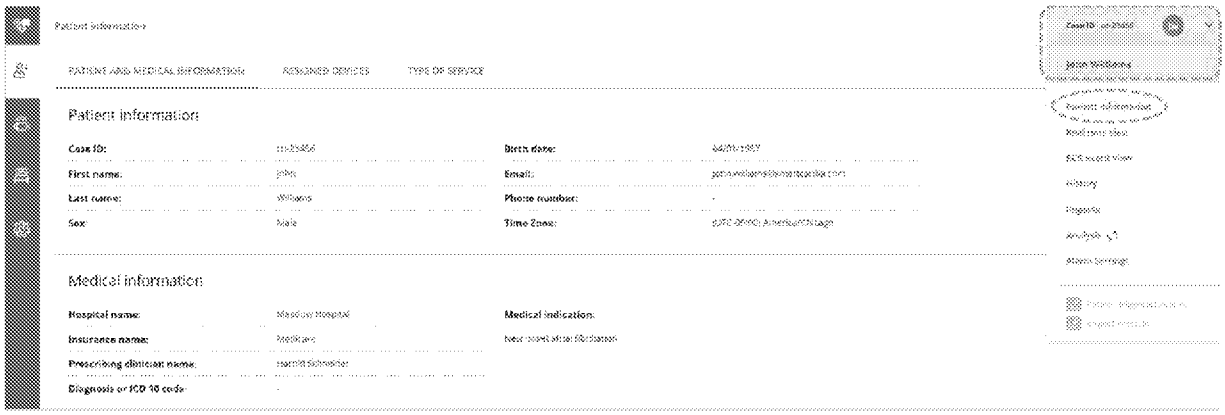
This dropdown menu displays the patient’s name and the options to view and manage this patient.

The term "Real Time" and "Real Time View" are used to indicate you can view the streaming ECG waveform and data as opposed to viewing the stored, retrospective data.



Patient Information/Medical Information

The following patient information is displayed for the selected patient. This data was entered manually when the patient was added to the system.



The information displayed is the patient's personal information (Case ID, first name, last name, sex, birth date, email, phone number, and time zone).

In addition, the medical information is displayed (hospital name, insurance name, prescribing clinician name, diagnosis or ICD 10 code, and medical indication).

This information can be edited by selecting the “Edit” button on the right side of the screen.

Questions? Contact FDA/CDRH/OCE/DHT8 at CDRH-PMISTATUS@fda.hhs.gov or 301-796-8118

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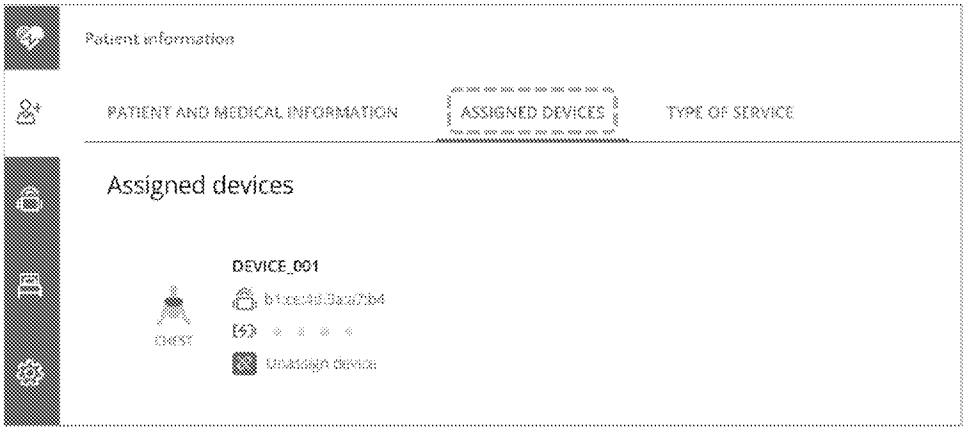
Assigned Devices

The "ASSIGNED DEVICES" tab displays the information related to the device (*7L Sensor*) for the selected patient. If the patient has an assigned device, it is shown next to the picture of the chest which is the location of the *7L Patch with 7L Sensor*. The designated device name, its MAC address, and the battery level are displayed.

In addition, the "Unassign device" button used to dissociate the patient to the device is shown.



The *7L Sensor* battery level displays as a percentage of fully charged.

Device battery is fully charged (100%)	
Device battery has 75% remaining	
Device battery has 50% remaining	
Device battery has 25% remaining	
Device battery level is critically low with less than 10% strength remaining	

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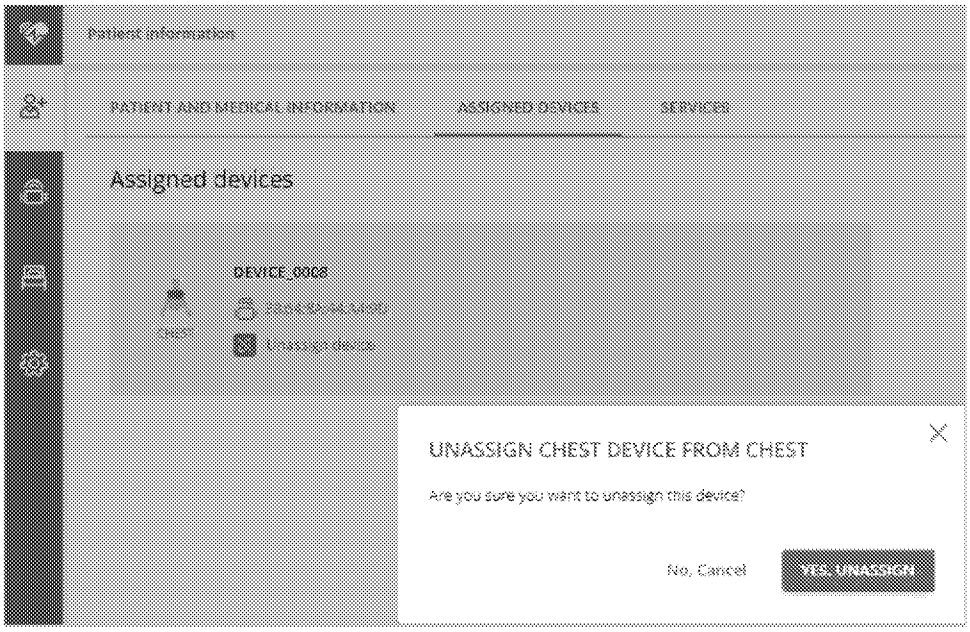
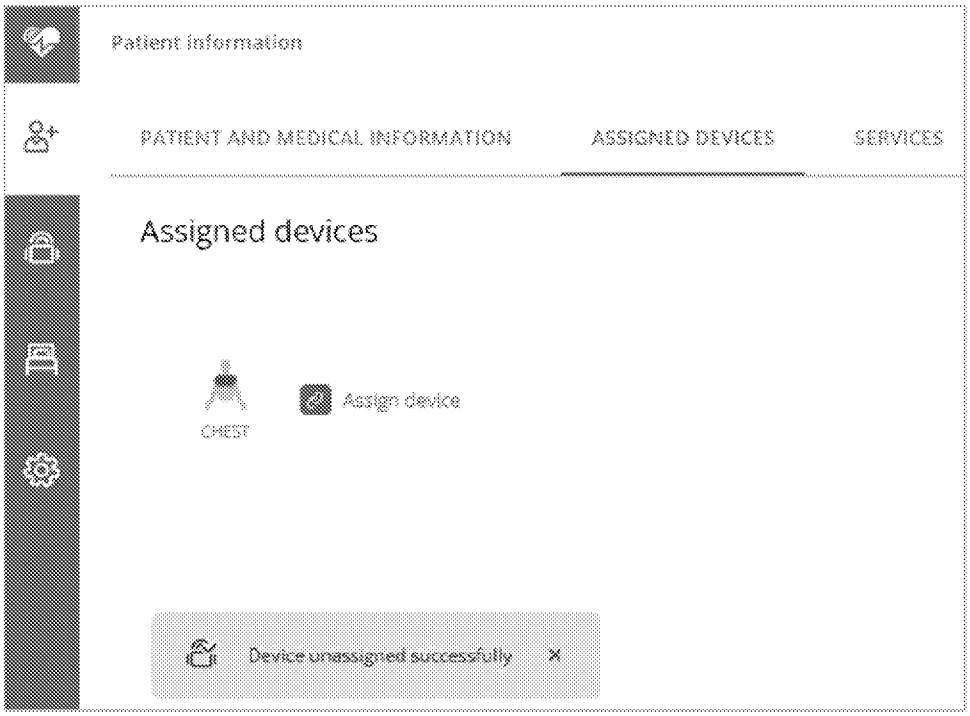
When you select the “Unassign device” button (in red text), a box is displayed with the options: “No, Cancel” or “YES, UNASSIGN”.



When “YES, UNASSIGN” is accepted, the confirmation message “Device unassigned successfully” in a green text box appears.



NOTE: You can only assign a device to a patient if the desired device has already been added to the device list.

Questions? Contact FDA/CDRH/OHT5/DHT5 at CDRH-PMISTAFF@fda.hhs.gov or 301-796-8118

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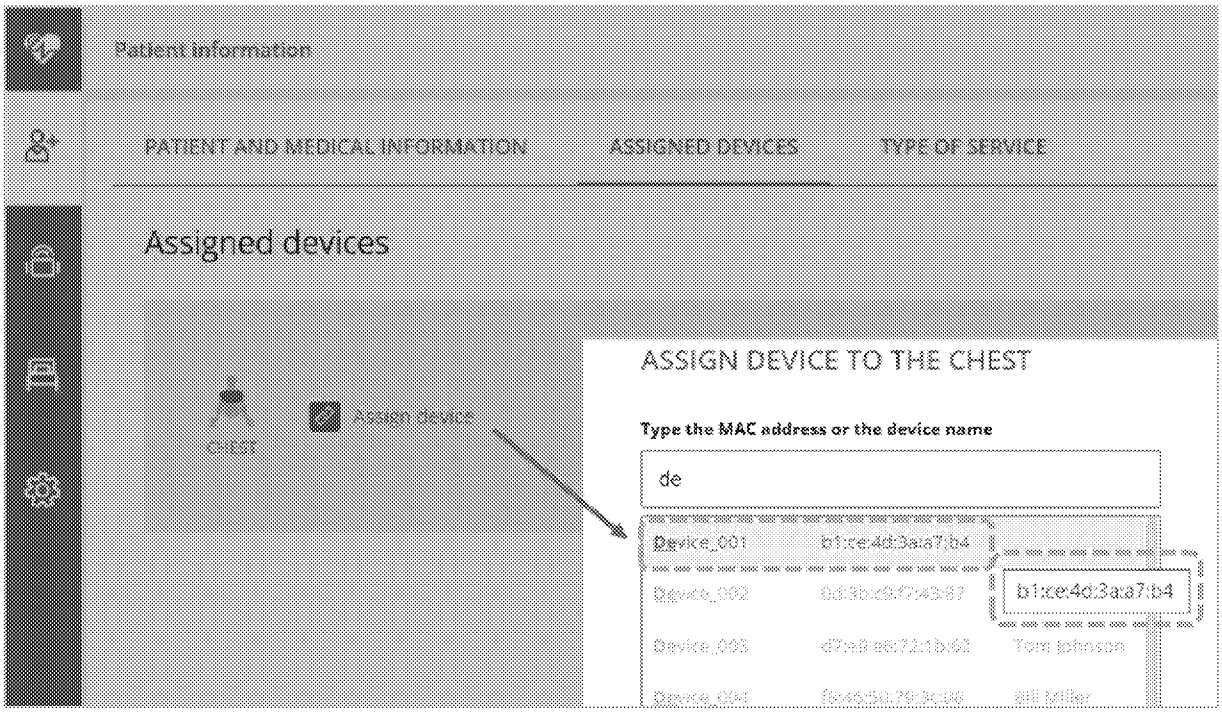
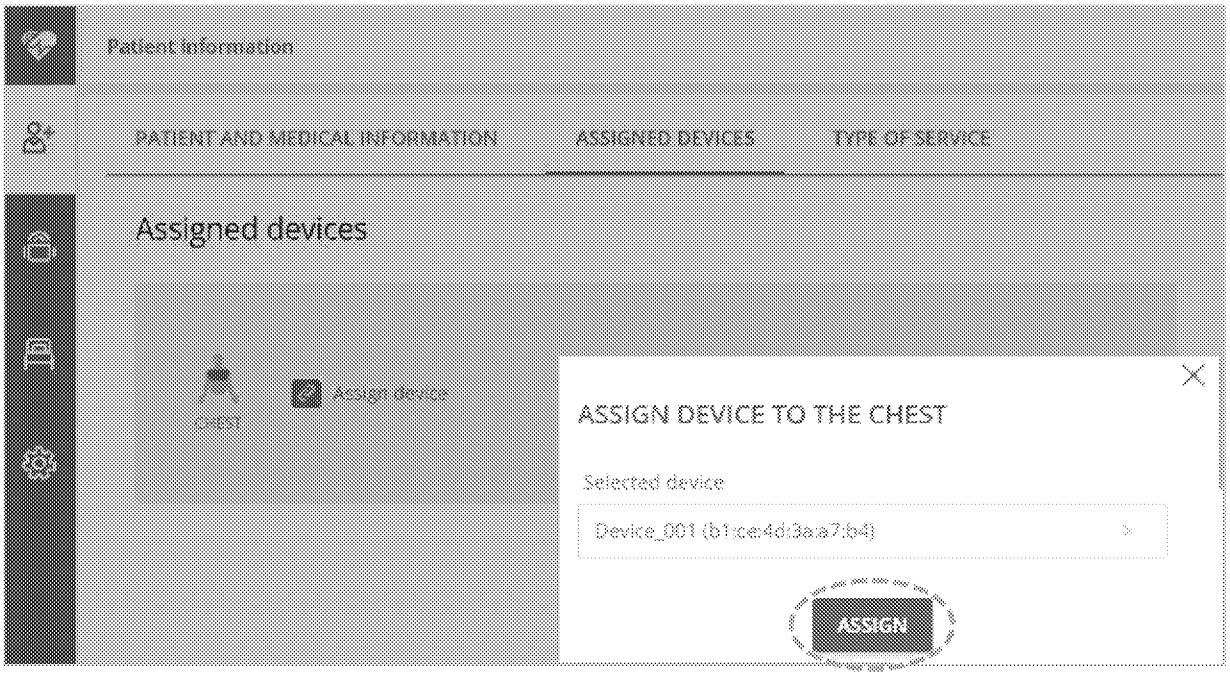
To help you interact with the application, when you start typing the name of the device or its MAC address, suggestions will appear in a text box. Listed devices in gray text indicate they are not available because they are assigned to a different patient. Available devices are those listed in black text that changes to blue text when hovering over it and it is selectable.



Once the desired device has been entered, select the “ASSIGN” button.



Questions? Contact FDAACCESS@fda.hhs.gov or 301-796-8118
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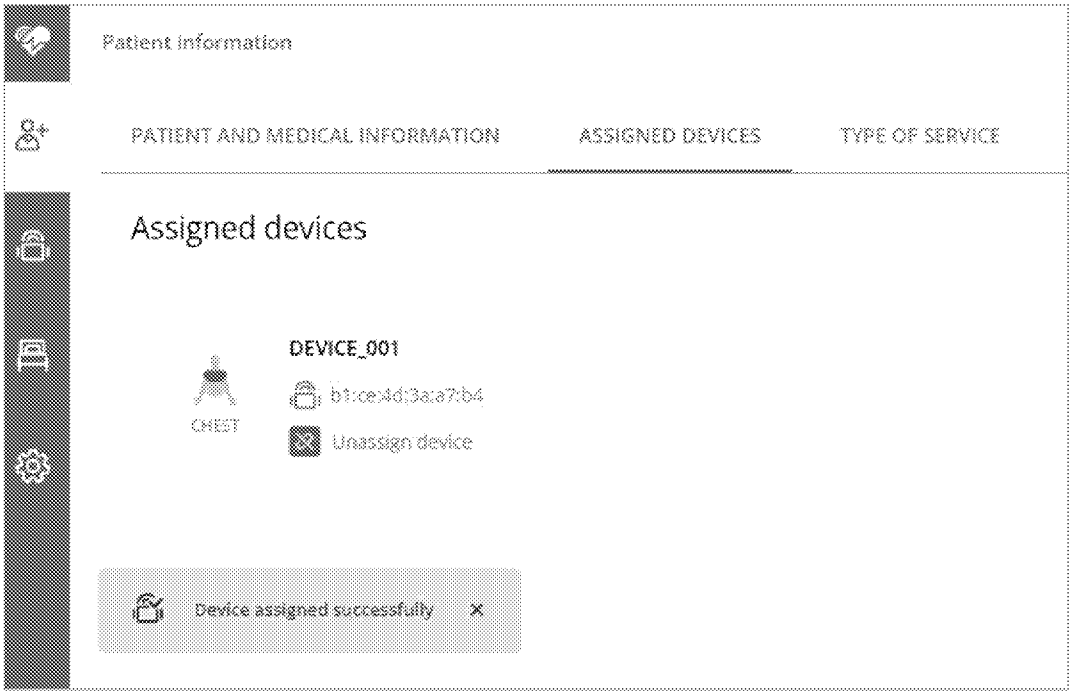
The confirmation message “Device assigned successfully” in the green text box is displayed. In case of an error, a red error message is displayed, explaining the error produced.

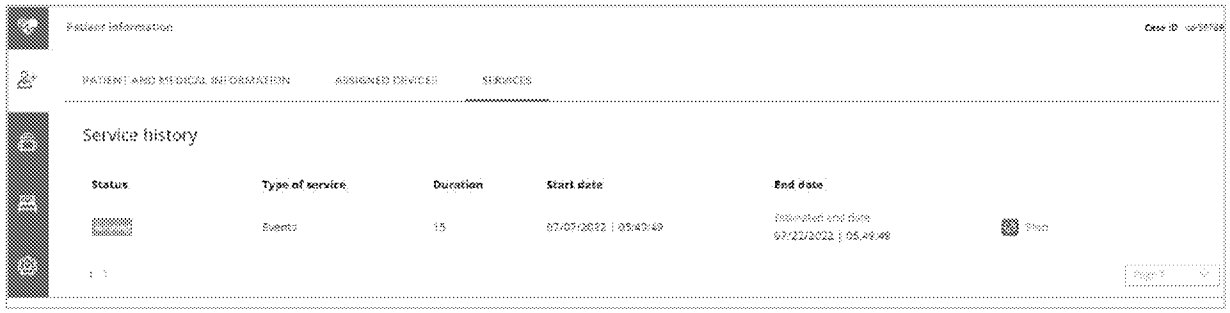


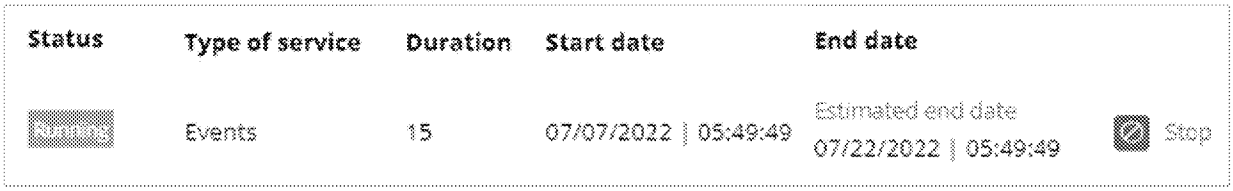
Type of Service

The type of service for monitoring is listed as ordered by the physician. Status is “Running” or “Not Started”. Service can be changed at any time as ordered by the physician.

NOTE: Service begins once the *7L Sensor* is on the patient’s body and connected to the *7L Mobile Application*.

Select “Stop” to change the type of monitoring service and/or the number of days.





Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATE@fda.hhs.gov or 301-796-8118
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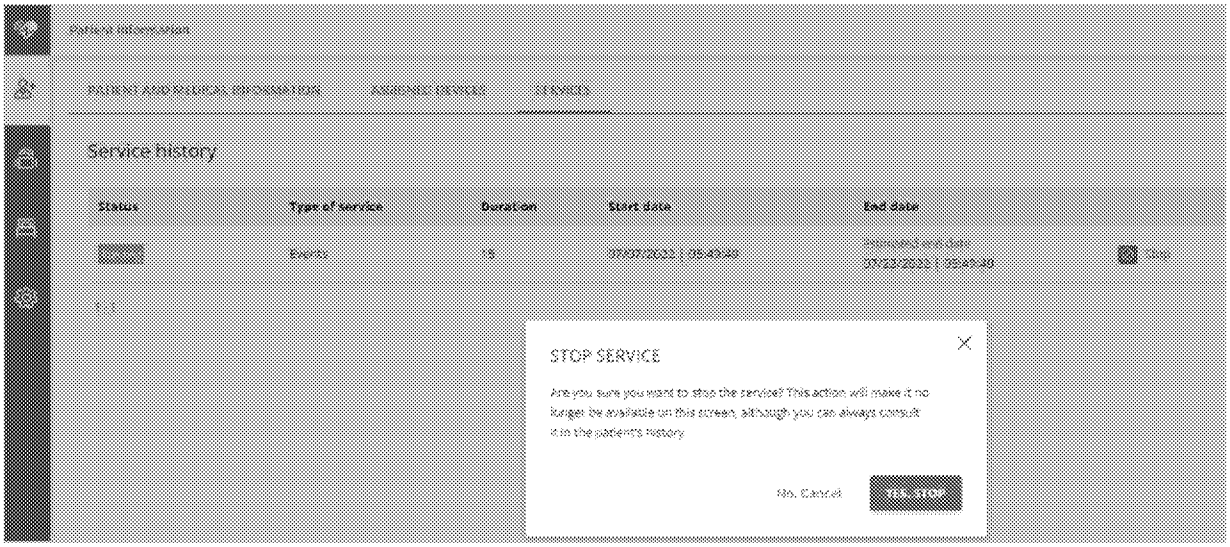
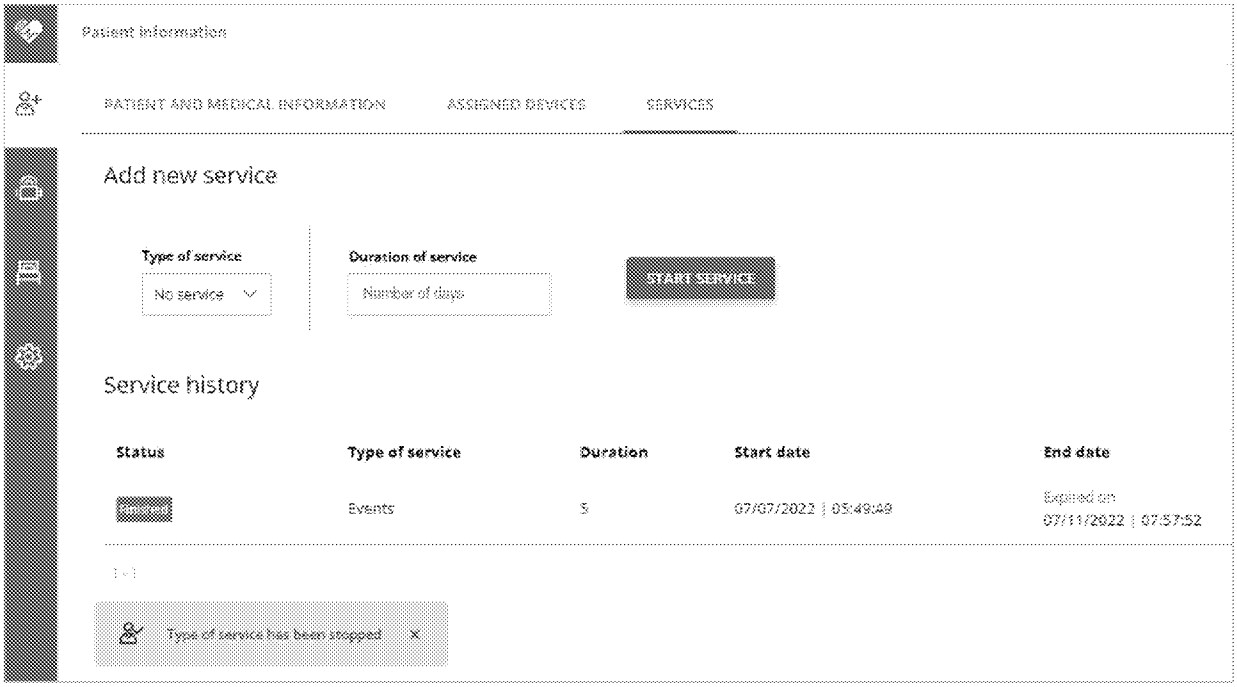
If monitoring is in progress, to discontinue current monitoring service type select “Stop”. The following text box is displayed with the option “No, Cancel” or “YES, STOP”.



Once service is stopped, the confirmation message “Type of service has been stopped” is shown in the green text box.



Questions? Contact FDAACDRHDOCSUB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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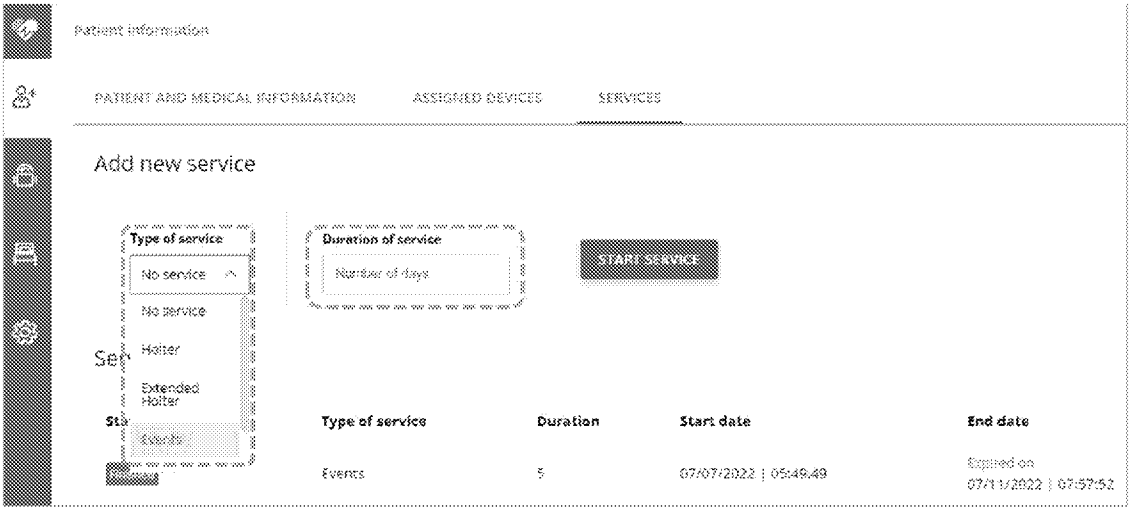
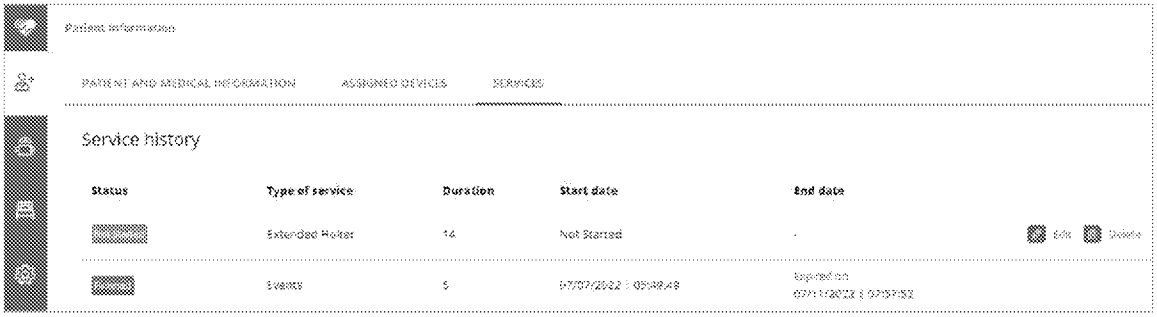
You can now make the new selection of type and duration of service

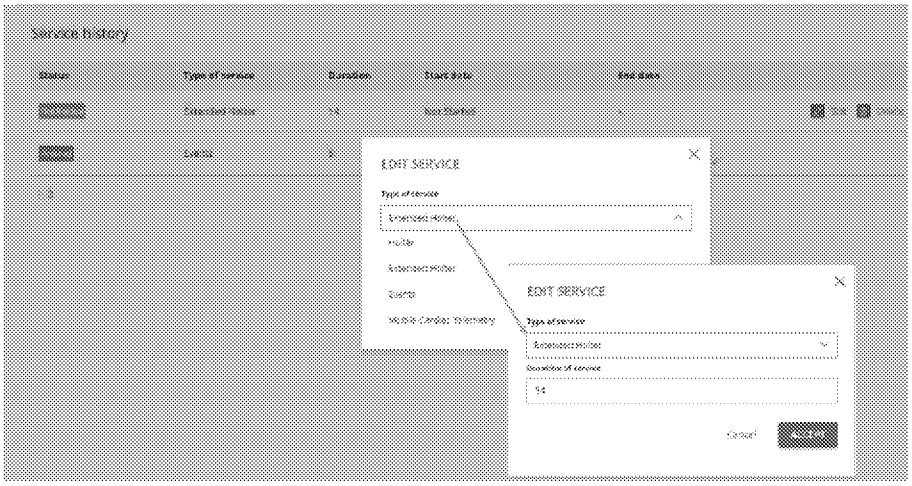


Once “START SERVICE” is selected, a message is displayed.

Service history is listed as shown below. Most recent service information is shown at the top with the option to edit or delete.



When “Edit” is selected, the box below allows you to make any changes then select “Cancel” or “ACCEPT”.



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118

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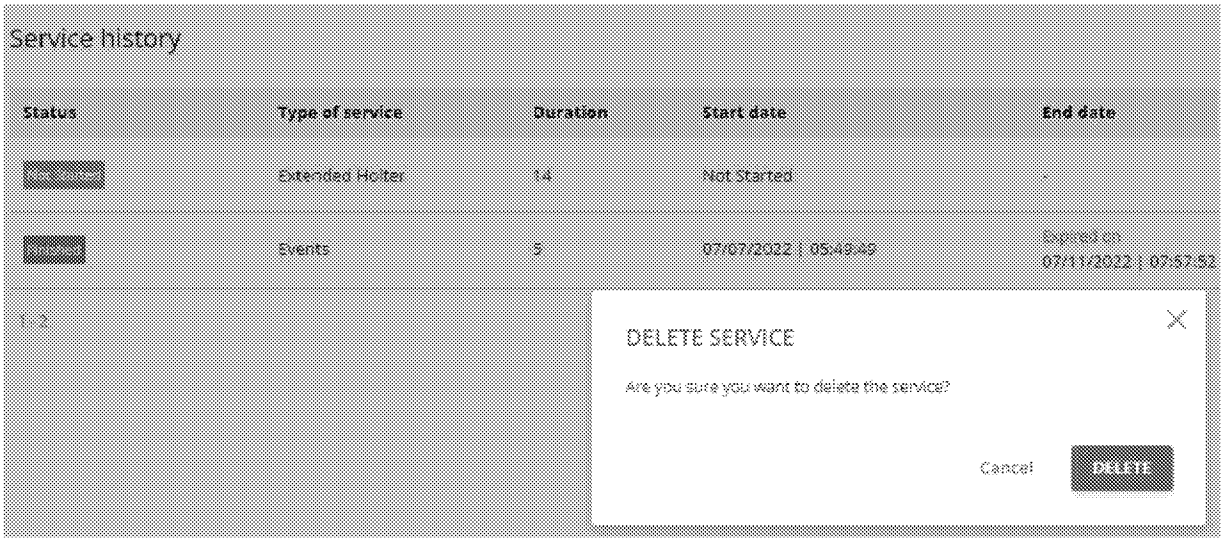
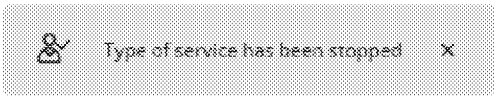
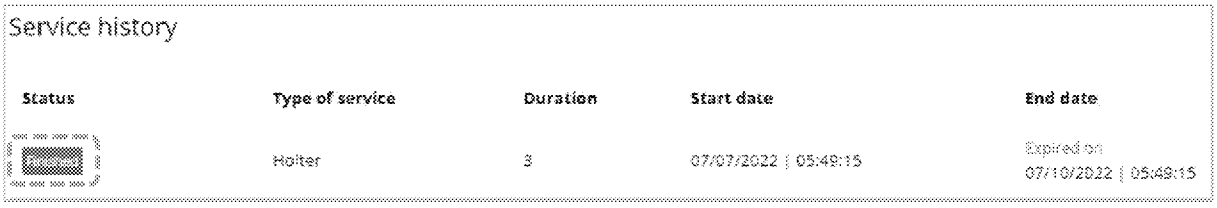
Selecting “Delete” provides option to “Cancel” or “DELETE”



Once service is deleted, it is no longer listed in Service history and a message is posted.



At the completion of the prescribed service period, select “Stop” to discontinue monitoring. The service history will display status as finished. The next step to discontinue monitoring is to Unassign device”. See page 105



Questions? Contact FDAACCDRH@OCS.HHS.gov or CDRH-POLSTATHELP@fda.hhs.gov or 301-796-8118
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Alarms and Alarm Management

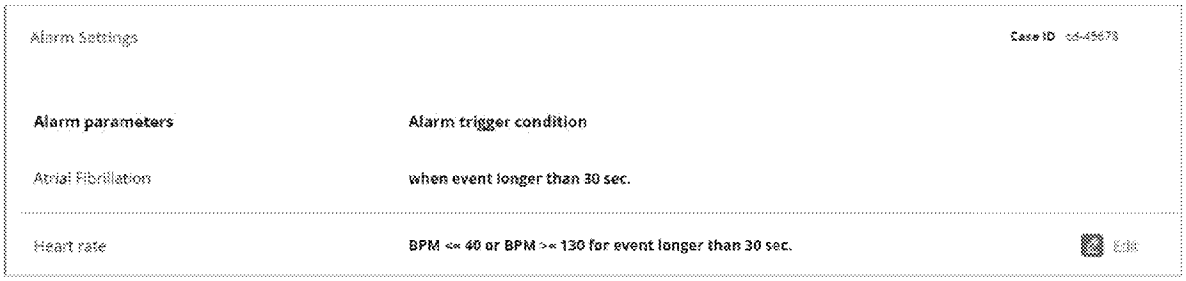
Alarm signals are created when a measured parameter value exceeds the threshold alarm limit settings or when algorithmic analysis (such as atrial fibrillation) detects an alarm condition. For additional information about the SmartCardia 7L Platform alarm system, see Attachment A.

Alarm Signals

Alarm signals are created and presented on the SmartCardia Web Browser when the heart rate exceeds pre-set limit thresholds or when specific arrhythmia events occur. Visual messages are shown when the heart rate and the ECG waveforms are displayed along with an auditory sound. It is the responsibility of the clinician to review and respond to alarm signals.

Alarm conditions that display an alarm signal include:

- Atrial fibrillation
- High or low heart rate



Alarm Signals and Indications

Parameter	Display Parameter	Alarm Trigger Condition	Visual and audio when alarm conditions are met	Alarm Priority
Electrocardiogram (ECG)	High heart rate (HR)	HR ≥ High HR threshold	HR parameter value display turns RED and background flashes Audio alarm provided every 10 seconds	High
	Low heart rate (HR)	HR ≤ Low HR threshold		
	Atrial fibrillation (AF)	Atrial Fibrillation Present	AF in yellow text posted on live ECG screen and flashes Audio alarm provided every 10 seconds	Medium

The following are the manufacturers preset limits for heart rate.

Vital Sign	Upper Threshold	Lower Threshold
HR	130 beats/min	40 beats/min

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATHS@fda.hhs.gov or 301-796-8118

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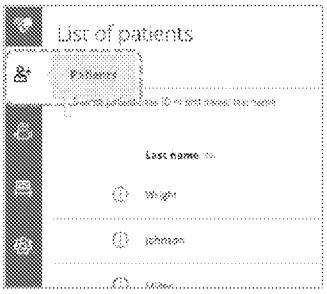
Customizing Alarm Settings for Individual Patients

Alarms are pre-set by the manufacturer, can be modified to meet the practice requirements, and can be customized for the clinical condition of the patient and any provider orders.

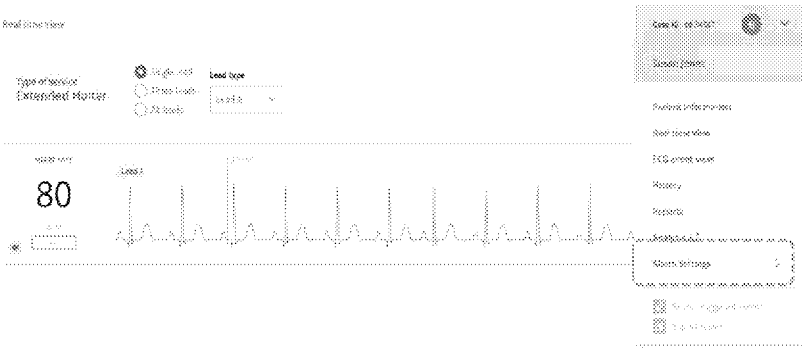
There are three ways to access the “Patient alarm settings” where you can adjust the patient alarm limit settings.

- Option 1: After adding a new patient, you are taken directly to the “Patient alarm settings” to review the current settings and customize to meet the clinical needs of the patient.
- Option 2: Select the patient from the list of patients, go to “Alarm Settings”.

  - On the left navigation menu, select “Patients” to bring up the list of patients



  - Next select the desired patient from the patient list and select “Alarm Settings” from the drop-down menu in the upper right corner



- Option 3: In the Multi-Patient view, on the desired patient tile, select the three dots in the upper right side, go to “Patient alarm settings”.

  - Select the three dots in the upper right corner
  - In the pop-up menu, select “Patient alarm settings”

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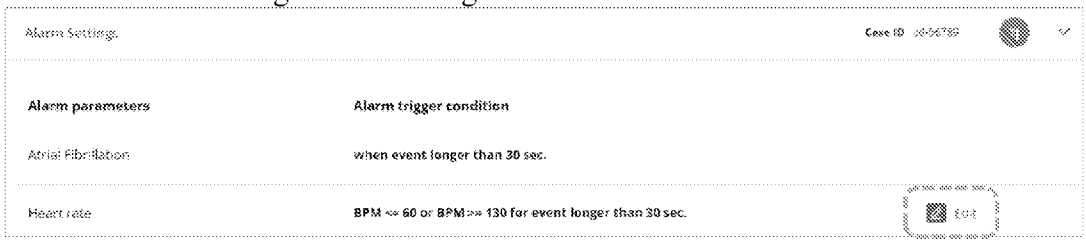
Heart Rate Alarm Parameter Settings

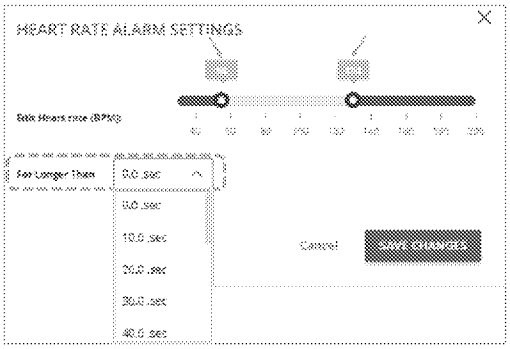
On the patient alarm settings screen, you can review the atrial fibrillation, heart rate alarms, and edit the heart rate alarm limits. (Lowest heart rate setting is 30 and highest heart rate setting is 200)

Customize the alarm trigger conditions

- Select “Edit” to change alarm setting values.



- In this Heart Rate Alarm Setting example, slide each circle above the scale to the left or right to adjust the alarm settings (options in increments of 5 BPM)
- Select length of time for the event, “For Longer Than”
  NOTE: Adding an alarm delay can help reduce clinical non-actionable alarms that result from momentary heart rates that exceed the limit settings
- Select “SAVE CHANGES” or “Cancel” if you choose to not make any changes



Responding to alarms

- Verify the alarm notification is clinically actionable (i.e., requires a patient intervention).
- Take appropriate action or notify the appropriate provider
- If the alarm is not clinically actionable, secure approvals from the provider to modify alarm settings
- Continue to monitor the patient. Call 911 (Emergency Services) if the patient's condition is an emergency

	WARNING: The SmartCardia 7L Platform is NOT an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATHS@fda.hhs.gov or 301-796-8118
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Arrhythmia Event Notifications

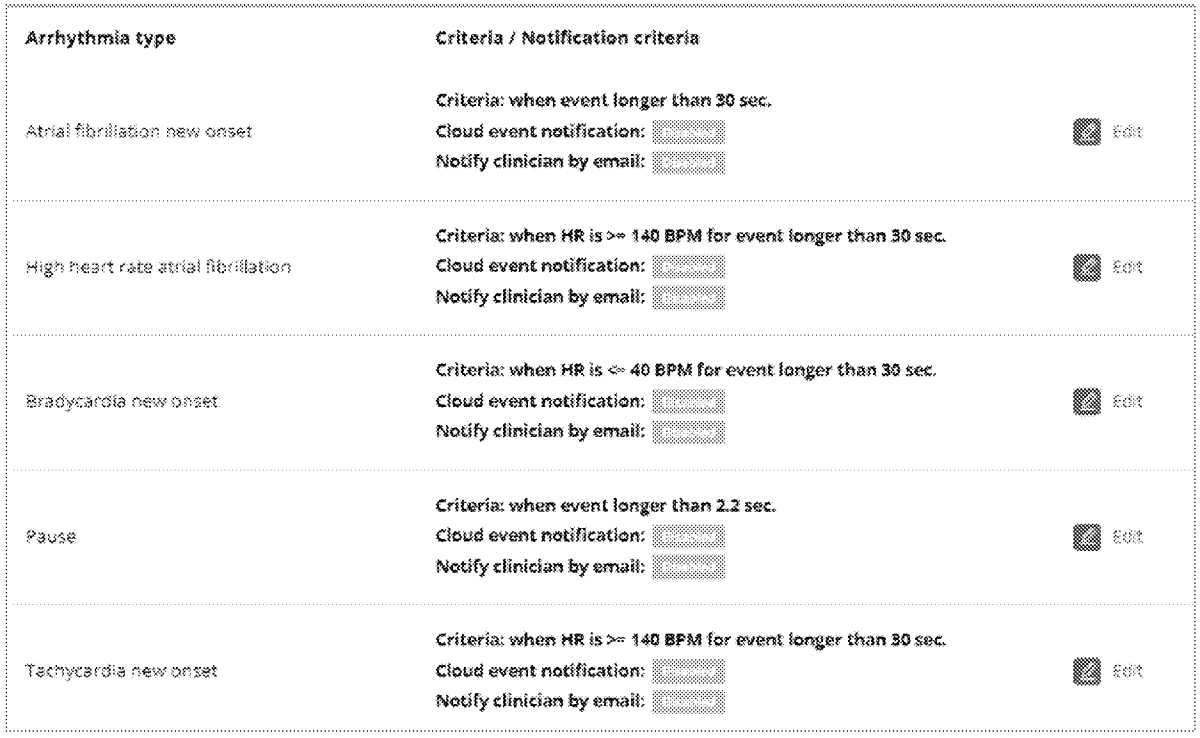
Arrhythmia Events

Arrhythmia events are triggered when specific arrhythmia criteria are met. Arrhythmia events are not alarms and do not provide automated alarm signal notifications. The user can view, accept, or discard an arrhythmia event. User settings can be enabled to notify a clinician of the event at their registered email address.

These events do not generate a real time visual or audible alarm signal.

Arrhythmia events include:

- Atrial fibrillation new onset
- Bradycardia new onset
- Pause
- Tachycardia new onset



When “Cloud event notification” is enabled, events will be identified and marked as pending in the patient list.

When “Notify clinician by email” is enabled, an email that describes the event will be sent to the clinician email that is registered in the system.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118
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Arrhythmia Event Notifications

The arrhythmia events or notifications are triggered as follows. The events are visible to the user and can be accepted or discarded. The accepted events go into subsequent reports generated by the clinician for the patient. The events that have not been accepted or discarded are visible to the user as "Pending Events".

Arrhythmia Condition	Cloud event Notification	Notification by email	Preset Thresholds for event notifications*
Atrial fibrillation new onset	User selectable for maximum number of event notifications per day	User selectable for maximum number of event notifications per day	Atrial fibrillation detection every 10 seconds using the last 30 seconds of ECG, maximum number of events per day set to 5
Bradycardia new onset	HR ≤ low HR threshold for N seconds	HR ≤ low HR threshold for N seconds	Low HR threshold = 40 beats/min for notification on cloud platform and notification by email. N is set to 40 seconds for cloud platform and notification by email
Pause	Pause ≥ Length, User selectable for maximum number of event notifications per day	Pause ≥ Length, User selectable for maximum number of event notifications per day	Length set to 2.2 seconds for cloud platform, 3 seconds notification by email
Tachycardia new onset	HR ≥ high HR threshold for N seconds	HR ≥ high HR threshold for N seconds	Notification when heart rate is 140 beats/min for greater than 30 seconds for cloud platform and notification by email

WARNING: Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a skilled clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.

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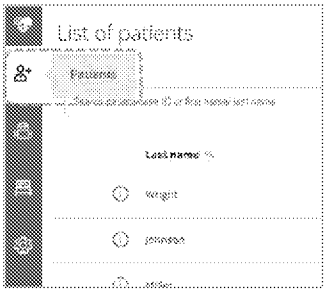
Customizing Notification Settings for Individual Patients

Alarms and notifications are pre-set by the manufacturer, can be modified to meet the practice requirements, and can be customized for the clinical condition of the patient and any provider orders.

There are three ways to access the "Patient alarm settings" where you can adjust the patient alarm limit settings, arrhythmia criteria and notifications.

- Option 1: After adding a new patient, you are taken directly to the "Patient alarm settings" to review the current settings and customize to meet the clinical needs of the patient.
- Option 2: Select the patient from the list of patients, go to "Alarm Settings".

  - On the left navigation menu, select "Patients" to bring up the list of patients



  - Next select the desired patient from the patient list and select "Alarm Settings" from the drop-down menu in the upper right corner

3. Option 3: In the Multi-Patient view, on the desired patient tile, select the three dots in the upper right side, go to "Patient alarm settings".

  - Select the three dots in the upper right corner
  - In the pop-up menu, select "Patient alarm settings"

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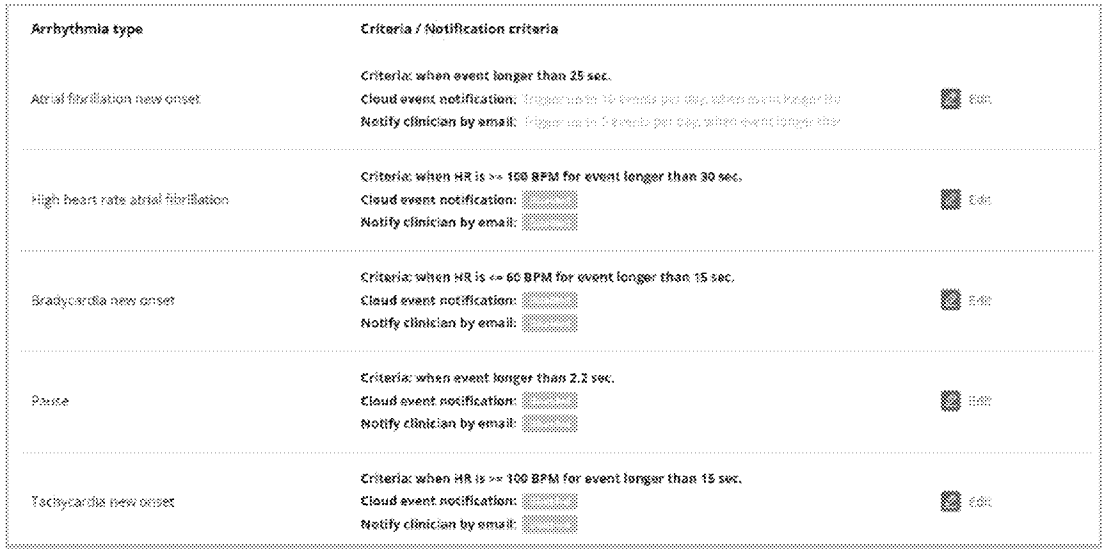
On the patient alarm settings screen, you can review the arrhythmia event notification, turn them on or off, and edit the settings value.



Arrhythmia Type Criteria and Notification Settings

Select “Edit” to change criteria and notification settings. You can also change and identify the events to be included in the patient’s report.

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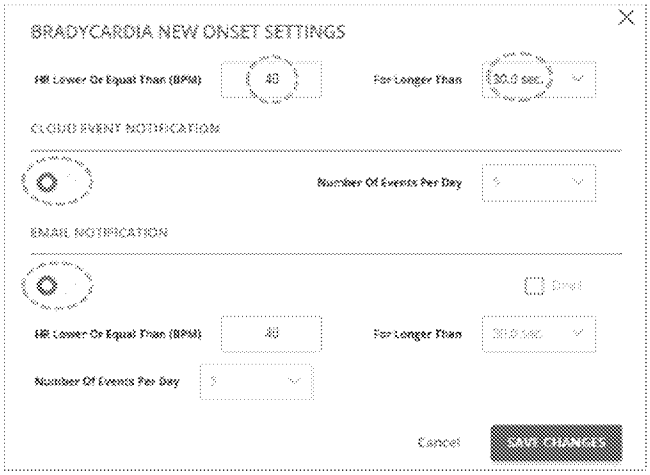
Customize the criteria and notification settings for each arrhythmia type

- Enter numerical value and select the number of seconds duration
- Cloud event notification- use radio button to turn Off/On and set number of events per day for notifications when enabled
- Email notification to clinician email listed in patient and medical information- use radio button to turn Off/On and enter the numerical value, select number of seconds duration, and number of events per day
- Select “SAVE CHANGES” or “Cancel” if you choose to not make any changes



⚠	**CAUTION: Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.**

Patient Preparation for Monitoring

There are two ways for the patient to begin monitoring with the SmartCardia 7L Platform.

- Patient goes to the physician office and the clinical staff applies the device
- The SmartCardia Kit is sent to the patient’s home for them to apply themselves

Refer to the Patient User Guide PN PL-08 that is included in the SmartCardia Patient Kit.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHS@fda.hhs.gov or 301-796-8118

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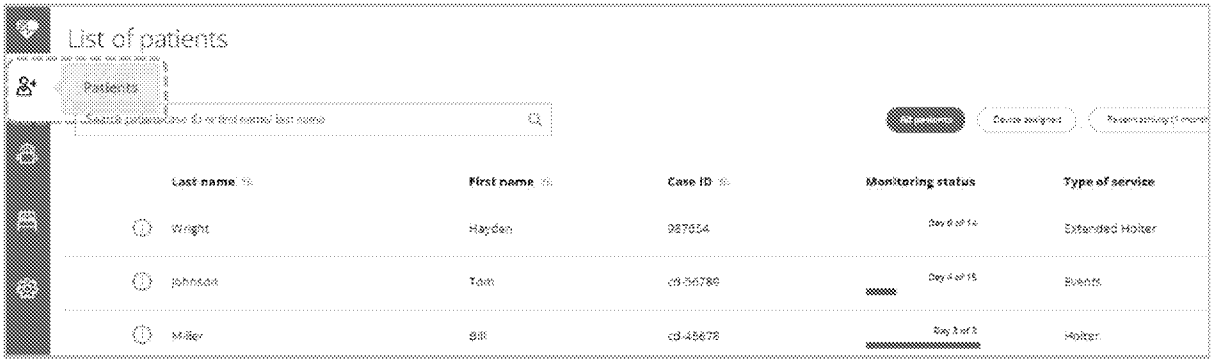
Viewing Patient Data

There are two ways to view a patient's ECG. You can view a patient one at a time or many patients on the Multi-Patient view.

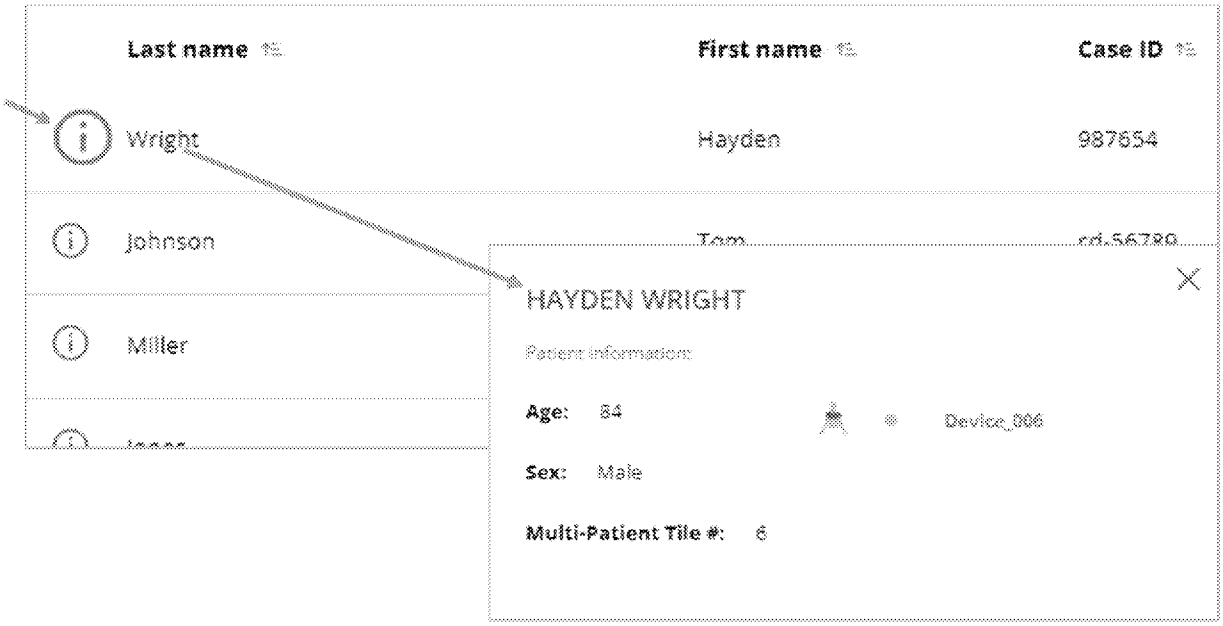
Individual Patient Page: Real Time View

Viewing one patient at a time

On the left navigation menu, click on "PATIENTS" to see the list of patients.



From the list of patients, select the patient's name you want to view. If you want to know additional details about the patient click on the "ⓘ" symbol to the left of the patient's last name to see additional information about the patient (Age, Sex, Multi-Patient Tile #, and Device name).



NOTE: If it is a new patient you wish to view and is not listed, you will need to first "ADD PATIENT", go to page 23.

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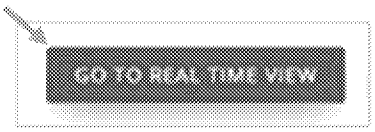
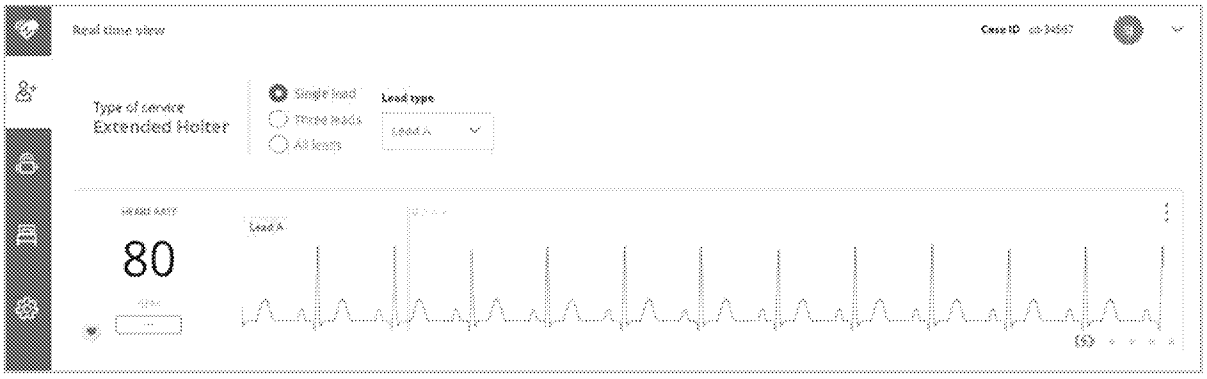
Real Time View

Once the patient's name is selected, their "Real Time View" is displayed. At that time, if you are not taken directly to the patient's real time view, on the left main menu select "Real time view" as pictured below.

NOTE: When you view a new different patient, you may be prompted to select "GO TO REAL TIME VIEW"





The following section will discuss all information shown and functionality available on this screen in detail.

At the top right of this screen, Case ID and patient initials are shown. When you pass the mouse over this information, there is a dropdown menu listing options for interaction with this patient's data as shown below.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATHB@fda.hhs.gov or 301-796-8118

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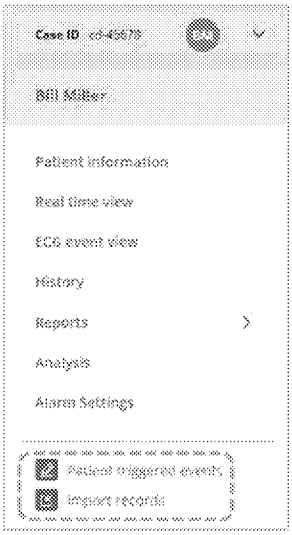
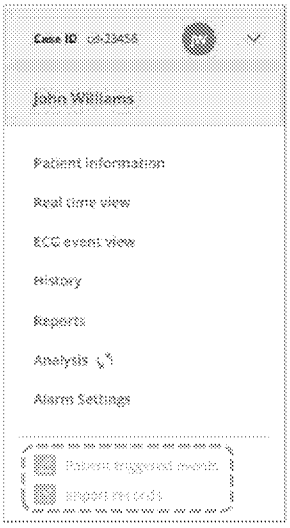
From this patient real time view page, you can view and manage “Patient triggered events” and “Import records”.

- “Patient triggered events” and “Import records” can also be accessed from Patient information, ECG event view, History, Reports, Analysis, and Alarm Settings.

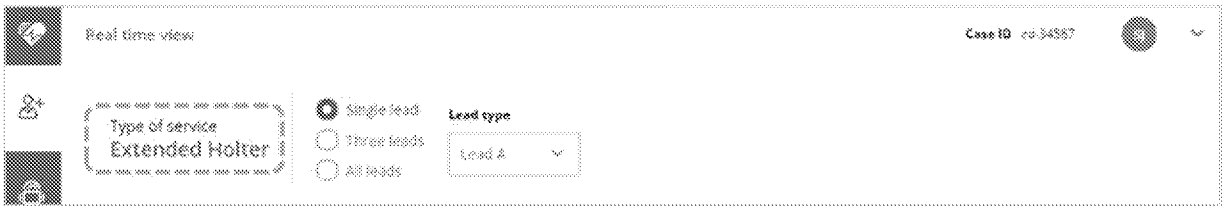


- If Analysis is in process “Patient triggered events” and “Import records” is not available and shaded in grey.



Type of Service Display

The “Type of service” selected to monitor the patient is shown in the upper left side of the screen (Holter, Extended Holter, Events). Detailed information about each type of service and how to make that selection is on page 26.



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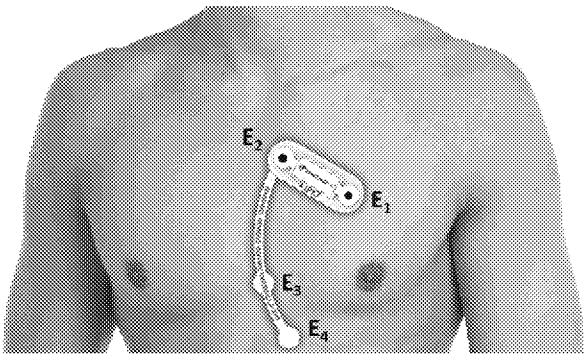
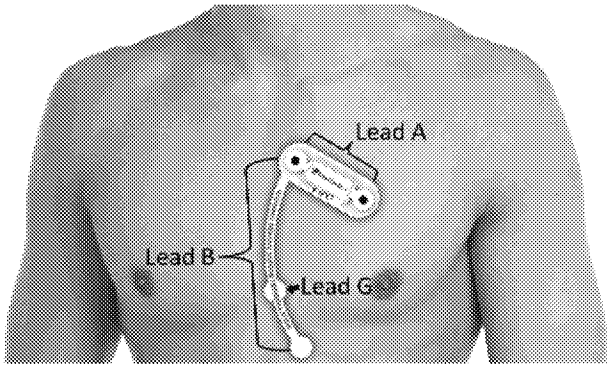
ECG Lead Display

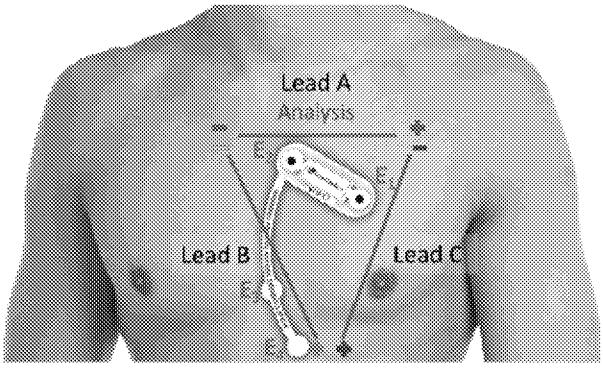
The four electrodes in the *7L Patch* transmit three vectors of ECG.
Seven ECG leads are computed and displayed (Leads A, B, C, D, E, F, G).
NOTE: Analysis is done on Lead A only.



ECG electrode identification



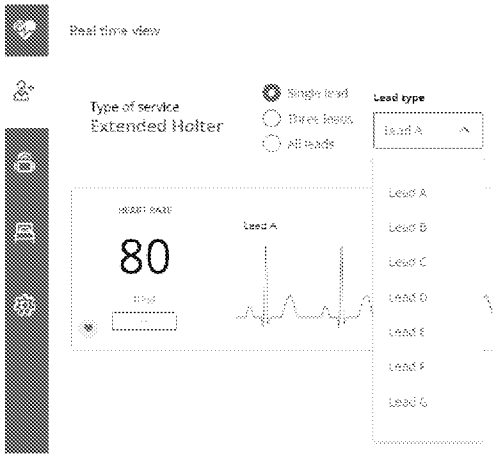
ECG channels transmitted



Polarity of measurements

The ECG lead display format options are selected using a radio button. The choices of lead options available to view include:

- Single lead - you can select either A, B, C, D, E, F, or G. Use scroll bar to select all available leads.



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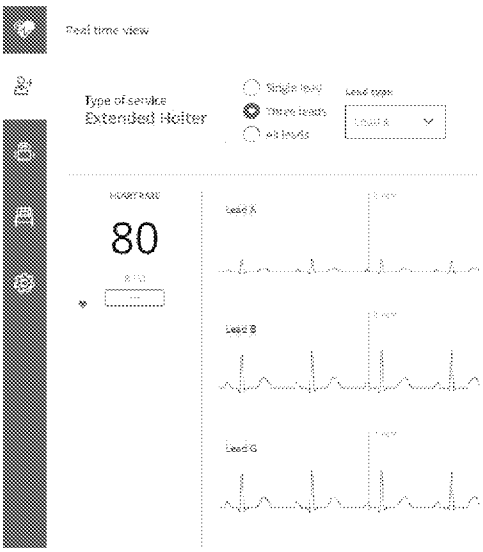
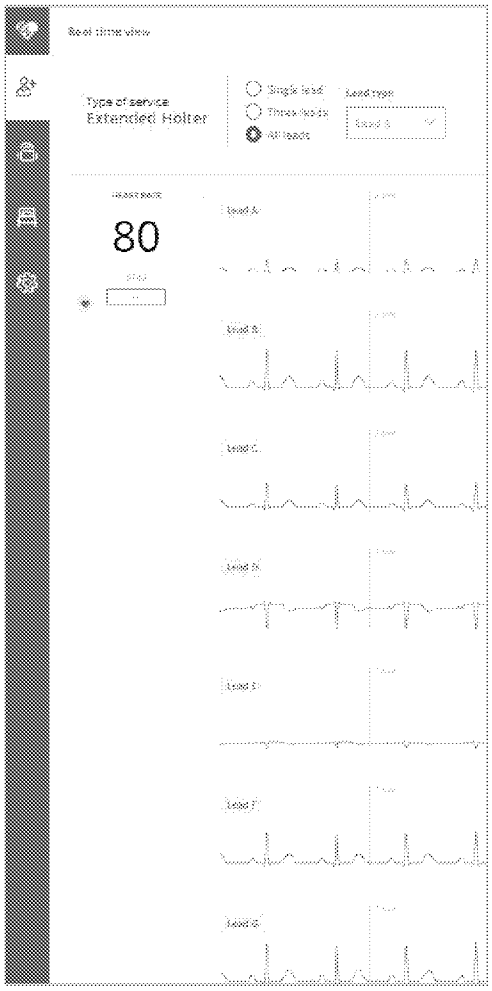
- Three leads - A, B, and G



- All seven leads - A, B, C, D, E, F, and G (Scroll down on the screen to view all leads)



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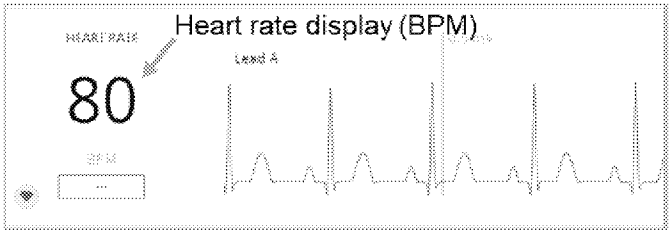
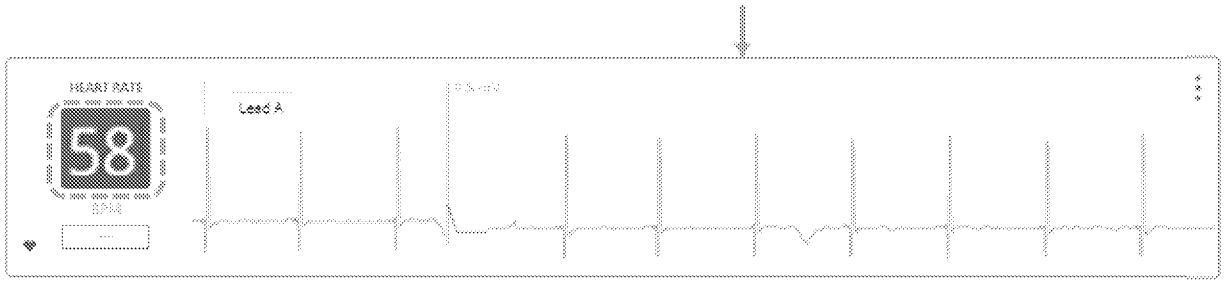
ECG Display

The lower section of the screen shows the real-time ECG. The number of leads and the specific leads selected are displayed.

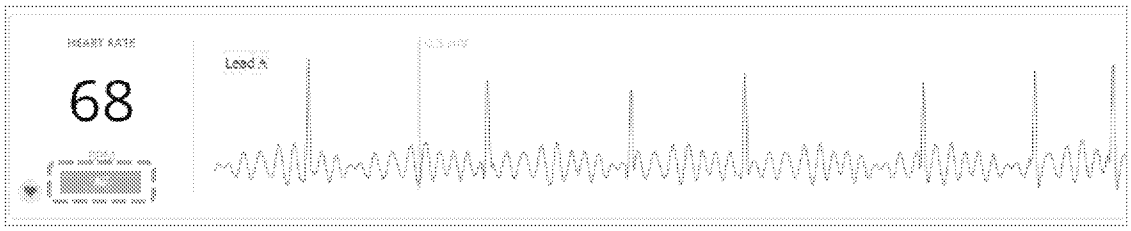
Heart rate (BPM) on the left



When the patient's heart rate is outside the set alarm limits, the patient tile is outlined in red, and the numerical heart rate box is shaded in red, and the high priority audio alarm sounds. In the example below, the patient's heart rate is outside the heart rate alarm limit setting. The patient tile is outlined in red, numerical heart rate display box shaded in red, and the high priority alarm sounds. See Alarms and Alarm Management section page 35 for additional information.

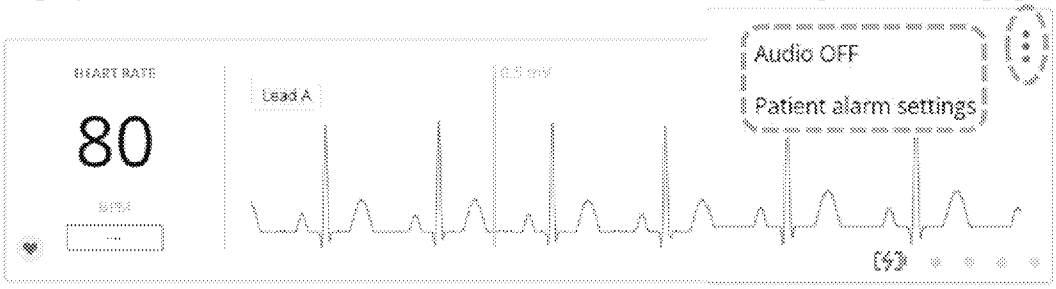


A visual alarm will be displayed in the case of atrial fibrillation. The following real time ECG view is an example of atrial fibrillation.



Navigation using Short Cut

A navigation shortcut using the three dots in the right upper corner of the ECG rhythm strip display selects "Audio OFF/Audio ON" or "Patient alarm settings" from the pop-up box.



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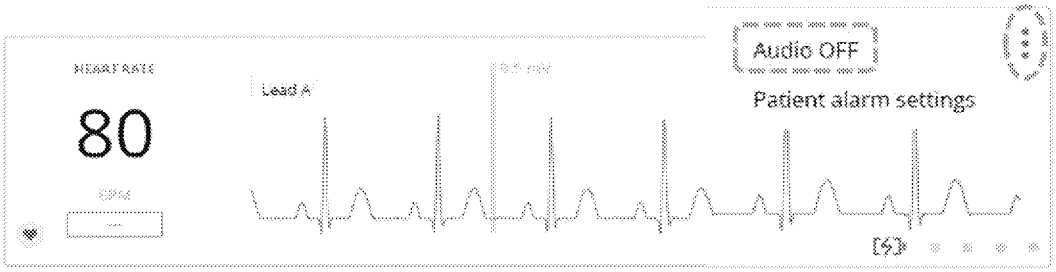
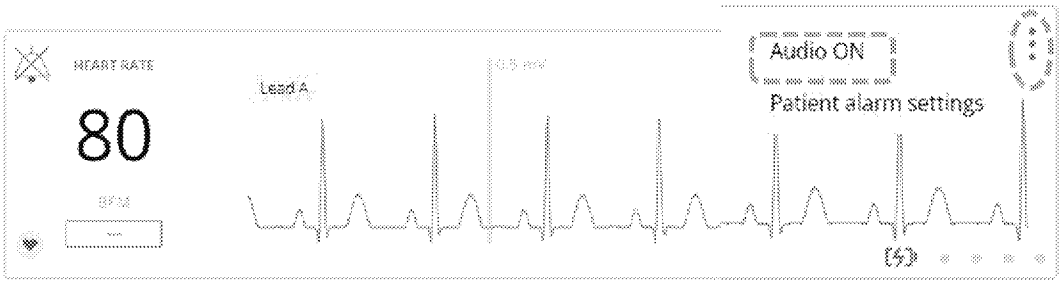
Short cut Audio OFF and Audio ON

In the right upper corner of the ECG rhythm strip display, clicking on the three dots brings up a pop-up box to select the alarm “Audio OFF” or “Audio ON” depending on the current audio alarm setting for the patient. In the strip below, the audio alarm is on and active. Therefore, the only option available to select is “Audio OFF” to turn off all audible alarms for this patient. Selecting “Audio OFF” for the patient, all auditory alarm sounds for that patient are turned off for five minutes



Audio OFF is indicated by a red “crossed bell” in the upper left corner of the patient tile. After five minutes of audio OFF, alarm audio turns ON automatically.



⚠	**WARNING: When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**

The SmartCardia 7L Platform checks the volume setting on the personal computer. If the volume is OFF or on Mute, a message will be shown in the top of the display.

If the volume is too low, the message will read "Low volume detected, please increase the volume of the computer".

Unmute and increase the volume of the computer to ensure auditory alarm signals can be heard.

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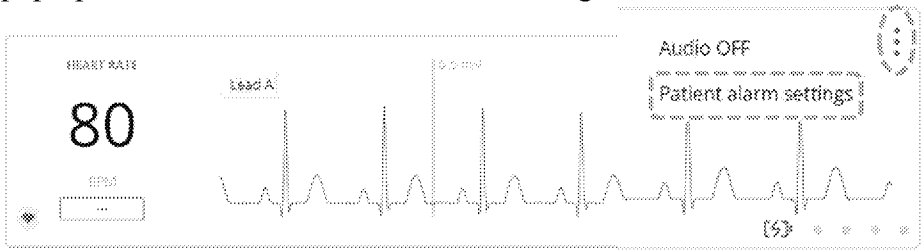
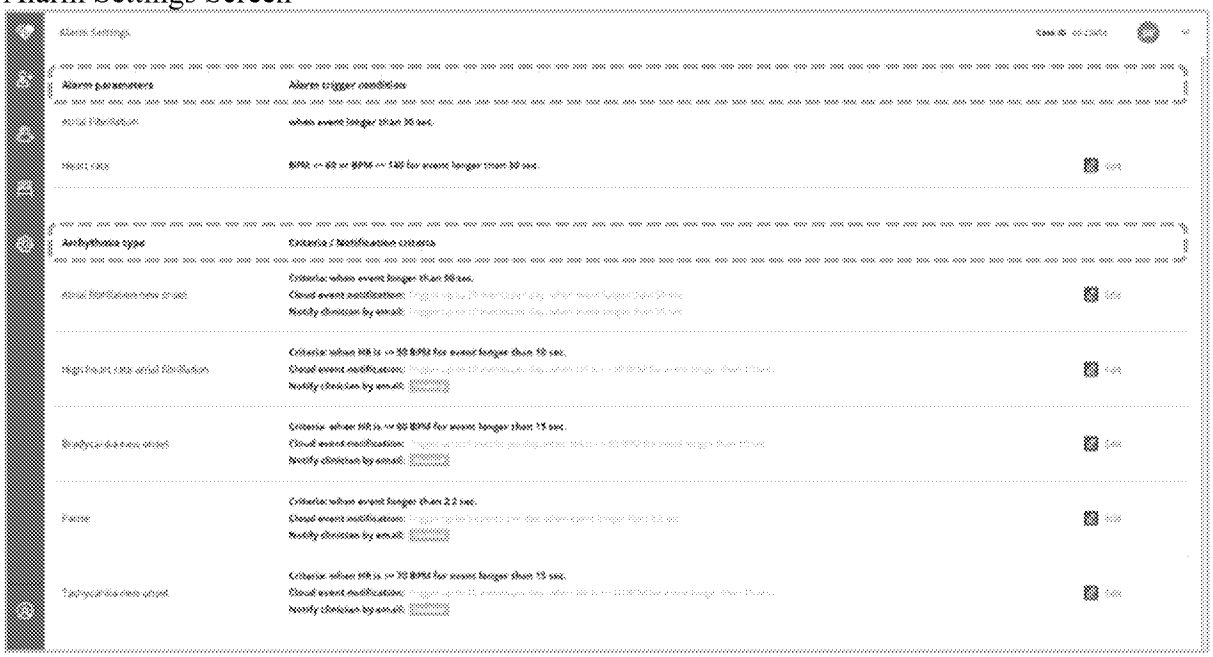
Short Cut to Patient Alarm Settings

In the right upper corner of the ECG rhythm strip display, clicking on the three dots brings up a pop-up box to select the “Patient alarm settings”.



Selecting “Patient alarm settings” takes you to the screen to adjust patient alarm parameters and arrhythmia notifications as shown below.

Alarm Settings Screen



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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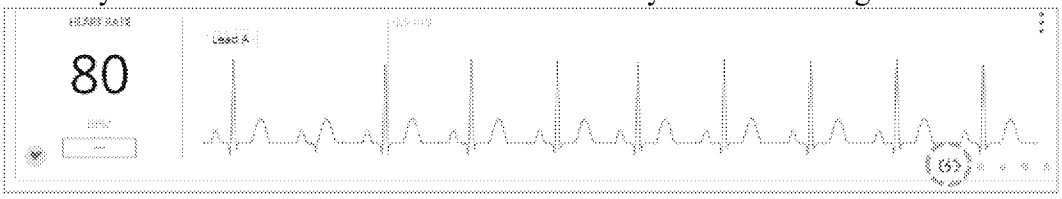
Battery Level Indicator

The device battery level of the *7L Patch / 7L Sensor* (device) worn by the patient is shown in the lower right corner of the ECG rhythm strip display. In the example below, the battery is critically low with 10% or less of the device battery level remaining.



Device battery is fully charged (100%)	
Device battery has 75% remaining	
Device battery has 50% remaining	
Device battery has 25% remaining	
Device battery level is critically low with less than 10% strength remaining	

NOTE: If the patient still needs monitoring, the patient should be contacted regarding direction to attach a new *7L Patch* according to facility protocol.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATTA@fda.hhs.gov or 301-796-8118

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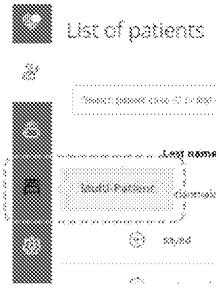
Multi-Patient View

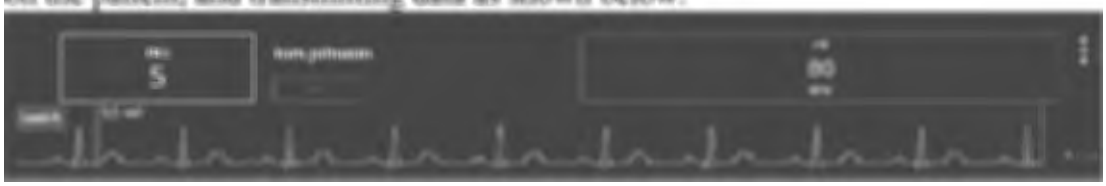
Multiple patient tiles can be viewed at one time. In this view, the clinician can view up to 12 patients at once on a single display screen. The data of many patients can be seen in a more detailed and comprehensive manner, similar to a hospital central monitoring unit. When a new patient is added they are automatically placed in a patient tile.
NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display.



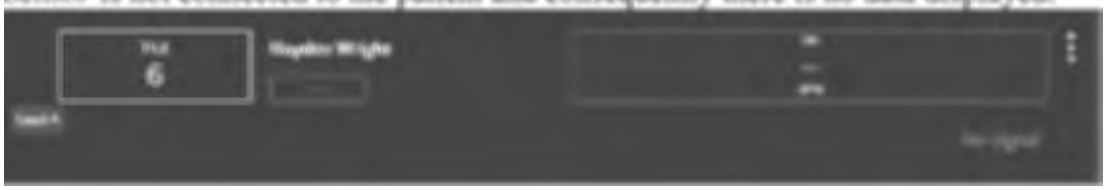
Select "Multi-Patient" on the left navigation menu to view all patients currently assigned to a patient tile.

In the Multi-Patient view, there are three variations of the patient tile screen display.

- The view when a patient is assigned to a patient tile, the *7L Patch* with the *7L Sensor* is on the patient, and transmitting data as shown below.



- This screen display below shows a patient is assigned to the patient tile but the *7L Sensor* is not connected to the patient and consequently there is no data displayed.



- This patient tile does not have a patient assigned.

	WARNING: When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.

Questions? Contact FDA/CDRH/OSEL/DAB at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118
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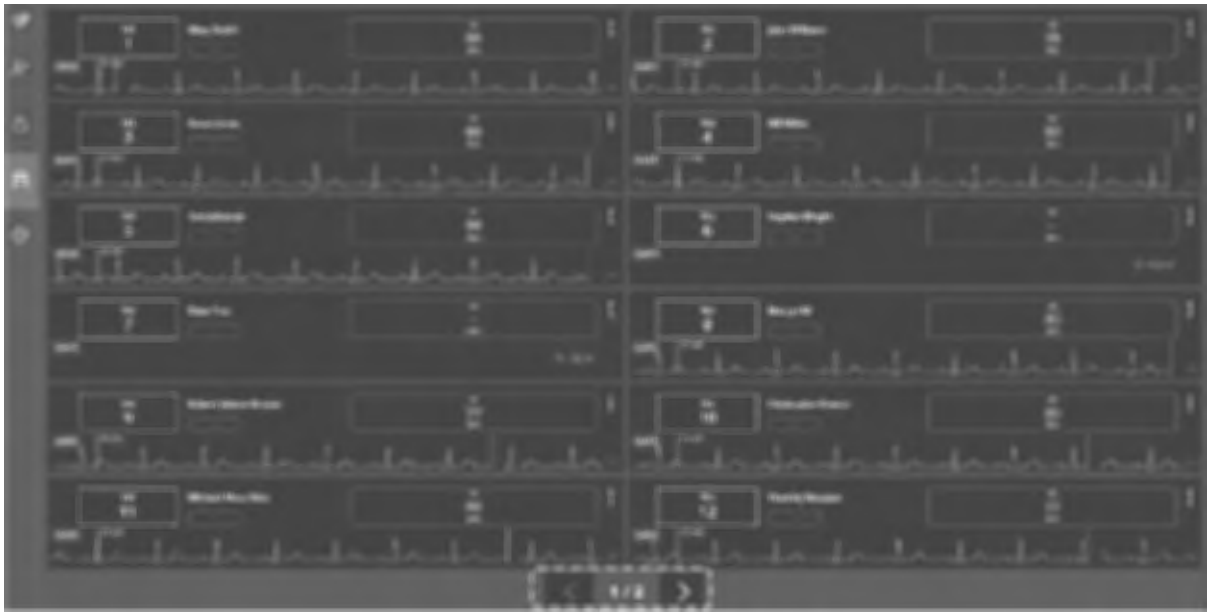
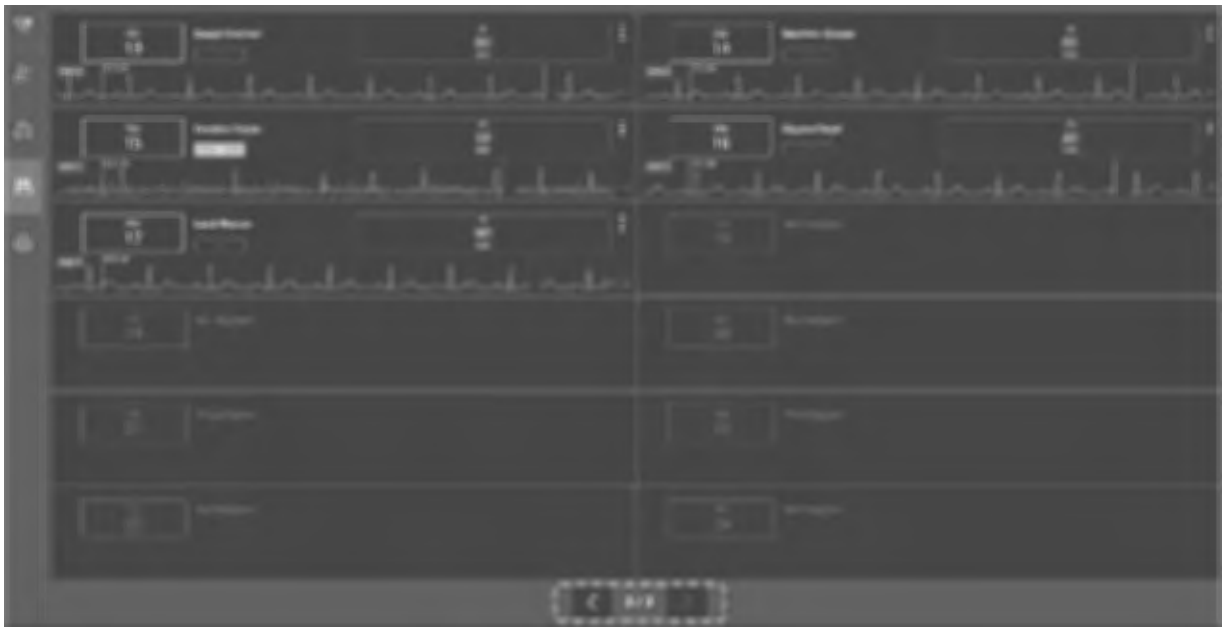
Multi-Patient View- using Multiple Displays

When monitoring more than 12 patients, ensure all patients are viewed at all times by opening another instance of the 7L Web Browser on additional displays.



Multi-Patient View- First instance of 7L Web Browser showing page one.
Display shows patient tiles 1-12



Multi-Patient View- Second instance of 7L Web Browser showing page two.
Display shows patient tiles 13-24

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATTS@fda.hhs.gov or 301-796-8118

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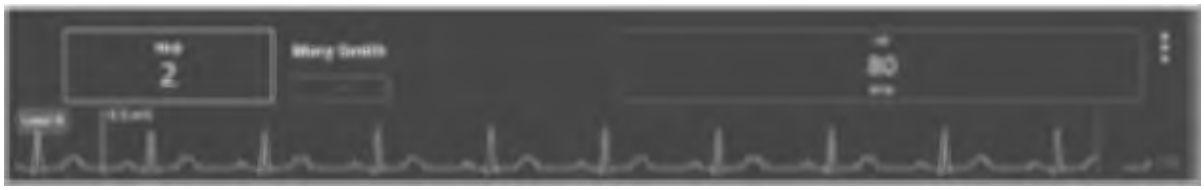
Patient Tile Display

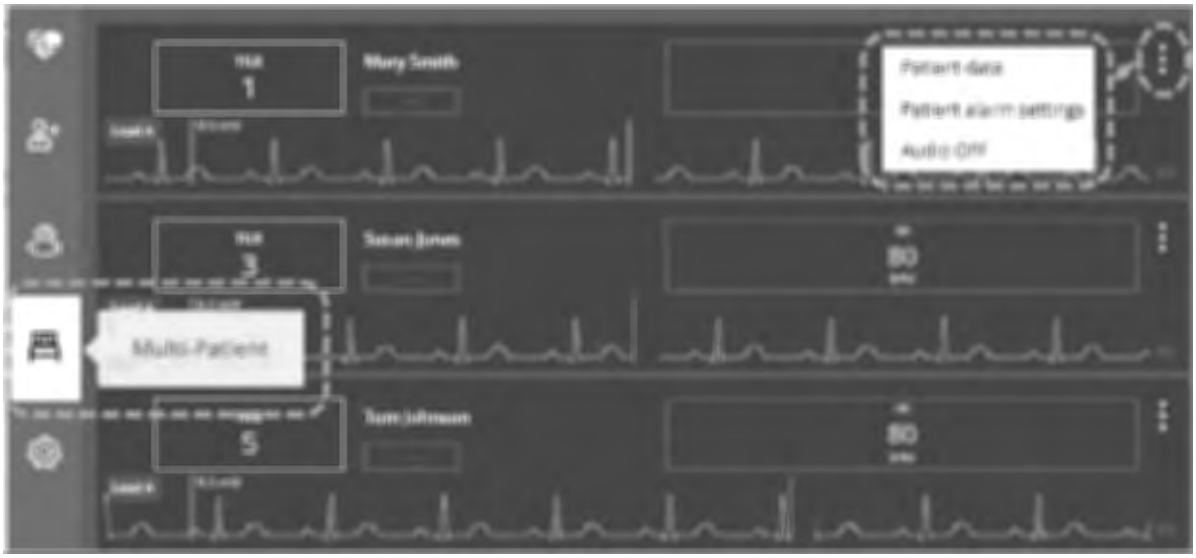
When a patient is assigned to a patient tile and the device is sending information in real time, the following information is displayed:

- Tile number
- Patient first and last name
- ECG signal
- Lead displayed
- Calibration pulse
- Heart rate beats per minute (BPM)



Navigation using Short Cut

There is a navigation shortcut using the three dots in the right upper corner of the patient tile display to select Patient data, Patient alarm settings, or Audio OFF/Audio ON.



Short Cut to Patient Data

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATTS@fda.hhs.gov or 301-796-8118

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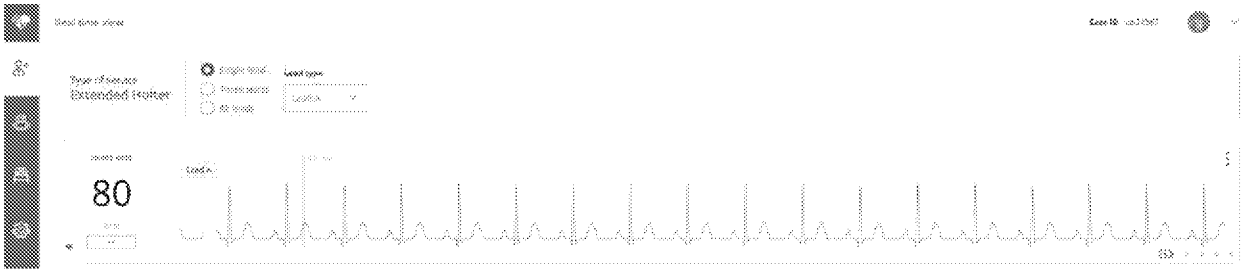
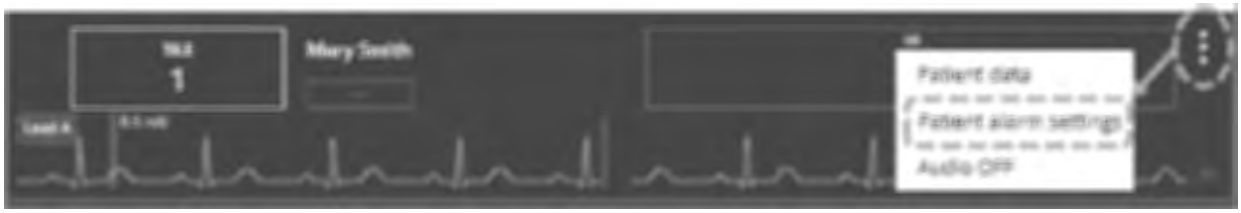
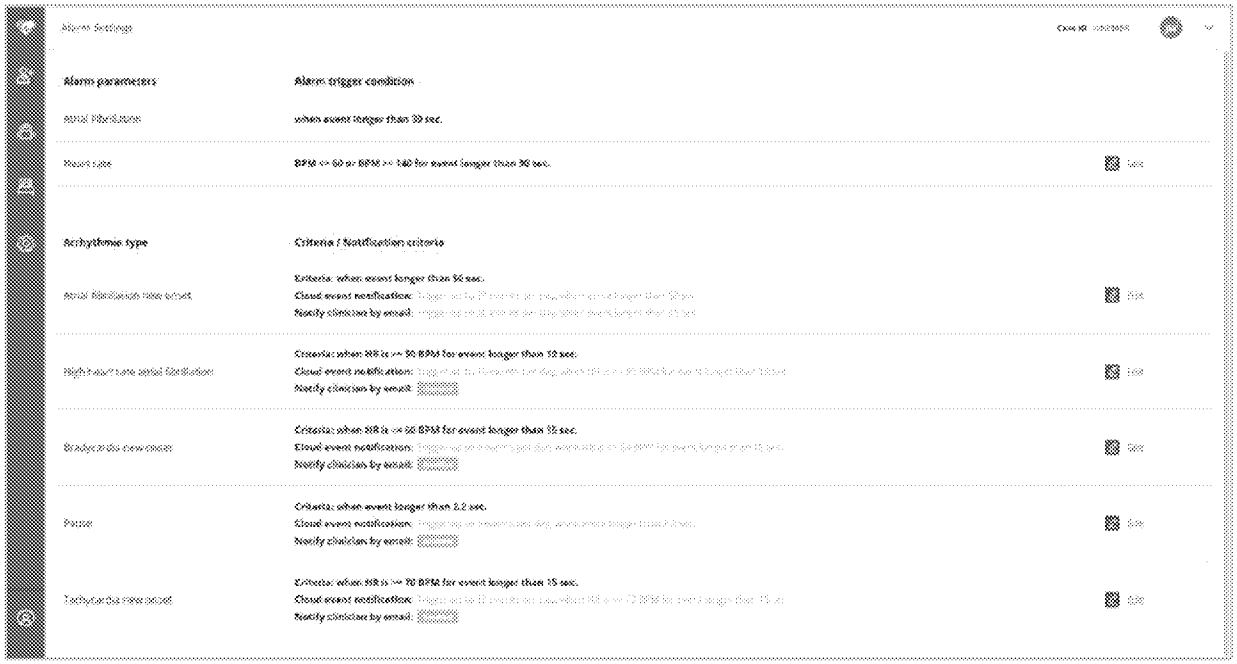
When you select “Patient data” the main patient information window opens displaying their “Real time view” of ECG. See page 43 for detailed information the patient’s real time view screen.



Short Cut to Patient Alarm Settings



Selecting “Patient alarm settings” takes you to Alarm Settings. Patient alarm and arrhythmia conditions and notifications can be adjusted as shown below. See Alarms and Alarm Management section on page 35 and Arrhythmia Event Notifications section on page 38 for additional information.



Questions? Contact FDA/CDRH/OCE/DHT8 at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118
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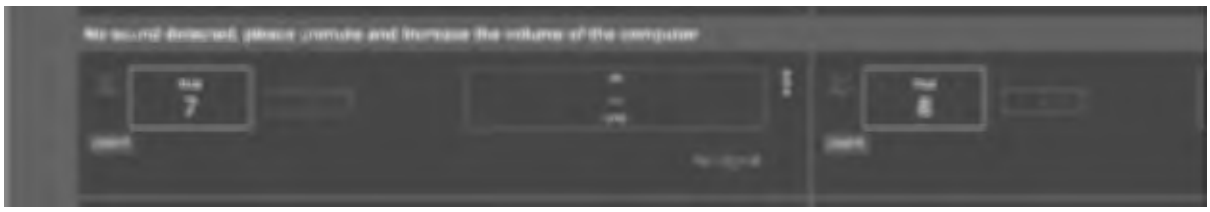
When you select “Audio OFF” all auditory alarm sounds are turned OFF for the selected patient. This is indicated by a red “crossed bell” in the upper left corner of the patient tile.

When Audio OFF is selected, the next time the menu is opened, it will show as Audio ON to turn on the auditory sound for all alarms. See page 49 for additional information.

⚠	**WARNING: When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.**

The SmartCardia 7L Platform checks the volume setting on the personal computer. If the volume is OFF or on Mute, a message will be shown in the center of the display.



If the volume is too low, the message will read "Low volume detected, please increase the volume of the computer".

Unmute and increase the volume of the computer to ensure auditory alarm signals can be heard.

Battery Level Indicator

When the battery level of the *7L Patch /7L Sensor* worn by the patient has less than 10% charge remaining the battery icon is shown in red on the lower right side of the patient tile. If the patient still needs monitoring, the patient should be contacted regarding direction to attach a new *7L Patch* according to facility protocol.

Questions? Contact FDA/CDRH/OCE/DHT9 at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118
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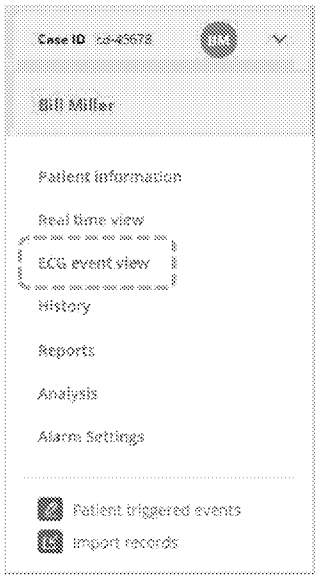
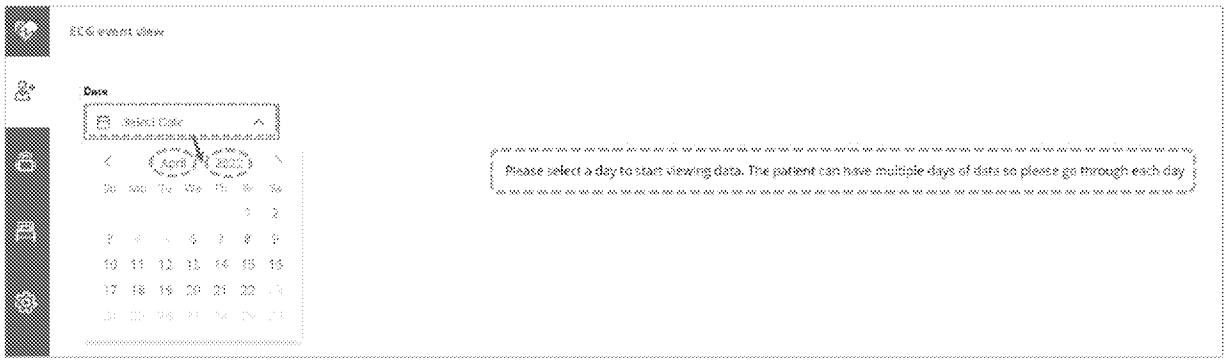
ECG Event View

On the patient page, select “ECG event view” on the expanded menu on the upper right side of the screen.



A screen will open to the calendar in the upper left corner and the message to select a day to start viewing data as shown below. The days where data is available are marked in black text, days when data is not available is grey text, and the current date is bold text. Use the calendar to enter the date to start viewing the data (to enter the year, select the year displayed then scroll to the one desired and select it. To enter the month, select the month displayed, then scroll to the appropriate one and select it.)



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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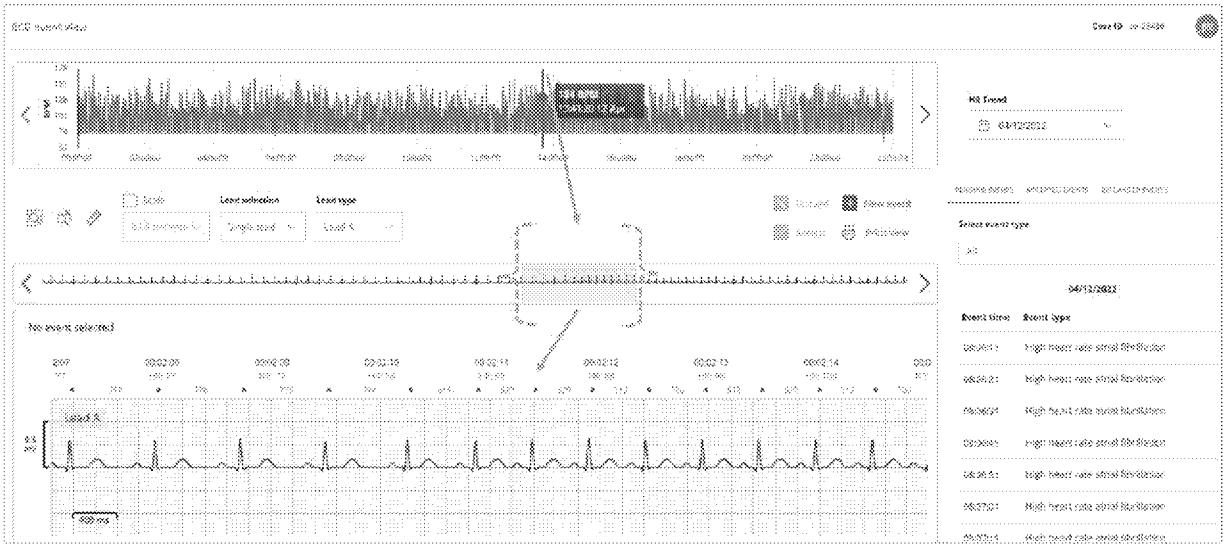
If there is available data, an image is shown as below.

Heart Rate Trend Display

At the top of the screen, there is a display of the heart rate trend shown over a 24-hour period. Clicking on any point in time there is data will show that selected section in the full disclosure bar display below and the rhythm strip from that point in time selected is also shown. The arrow keys on each side of the summary and full disclosure display provide scrolling backward or forward in time.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTATUS@fda.hhs.gov or 301-796-8118

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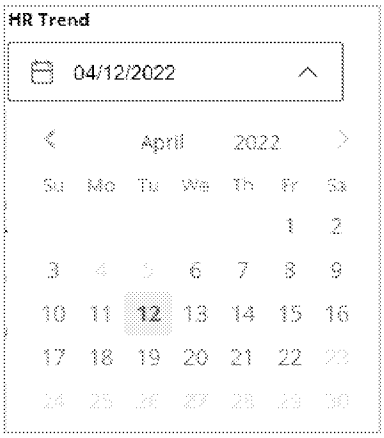
In this view with the data displayed, the calendar is in the upper right side of the screen. When the date box is clicked, a calendar appears. The days where data is available are marked in black text, days when data is not available is grey text, and the date currently being viewed is shaded in blue.



Review of Rhythm Strip

The tools below the HR Trend graph can be used to review and analyze the selected rhythm strip.

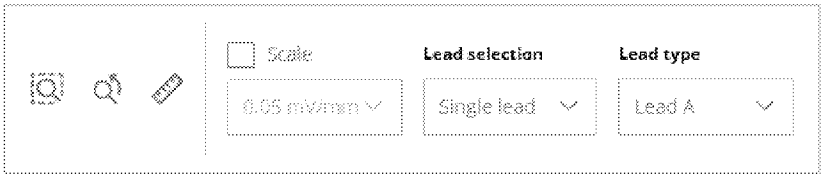
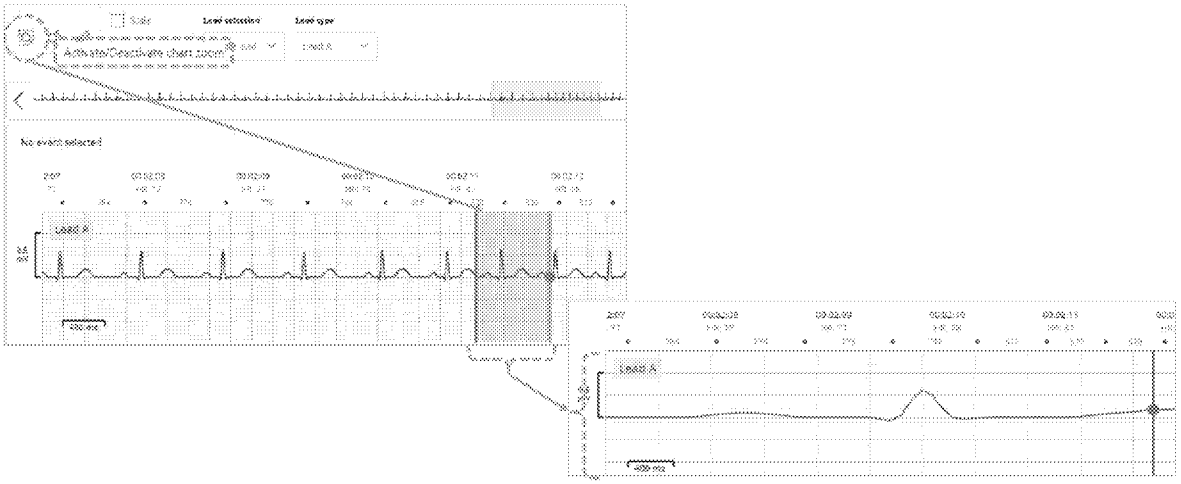


Chart Zoom

When Activate/Deactivate chart zoom is selected the icon turns red showing the tool is ready to use. On the rhythm strip, use a left mouse click at the beginning of the segment to enlarge and drag it over the area then left click to end. The zoomed in segment will display so that visual inspection can take place.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PDISTAFF2@fda.hhs.gov or 301-796-8118

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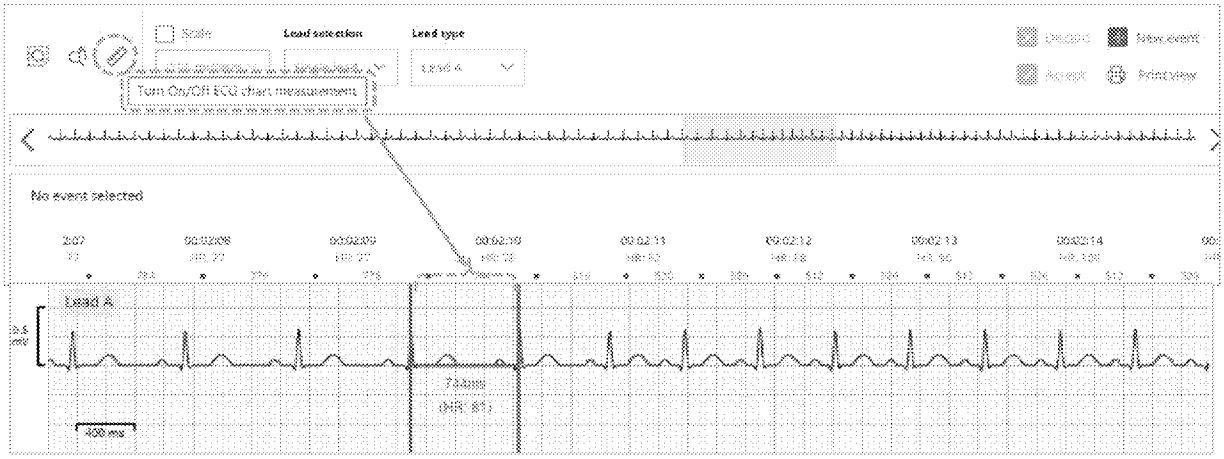
To return to the normal view, select the activate/deactivate chart zoom button again or select the restore chart zoom button.

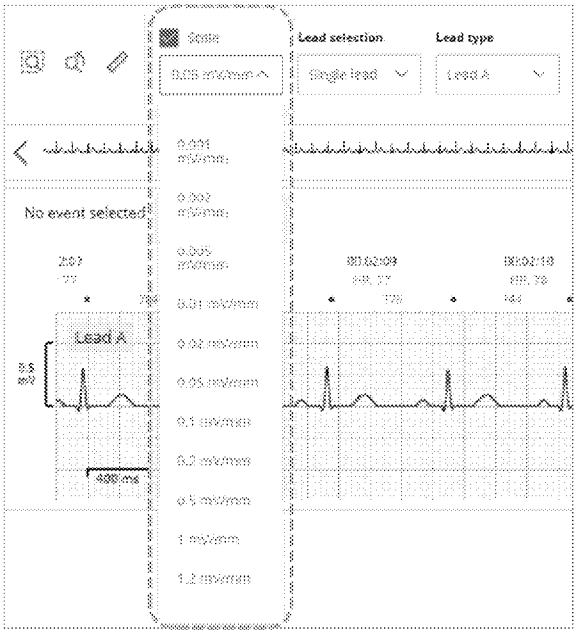
Measure



Heart rate can only be measured over one R-R interval. If you move the calipers to two R-R intervals, the heart rate will be one-half the actual rate.

Scale

The scale of each ECG graph is measured in millivolts per millimeter on the Y-axis. It is calculated automatically, but it can be changed by selecting the “Scale” box then choose the desired setting.



Questions? Contact FDA/CDRH/OHT5/DHP at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118

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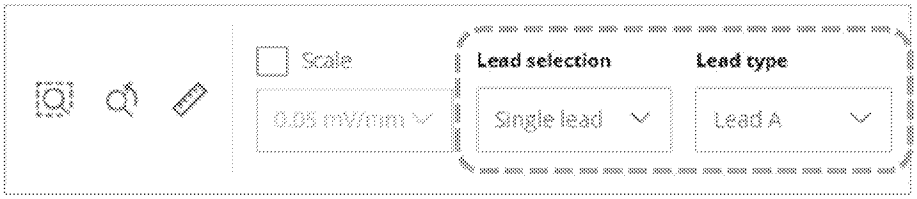
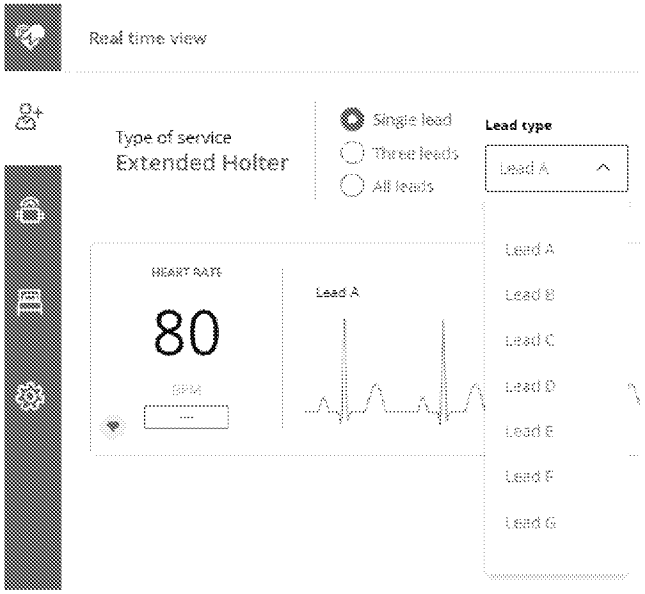
ECG Lead Display

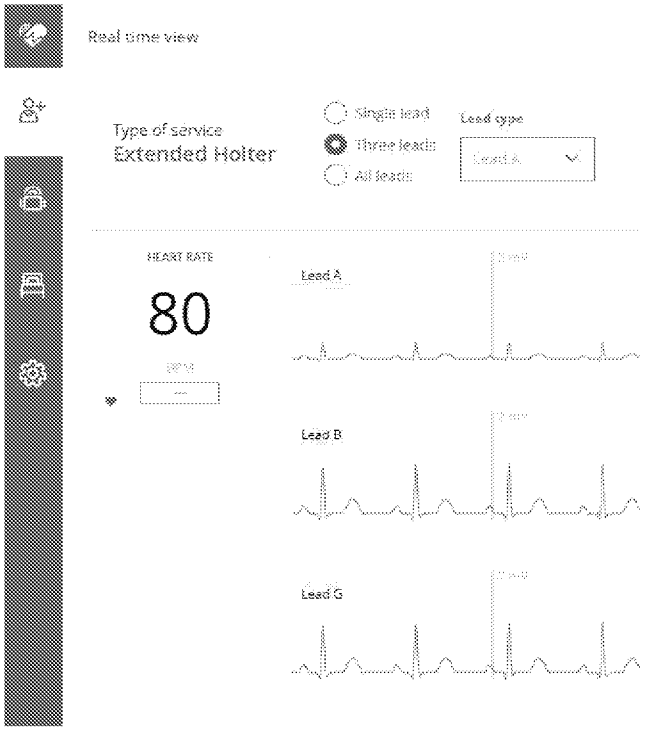
The ECG lead display format options are selected using a radio button.



- Single lead - you can select either A, B, C, D, E, F, or G



- Three leads -A, B, and G



Questions? Contact FDAAccessData@fda.hhs.gov or 301-796-8118

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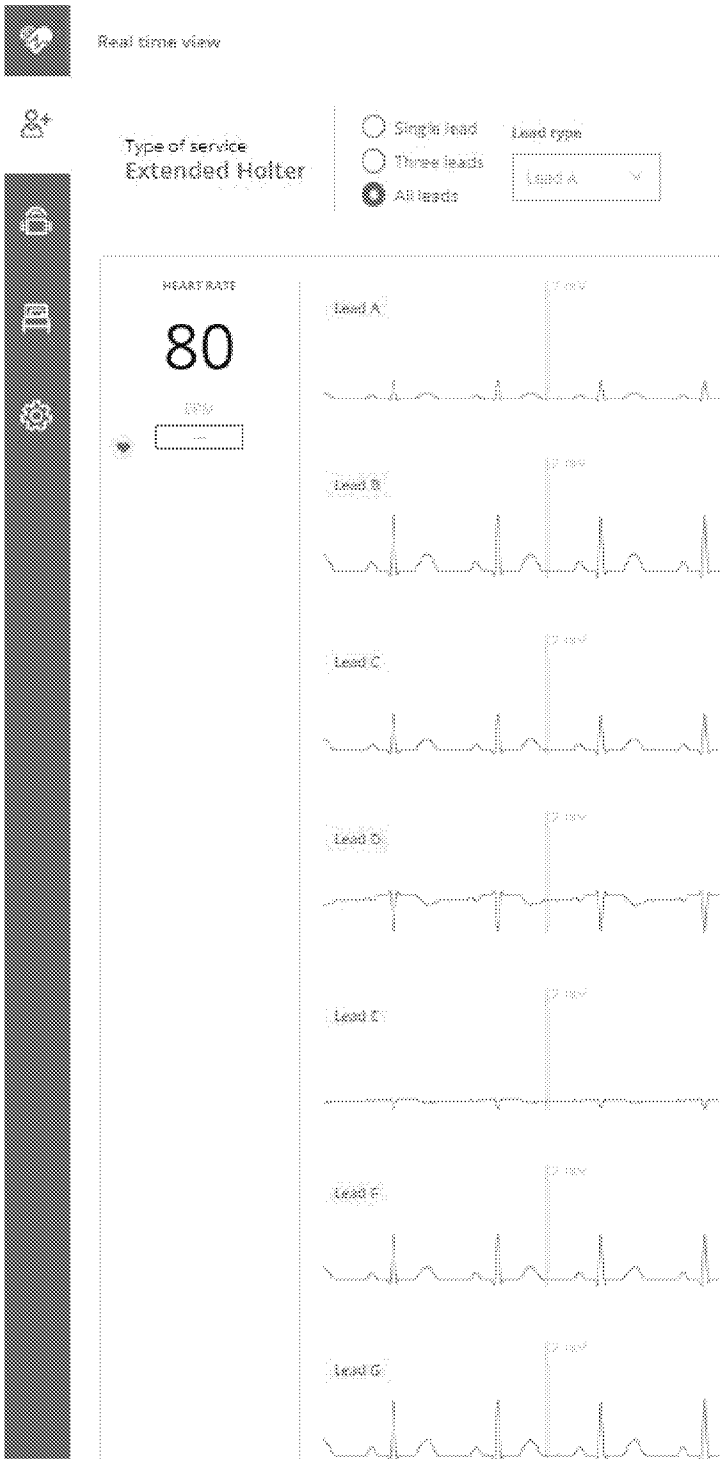
- All seven leads - A, B, C, D, E, F, and G (Scroll down on the screen to view all leads)



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATIS@fda.hhs.gov or 301-796-8118

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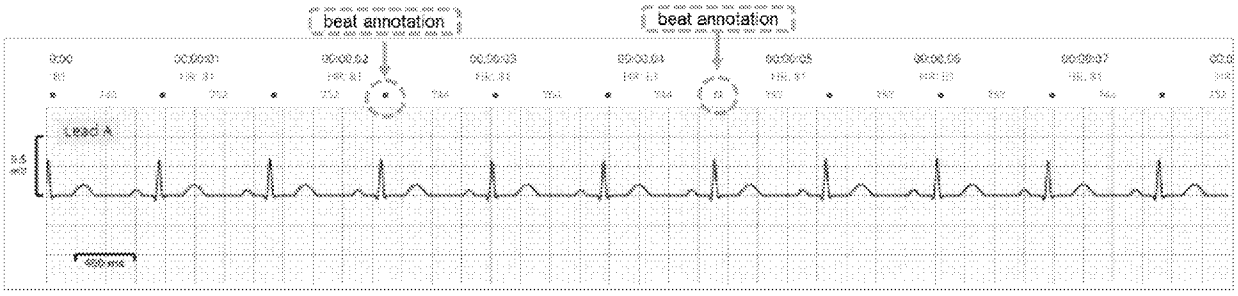
Beat Identification

The beat annotation is displayed as " ● " when a beat is detected by the 7L Sensor. Once Analysis processing is completed by the analysis service, beat types N, V, and SV are automatically detected by the analysis tool and labeled on the ECG. If the user wants to indicate the presence of a heartbeat that was not previously located, this new heartbeat must belong to one class. If the class cannot be determined, but the presence of the heartbeat must be explicitly indicated, the user can use the 'Indeterminate' class, which describes the beats that cannot be labeled clearly. The following table shows the list of heartbeats that can be marked on the ECG graph.

Label	Description	Definition
?	Unknown beat type	Clinician must always indicate a label classification Automatic annotation by SmartCardia analysis tool
N	Normal shape beat	Normal beat Automatic annotation by SmartCardia analysis tool
V	Ventricular Extrasystole	QRS complex arising from an ectopic focus in the ventricles of abnormal shape and duration. Also used to mark premature ventricular contractions (PVCs) Automatic annotation by SmartCardia analysis tool
SV	Supraventricular Extrasystole	Premature contraction arising from an ectopic focus above the bundle branches (includes the SA node, atria, and AV junction) Automatic annotation by SmartCardia analysis tool
I	Indeterminate Single Beat	Abnormal beat that cannot be identified

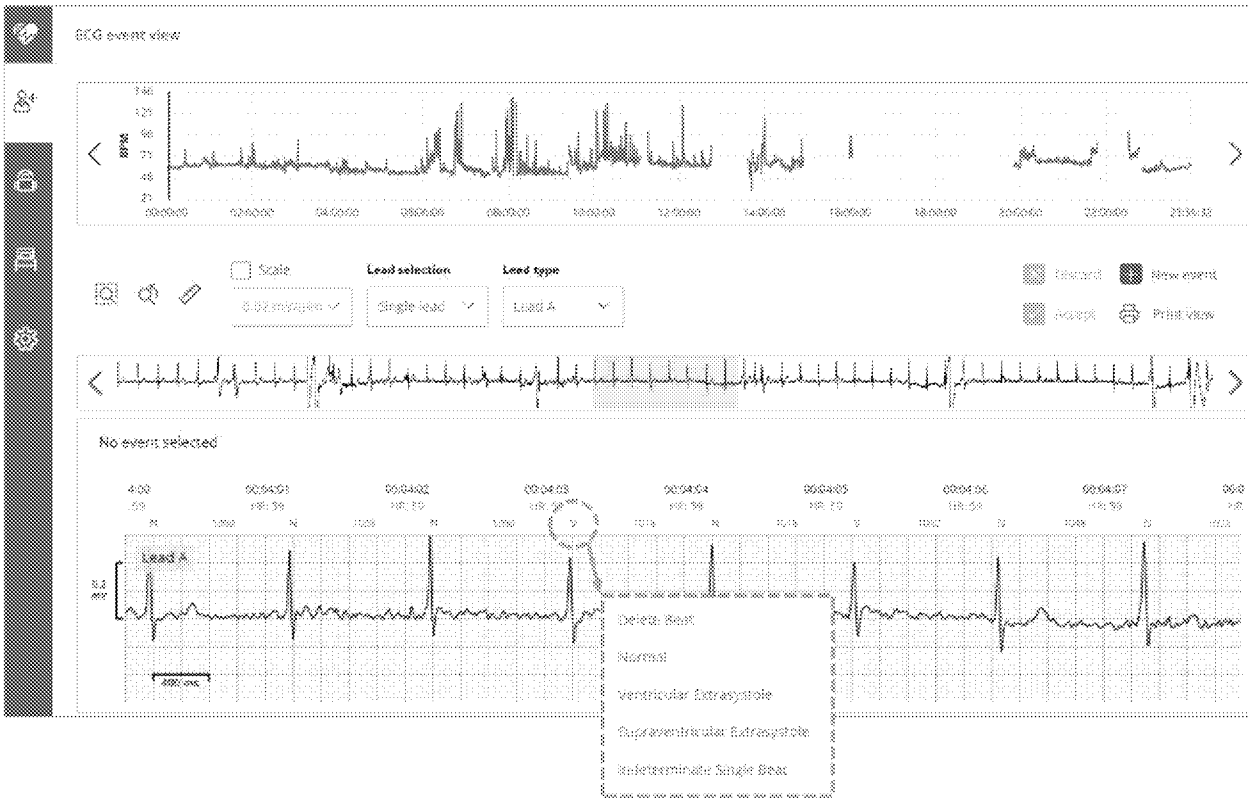
Beat Annotation

In one lead, three leads, and seven lead ECG views, the annotation for each beat is located at the top of the ECG graph. The annotation is either a letter label such as ?, N, V, SV, I, or " ● ".

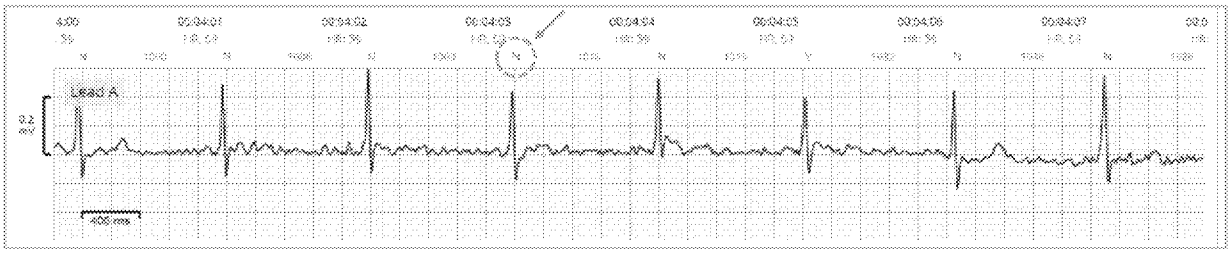


Clicking the mouse on any annotation brings up a pop-up box to delete or change the annotation for that beat. Choices include Delete Beat, Normal (N), Ventricular Extrasystole (V), Supraventricular Extrasystole (SV), and Indeterminate Single Beat (I).

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATRS@fda.hhs.gov or 301-796-8118



Once the new annotation is selected it replaces the one that was previously shown.



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-BIOSTATHB@fda.hhs.gov or 301-796-8118

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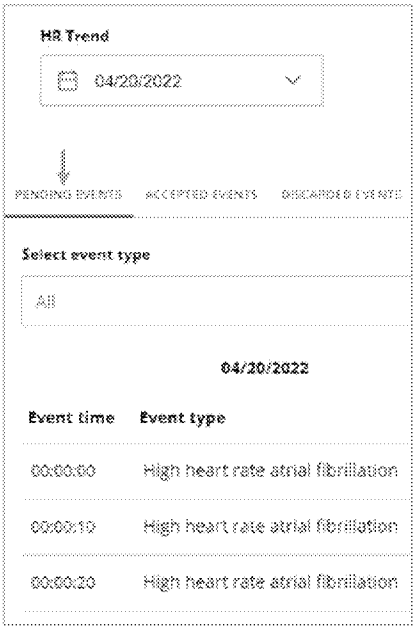
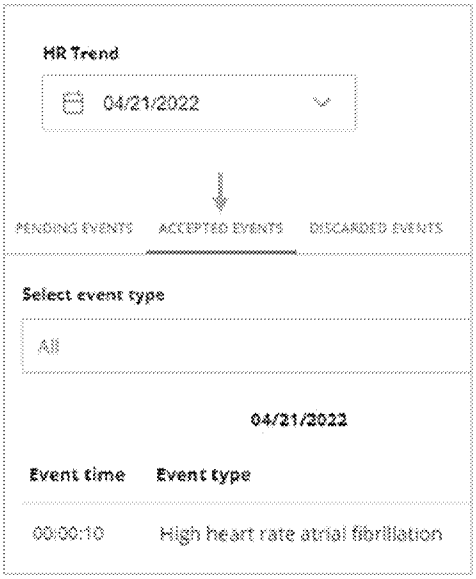
List of ECG Events

On the right-hand side of the screen is the list of events. The event date, time, and type of event are listed. There are tabs to view PENDING EVENTS, ACCEPTED EVENTS, and DISGARDED EVENTS. Select each one to view the respective list of events. Click on the box below “Select event type” to bring up the drop-down list of various arrhythmia events to filter the events listed.

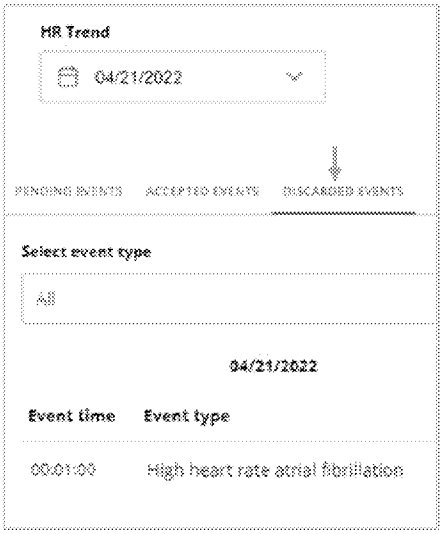
PENDING EVENTS



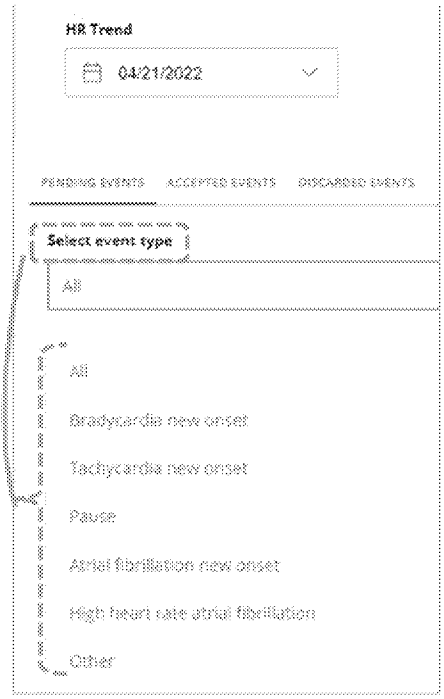
ACCEPTED EVENTS



DISCARDED EVENTS



Select event type to view



Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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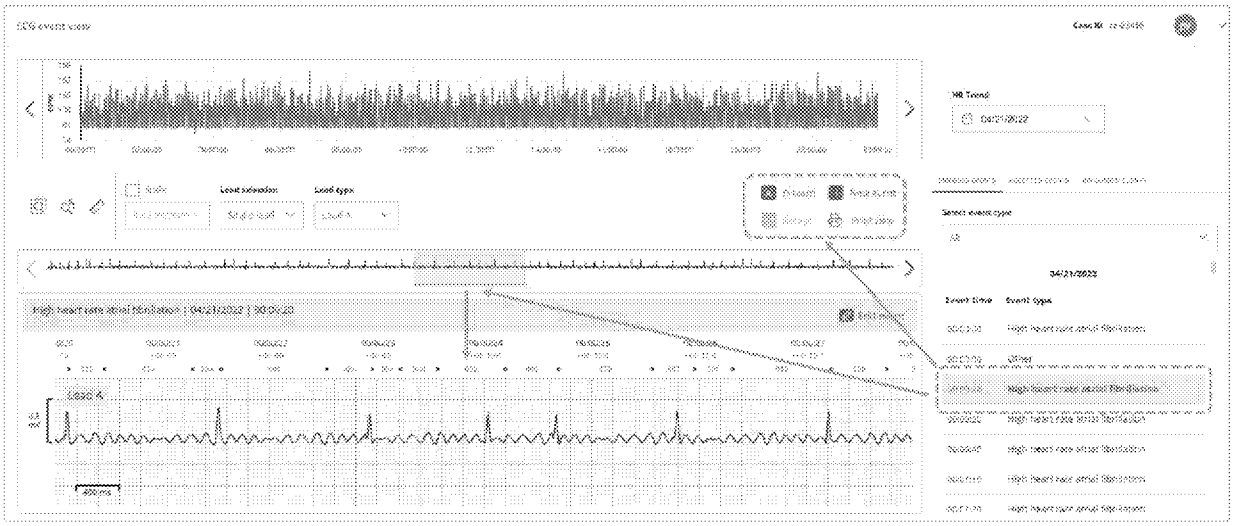
Select the event to review, analyze, and change any annotated beats. The event selected is shaded in blue. Notice the red line under the selected segment in the full disclosure bar indicating this is a listed event.



When an event first occurs, it is pending. After review of the event, it is either accepted or discarded by selecting the appropriate button.

In the following list of events, the red bell indicates that the clinician was notified of that event by email.

Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATS@fda.hhs.gov or 301-796-8118

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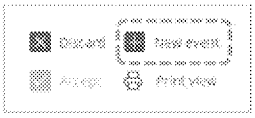
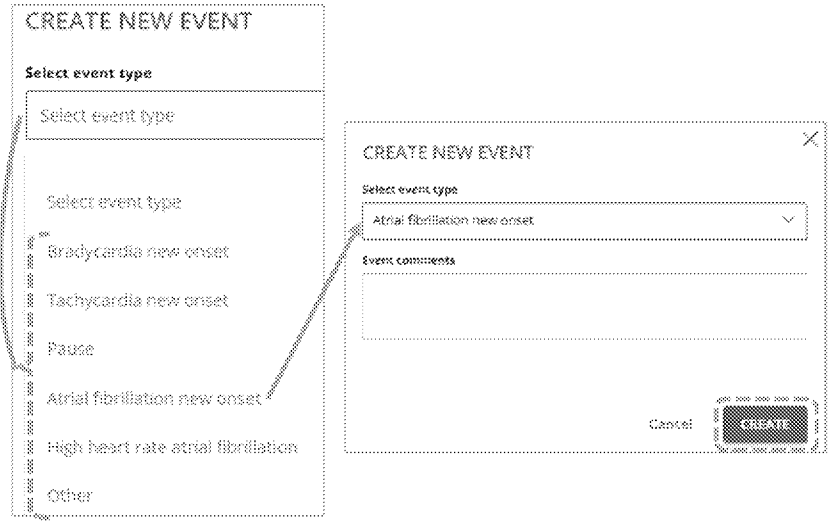
Create New Event

To document a new ECG event, select the “New event”.

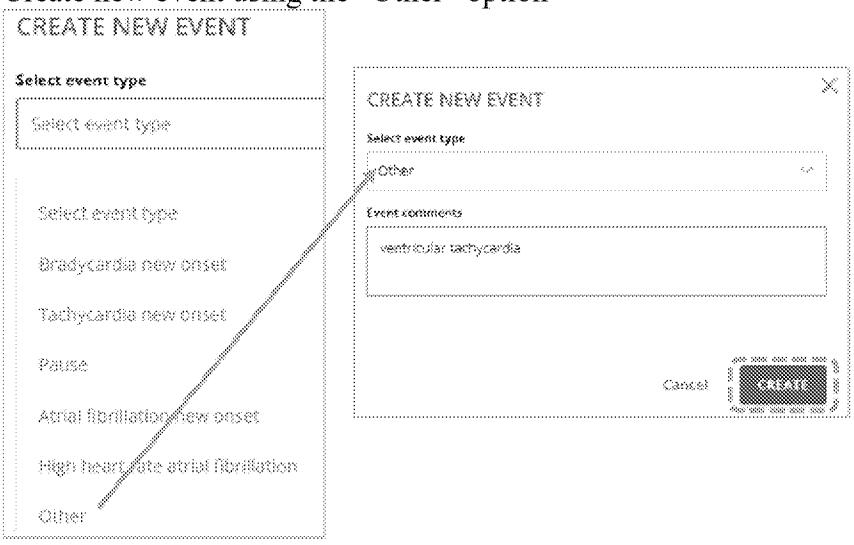


Select event type from drop-down menu and add any comments, then select “CREATE”. This new event will be listed under PENDING EVENTS. It can be reviewed and analyzed then either accepted or discarded.

Create new event from list of arrhythmia types



Create new event using the “Other” option



Questions? Contact FDA/CDRH/OCE/DHP at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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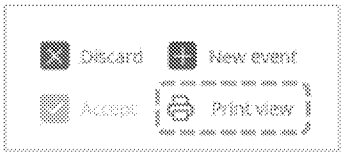
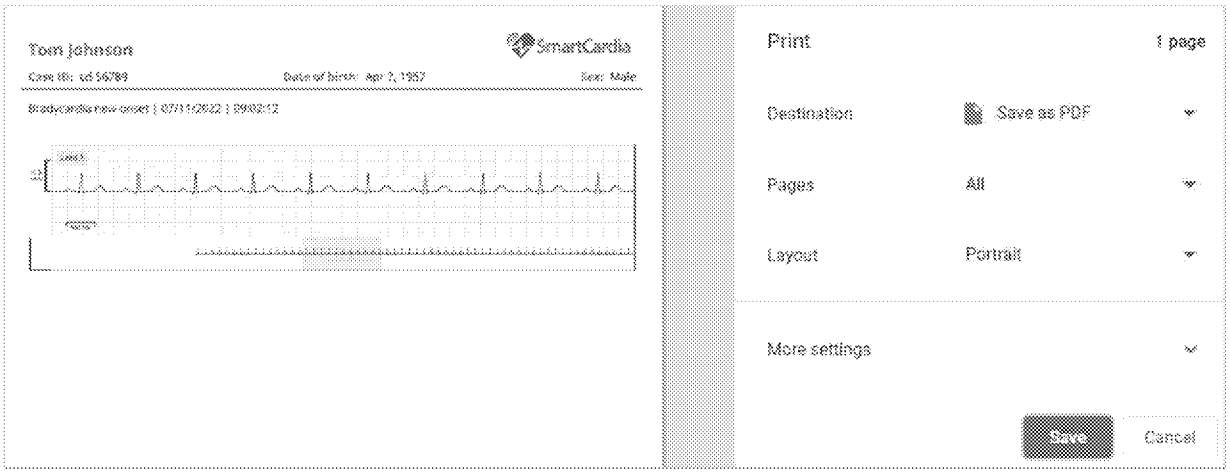
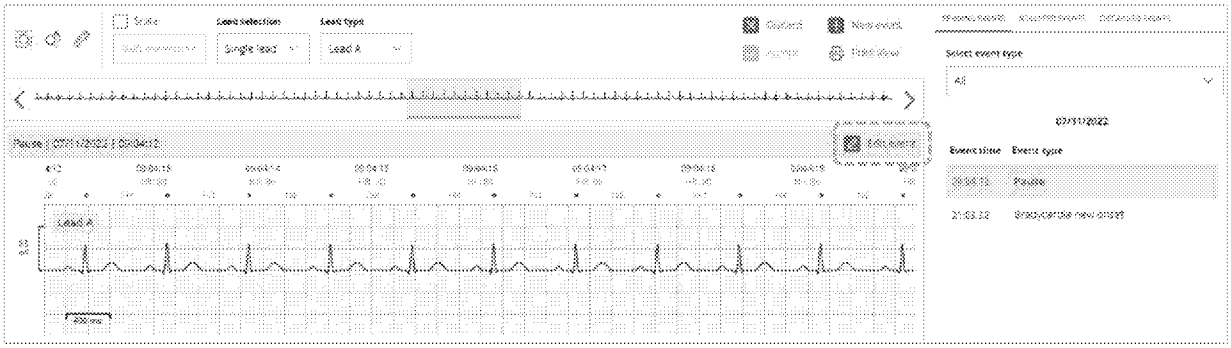
Print View

Print view can be selected and print the copy or cancel print

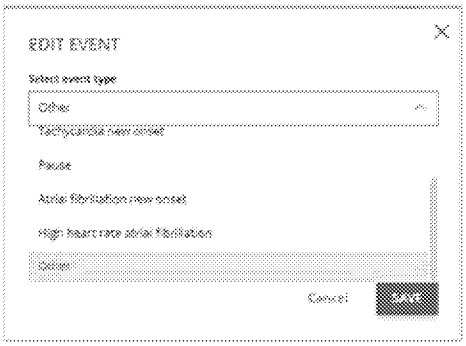


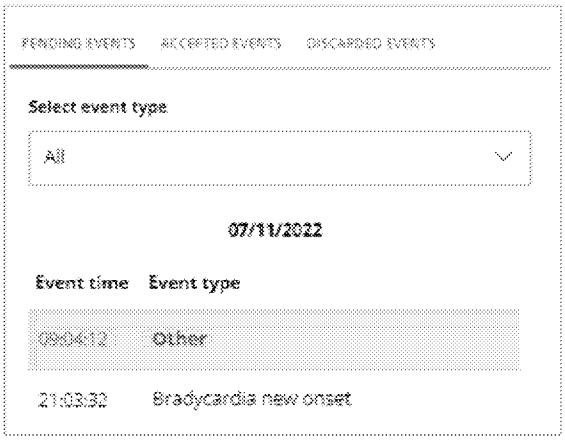


Edit Event



Select Edit event, choose the event type, and SAVE to complete the edit.





Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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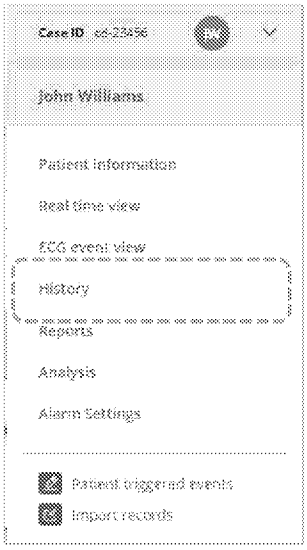
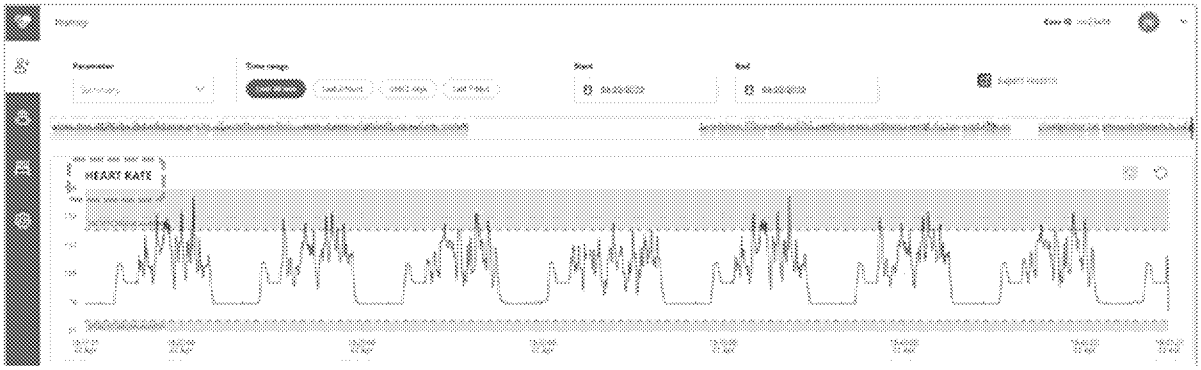
History

On the patient page, select “History” on the expanded menu on the upper right side of the screen.



The summary view displays heart rate when data is available.



Parameter and time range are two sections in the header at the top of the screen. In addition, the start and end date to review can be selected.

Questions? Contact FDA/CDRH/OCE/DHB at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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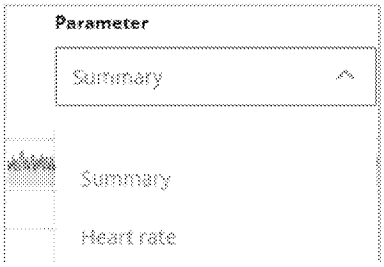
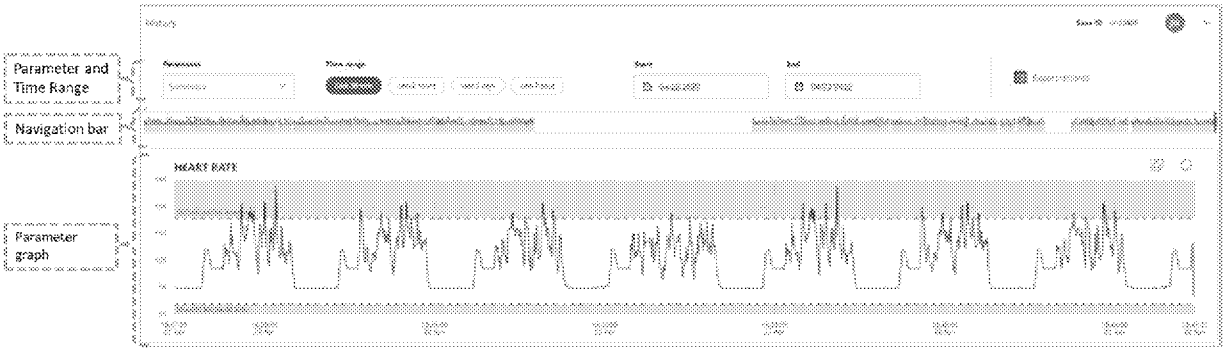
Parameter

At the top of the list is the summary option which displays heart rate graphs all in one view. Selecting the parameter box provides the option to view only the heart rate graph.



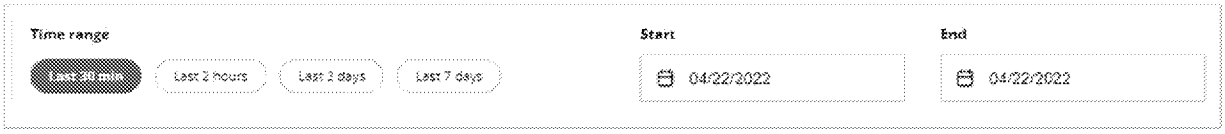
The summary and parameter page contains three elements:

- Header with the sections of parameter, time range, start and end date
- Navigation bar that displays the time of data
- Parameter graph



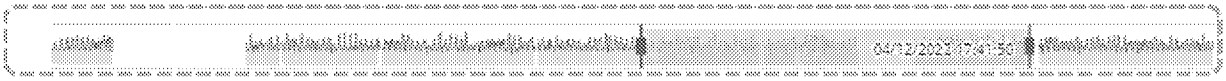
Time Range

In the time range section, data can be displayed for the last 30 minutes, 2 hours, 2 days, or 7 days. The calendar can also be used to select the start and the end dates of the data to display.



Navigation Bar

The bar shown just below symbolizes the graph of heart rate values in the period of the patient's stored data. The section appears blank if there is no data and shaded in gray when there is data. Sliding the blue bars can adjust the time of the data displayed.



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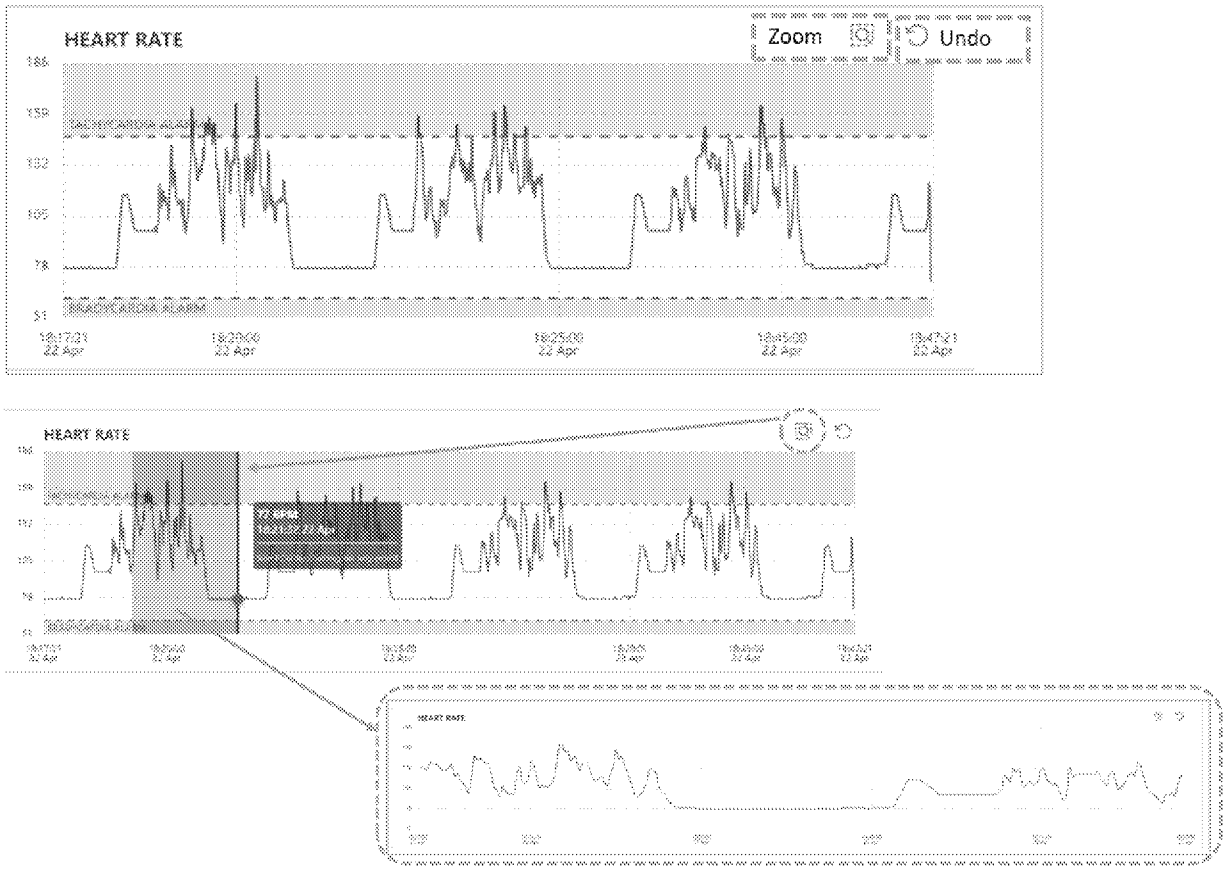
Parameter Graph

The summary view includes a parameter graph of the heart rate graph all in one view. In the graph, the x-axis shows the dates, and the y-axis shows the units of the parameter. If there is no data, the graph is blank. When data is available and inside the set limits, it is displayed in gray and data outside of the set limits is red. The threshold limits for the parameter are marked in the graph.

Chart Zoom

The parameter graph has the same format with the tools to review the graph in detail at the top right corner (Zoom, Undo, and Restore). The user can zoom in on an area of interest by activating the "Zoom" function (icon turns from grey to blue). Once it is active mark a point on the graph and drag it to the desired place. The undo function returns to the original time.



In the history summary, the graph displays a line, when the user moves the mouse over it, the line indicates the point of time in the plot. Moreover, if the user clicks in the plot, a pop-up window appears where the user can see 30 seconds of ECG centered at the click point.

When the user passes the mouse over the graph, the following information is observed:

- Heart rate
- Time and date

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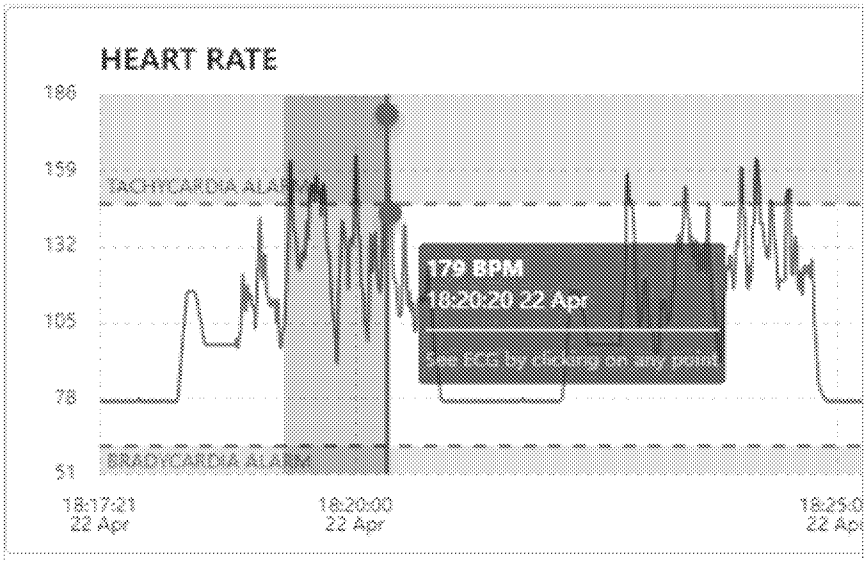
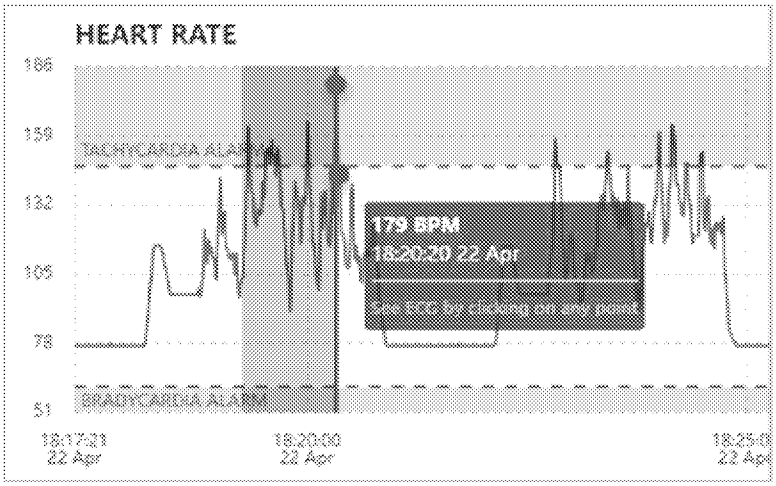
The heart rate graph is displayed in beats per minute (BPM). The red dotted line indicates the thresholds for tachycardia and bradycardia, respectively. The area above is shaded in red, indicating tachycardia alarm. Similarly, the area below is shaded in red indicating bradycardia. When the mouse is moved over the graph, the information box displays the heart rate value at that time with the date and time listed.



Clicking on one of the blue circles in the graph or on the bar line in the picture below, brings up the ECG graph observed at that precise moment and is displayed in the following picture below the summary graph.



The blue line in the middle of the rhythm strip indicates the exact time selected on the parameter graph. Selecting the arrows on either side of the displayed rhythm move forward or backward in time to review the ECG data.

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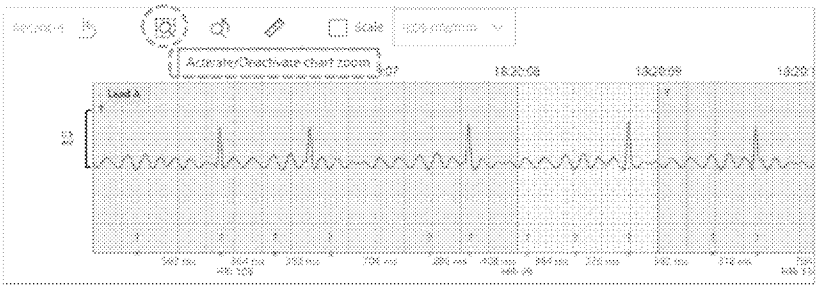
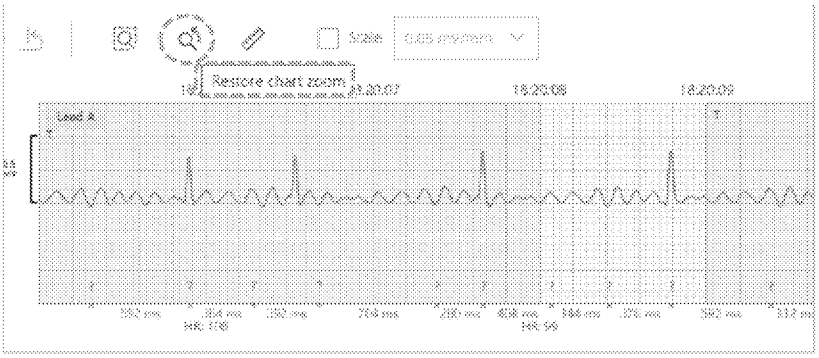
The yellow shading indicates an alarm condition is present. When two or more alarm conditions occur, the yellow shading is darker. The section at the end of the strip that is not highlighted indicates the ECG is within set thresholds and no alarm occurred.

The following functions found in the upper left corner are available to review the ECG rhythm strip:

- Activate/deactivate chart zoom



- Restore chart zoom



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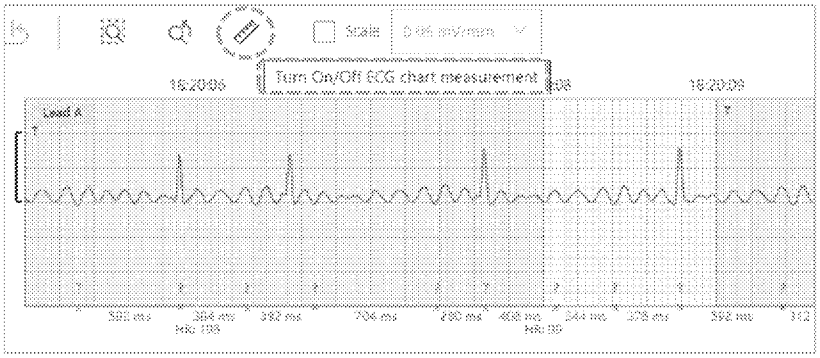
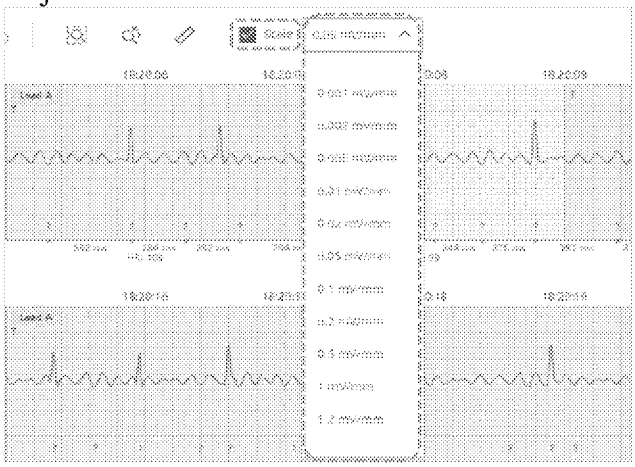
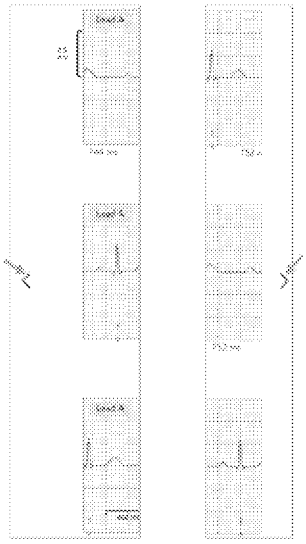
- Turn on/off ECG chart measurement



- Adjust scale as needed



To view more data scroll through the ECG using the arrow keys.



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The “Recentre” (Recenter) button in the upper left corner can be used to return instantly where previously clicked.

At the top left corner of the rhythm strip the rhythm is identified with AFIB or an initial for the rhythm type.

Rhythm Types

The following chart lists the rhythm labels, description, and any related notes. Unless stated in the "Note" column, the rhythm is not automatically marked by the 7L Platform and can only be manually marked by a clinician/technician.

Label	Description	Note
NSR	Normal Sinus Rhythm	
A	Artifact or Noise	Extra spikes, waves, or complexes in signal
AFIB	Atrial Fibrillation	Automatic annotation by SmartCardia analysis tool
VFIB	Ventricular Fibrillation	
AFL	Atrial Flutter	
VFL	Ventricular Flutter	
MAT	Multi-focal Atrial Tachycardia	

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Label	Description	Note
VT	Ventricular Tachycardia	Automatic annotation by SmartCardia analysis tool
T	Tachycardia	Automatic annotation by SmartCardia analysis tool
Vx1	Isolated Ventricular Heartbeat	Also called VEB Automatic annotation by SmartCardia analysis tool
Vx2	Ventricular Couplet	Also called V Couplet Automatic annotation by SmartCardia analysis tool
Vx3	Ventricular Triplet	Also called V Triplet Automatic annotation by SmartCardia analysis tool
VRUN	Ventricular Run	Run of 4 or more VEBs. Automatic annotation by SmartCardia analysis tool
V2	Ventricular Bigeminy	Automatic annotation by SmartCardia analysis tool
V3	Ventricular Trigeminy	Automatic annotation by SmartCardia analysis tool
SVx1	Isolated Supraventricular Heartbeat	Also called SVEB Automatic annotation by SmartCardia analysis tool
SVx2	Supraventricular Couplet	Also called SV Couplet Automatic annotation by SmartCardia analysis tool
SVx3	Supraventricular Triplet	Also called SV Triplet Automatic annotation by SmartCardia analysis tool
SVRUN	Supraventricular Run	Run of 4 or more SVEBs. Automatic annotation by SmartCardia analysis tool
SV2	Supraventricular Bigeminy	Automatic annotation by SmartCardia analysis tool
SV3	Supraventricular Trigeminy	Automatic annotation by SmartCardia analysis tool
AV1	AV Block (First degree)	
AV2	AV Block (Second degree)	
AV3	AV Block (Third degree)	
P	Pause	Automatic annotation by SmartCardia analysis tool
B	Bradycardia	Automatic annotation by SmartCardia analysis tool
ASYS	Asystole	
PM	Pacemaker Rhythm	
MaxHR	Maximum HR	*Meta-label* to indicate that the segment contains an example of maximum heart rate of the recording Automatic annotation by SmartCardia analysis tool
MinHR	Minimum HR	*Meta-label* to indicate that the segment contains an example of minimum heart rate of the recording Automatic annotation by SmartCardia analysis tool
REPORT	Printable Strip	*Meta-label* denoting that this strip is of interest for a report

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Heartbeat Types

The type of heartbeat is shown in blue in the lower line of the graph. The red x indicates a beat was detected.

The beat types N, V, SV, and ? are automatically detected by the analysis tool, while the user can manually add /edit the rest. If the user wants to indicate the presence of a heartbeat that was not previously located, this new heartbeat must belong to one class. If the class cannot be determined but the presence of the heartbeat must be explicitly indicated, the user can use the 'Indeterminate' class, which describes the beats that cannot be labeled clearly. The following table shows the list of heartbeats that can be marked on the ECG graph.

Label	Description	Definition
?	Unknown beat type	Clinician must always indicate a label classification Automatic annotation by SmartCardia analysis tool
N	Normal shape beat	Normal beat Automatic annotation by SmartCardia analysis tool
V	Ventricular Extrasystole	QRS complex arising from an ectopic focus in the ventricles of abnormal shape and duration. Also used to mark premature ventricular contractions (PVCs) Automatic annotation by SmartCardia analysis tool
SV	Supraventricular Extrasystole	Premature contraction arising from an ectopic focus above the bundle branches (includes the SA node, atria, and AV junction) Automatic annotation by SmartCardia analysis tool

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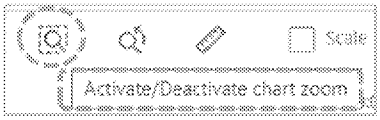
Label	Description	Definition
M	Missing QRS. This occurs in a heartbeat when the QRS complex is not present or not visible.	QRS complex is not present or not visible for a heartbeat
P	Paced beat	Beat from artificial pacemaker
F_V	Ventricular Fusion Beat	More than one electrical impulse fires at the same time in the ventricles causing the resulting complex to be varied in configuration and height
F_A	Atrial Fusion Beat	More than one electrical impulse fires at the same time in the atria with the resulting complex varied in configuration and height
X	Phantom Beat	Unclassified beat
I	Indeterminate Single Beat	Abnormal beat that cannot be identified

Chart Zoom

The chart zoom function can be activated and deactivated using these tools.

- Activate/Deactivate chart zoom



- Restore chart zoom

In the example below, the chart zoom icon is red indicating it is activated. The darker yellow shaded area was selected by placing the mouse cursor on the beginning point to review and dragging it to the last point to review.

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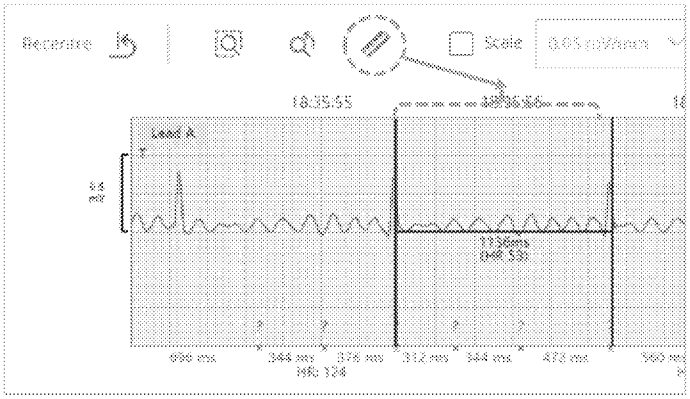
The example below shows the top strip with the highlighted beats using the zoom function. The second strip shown, is the normal view which can also be expanded using the zoom function if desired.

ECG Chart Measurement

ECG chart measurement can be turned on to analyze the ECG in more detail. The gray icon indicates the measurement function is off and red shows measurement is on as pictured below. The location of R peaks and the time between consecutive R peaks can be measured in milliseconds and heart rate is shown. The amplitude can also be measured in mV and displayed in the information box.



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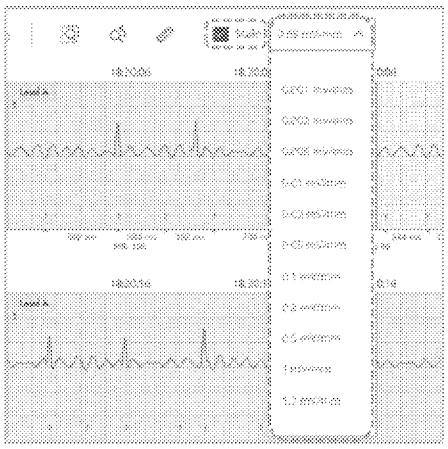
Scale for Display

The scale for rhythm display can be adjusted as desired.



After review of the detailed ECG chart view use the X to exit this screen to return to the graph view.

Export Records

From this view in “History”, clinicians can export the signals of a patient in the SmartCardia files’ format (*.SC). These files can be uploaded (imported) again to the same patient.

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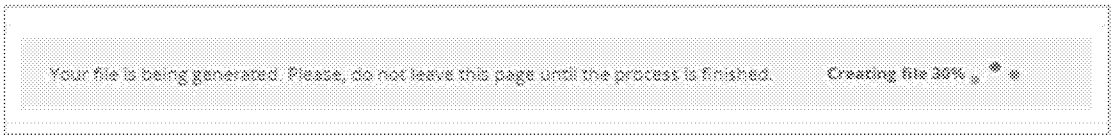
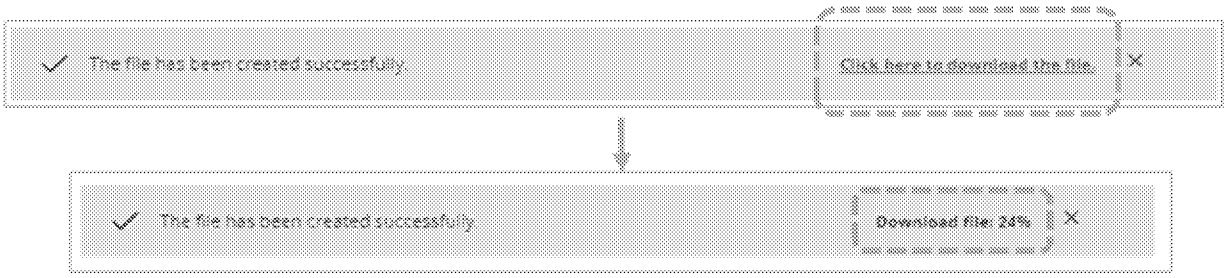
To create a *.SC file with the signals of a patient, a clinician must select the time range using the navigation bar. They can also use the buttons at the top-left corner to select one of the pre-defined options (last 30 minutes, last 2 hours, last 2 days and last 7 days with data). Select “Export records”

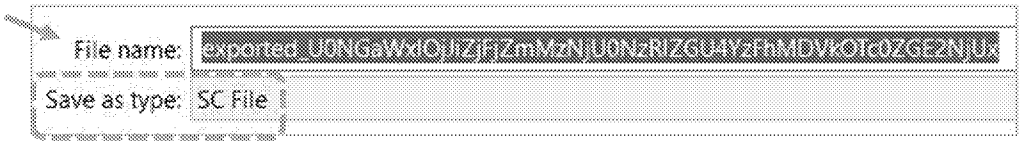
When selecting a large amount of data, the following message will show the progress of file generation and reminder to not leave this page until the process is finished.



Once the process finishes and the file is ready to be downloaded, the user will see a notification with a link. Clicking on that link will start the download process. A message will state the progress of the file download.



Clinicians must select the path and the name of the recording, and the file will be downloaded.



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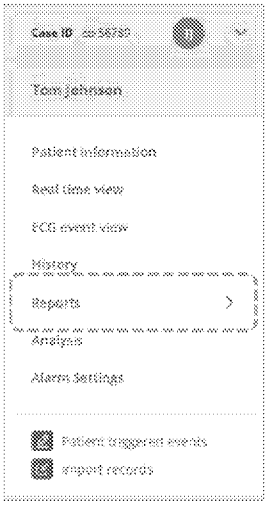
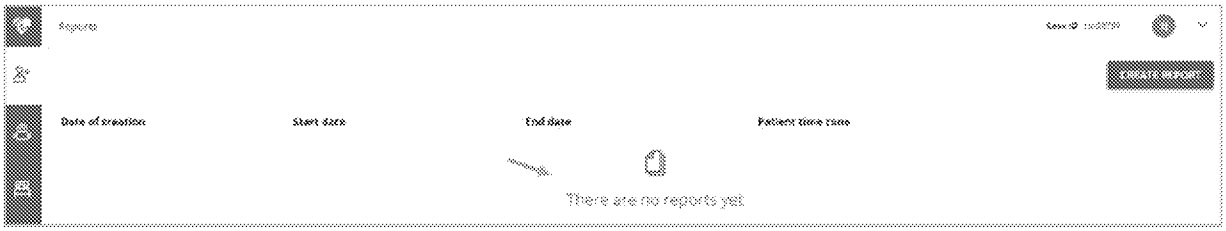
Reports

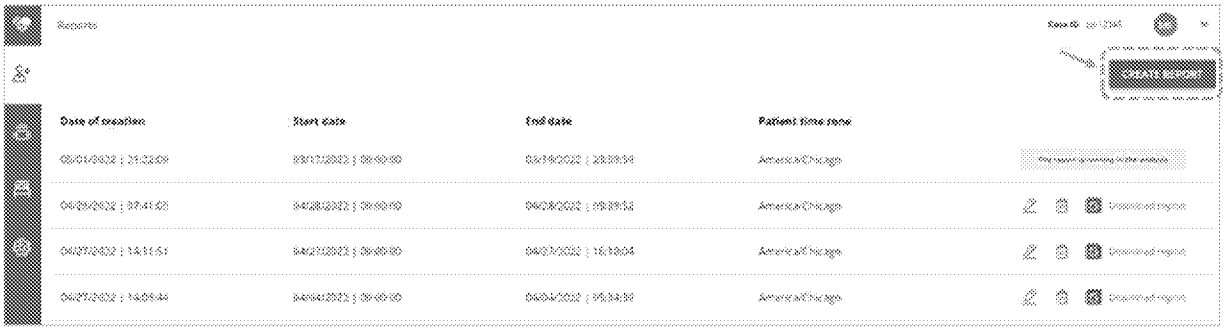
Reports of Analysis done for a patient can be managed by selecting “Reports” from the expanded menu on the upper right side of the screen.



If there are no reports available for the patient, there is a statement on the list of reports page that says, ‘There are no reports yet’.



This page below displays the list of reports that have been generated for the patient.
To generate a new report, select “CREATE REPORT”.



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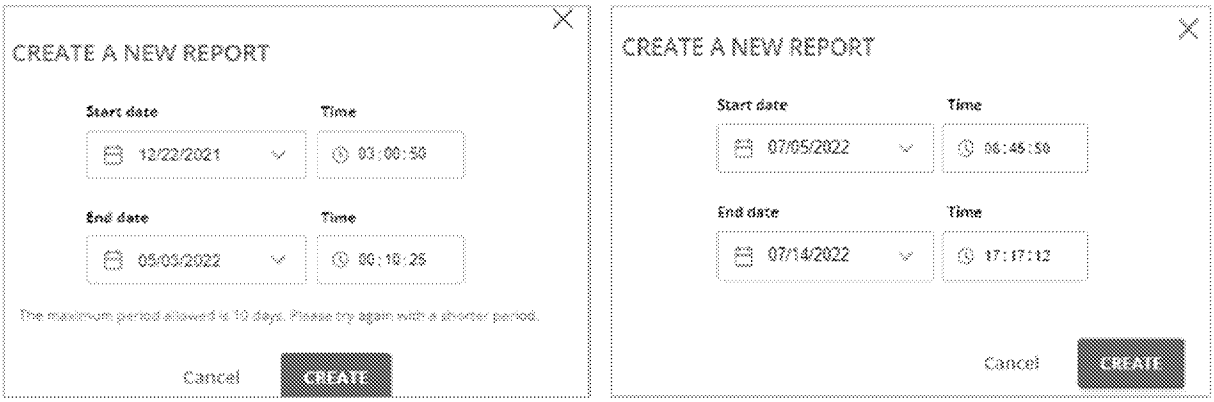
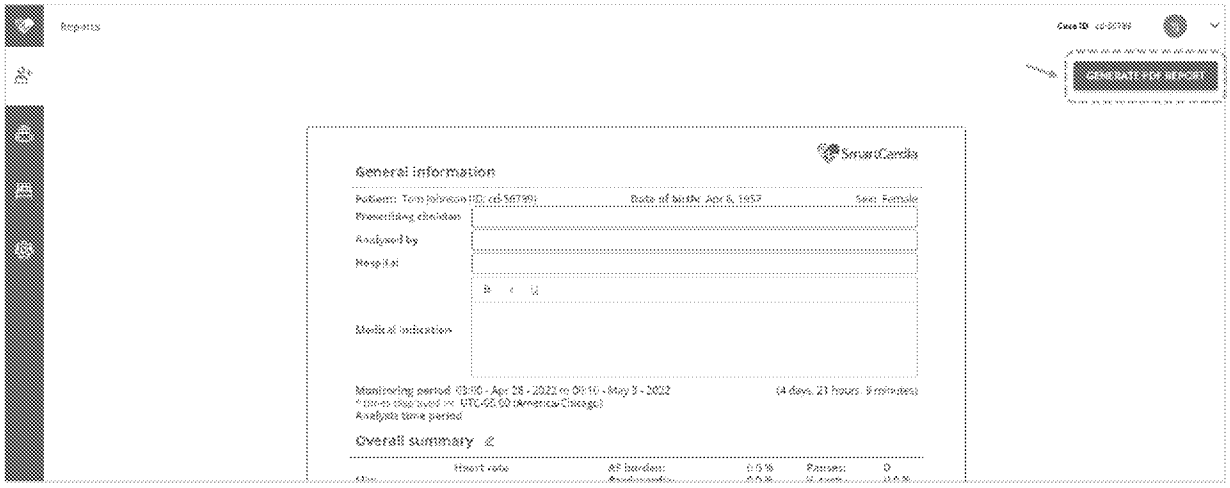
In the pop-up box, enter the start date and time along with the end date and time. Ten days is the maximum number of days possible for the report time period.

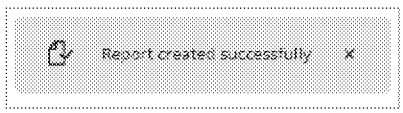
NOTE: The first screen shot below is an example when you try to enter more than ten days for the report time period. Once the date information is corrected the “CREATE” button changes color from gray to blue and is active.



Once “CREATE” is selected the report is created and displayed with the option to “Generate PDF Report”.



The report was created successfully, and the report is now added to the list of reports.



NOTE: If a long period of time is requested, it will take longer to create the report.

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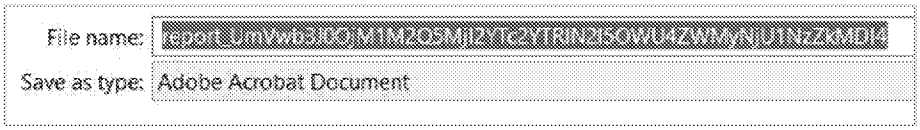
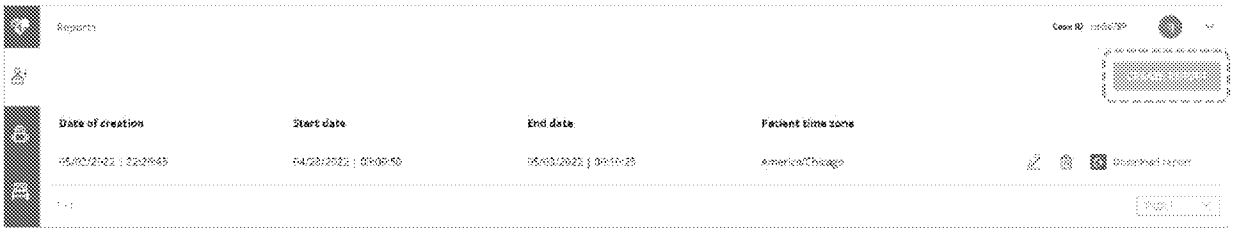
The report list has column headers of the creation date, the selected start and end date of the report, and patient time zone. For each report listed, there is a button to edit, delete, or download the report.

The edit function provides the ability to add and edit a comment on each report. Once edits are complete, select “GENERATE PDF REPORT”.

The report can be deleted or download as a PDF file.



NOTE: The “CREATE REPORT” button is shaded in gray and not active while Analysis is in process for the patient, as shown in the example below. During that time, the only function available is to work with an available report.



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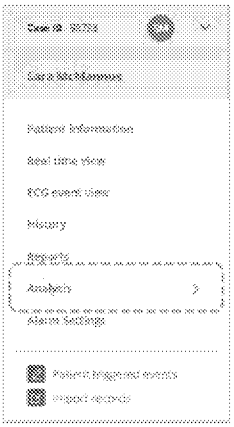
Analysis

Selecting Analysis provides a software tool to perform marking of long electrocardiogram (ECG / EKG) recordings. This was created with special emphasis on the ease of use for the clinician. The application has been developed to mark ECG recordings sampled at different resolutions and voltage levels, enabling the marking of heartbeat types, the underlying rhythm as well as episodic rhythm changes and artifacts. Analysis also provides processing functionalities to perform semi-automatic detection of different abnormalities aiding the marking process.

There are two ways to get to the Analysis function.

- From the "PATIENTS" list, select the patient's name that you want to perform analysis.



- From the "Multi-Patient" view, on the patient tile of the patient that you want to perform analysis, click on the three dots in the upper right corner of the patient tile.

Select Patient data in the pop-up window, then go to the options for that patient in the upper right side of the screen and select "Analysis".

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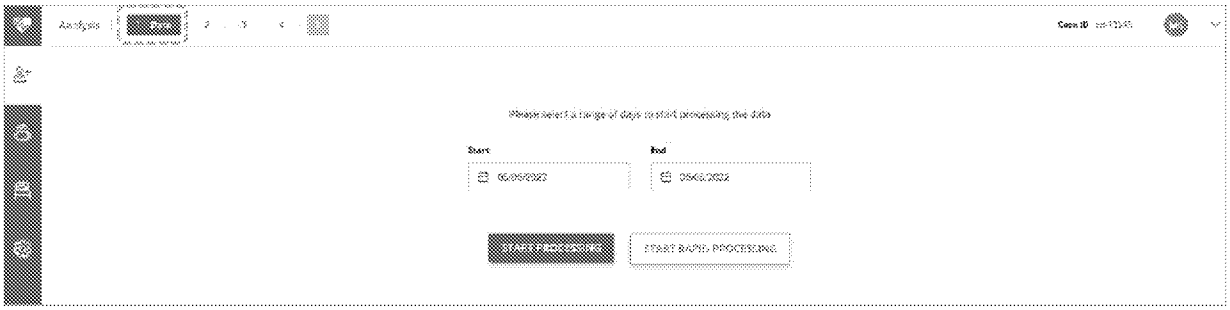
Holter Report Preparation- Standard Processing

Processing the data is done in five steps

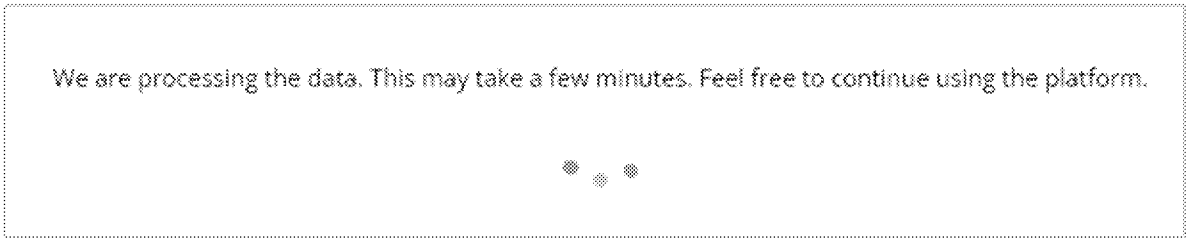
Step 1 Date

- Select the range of days to start processing the data. Use the calendar to set the start and end dates.
- Click on “START PROCESSING” or “START RAPID PROCESSING”



If analysis was done previously a pop-up asks if you want to do a new analysis.

If YES is selected in this case, data processing begins.



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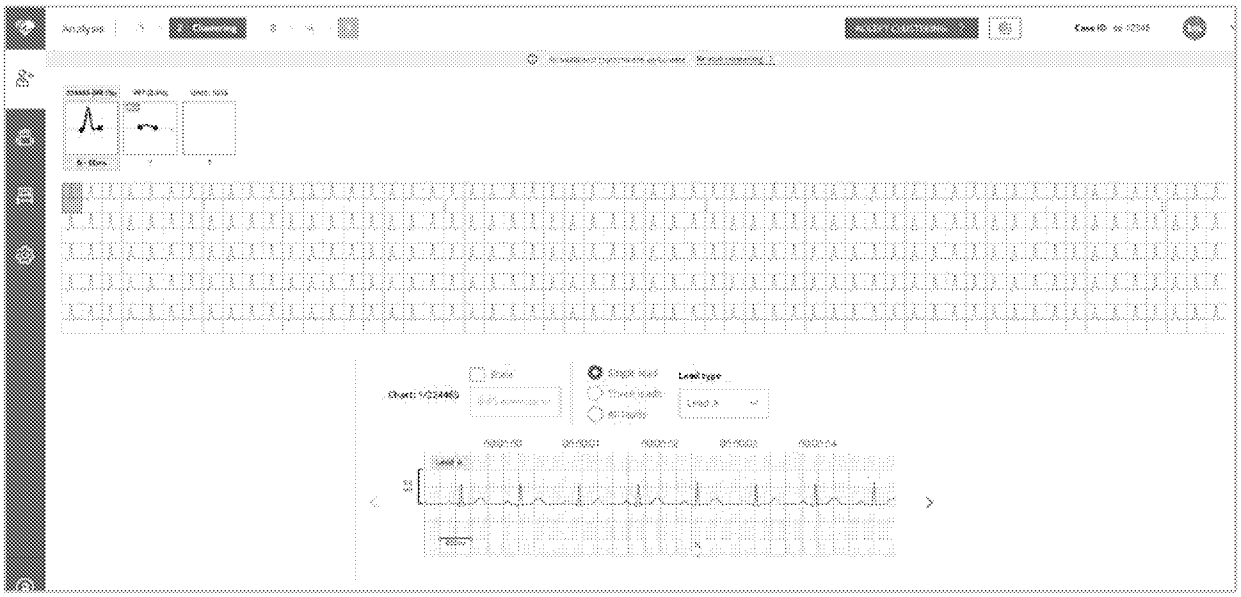
Step 2 Clustering-Beat clustering analysis



Reviewing the heartbeat clusters

Each cluster represents a group of heartbeats (QRS complexes) that are similar in morphology. The clusters are presented in descending order according to the number of heartbeats belonging to the cluster.

The template of each morphology is shown in a square.

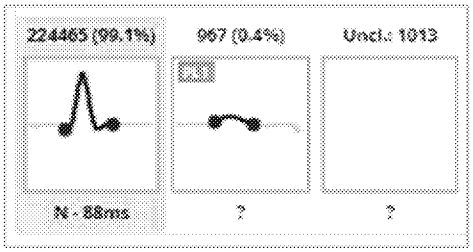
Above the cluster square is displayed:

- Number of the same morphology QRS beats
- Percentage of their occurrence

If a cluster has premature QRS complexes, the relative degree of prematurity will be shown in the upper left corner. The prematurity of the beats inside the cluster is indicated in three levels:

- Premature (PL1)
- Very premature (PL2)
- Extremely premature (PL3)

Below the cluster square is an estimation of the QRS length of the template as well as a tentative suggestion for the label to apply to the cluster.



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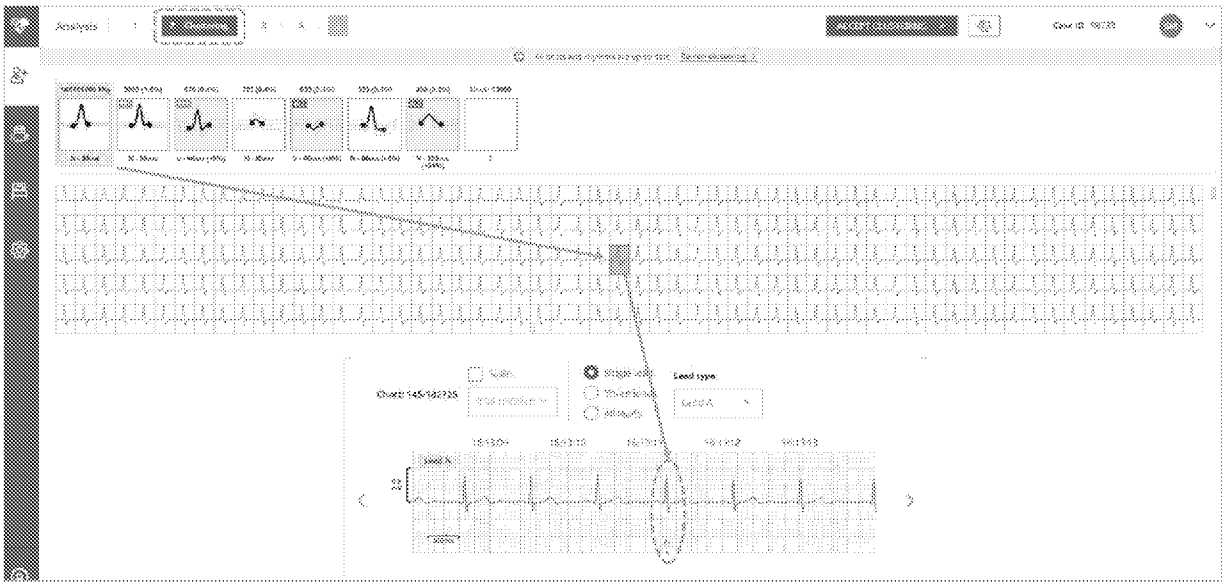
The background of each template is color coded:

- Green for Normal clusters (denoted with the label 'N')
- Yellow for any other type
- White for clusters of unknown type (denoted with the label "?")

QRS and ECG Preview

For each cluster, the individual heartbeats can be reviewed in greater detail.



ECG Time and Voltage Scales

As in a standard ECG rhythm strip, on the horizontal dimension (time axis), each 1mm box corresponds to 0.04 seconds (40 milliseconds) and each 5mm box corresponds to 0.2 seconds (200 milliseconds). In other words, the ECG is displayed at 25 mm per second. On the vertical dimension (voltage axis), the tool adapts the scale to optimally display the ECG signal. This ratio is expressed in millivolts per millimeter (mV/mm) and is indicated in the Scale pop-up selector.

While the tool automatically adapts this scale when changing from signal to signal (e.g., after loading a new file), the ratio can be manually changed by the user selecting the desired value using the pop-up selector for scale.

ECG preview leads

The ECG lead display format options are selected using a radio button. The choices of lead options available to view include:

- Single lead - you can select either lead A, B, C, D, E, F, or G

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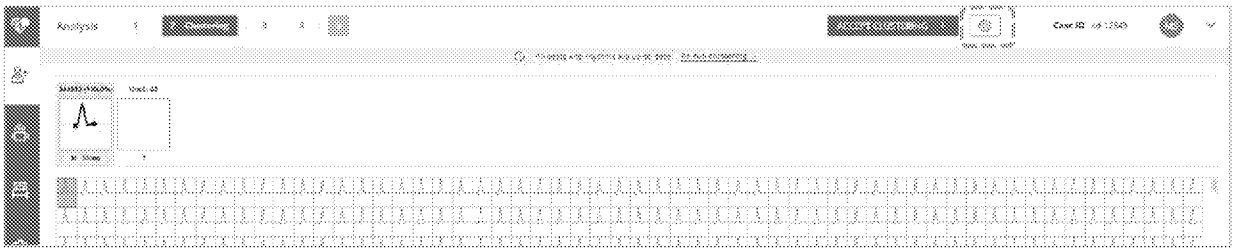
- Three leads - A, B, G
- All seven leads - A, B, C, D, E, F, or G (Scroll down to view all leads)

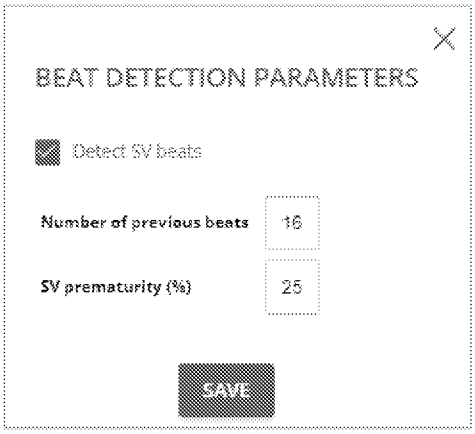
Beat detection parameters

Adjustments can be made to the parameters for beat detection.

- Click on the gear icon at the top right of the screen to the right of ACCEPT CLUSTERING

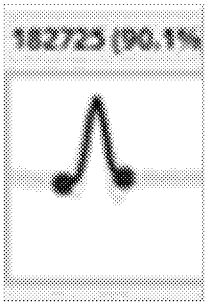


In the "pop up" box, BEAT DETECTION PARAMETERS make any adjustments to detect SV beats, number of previous beats and SV prematurity %. And "SAVE" changes.



Navigation through heartbeat clusters

Click on the square of the desired heartbeat (QRS) cluster to look at in detail. A blue box will outline the cluster.



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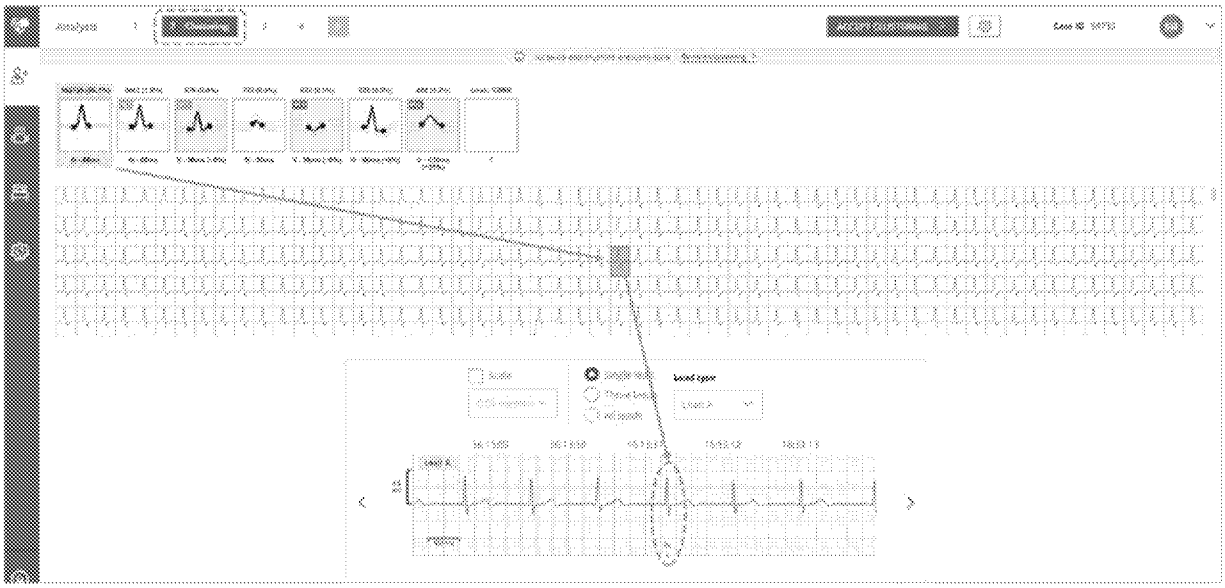
The first heartbeat of the recording belonging to this group will be highlighted on the top of the full disclosure ECG view and on the enlarged rhythm strip. Heartbeats are sorted by how similar they are to the template of the clusters where they belong, rather than chronologically.



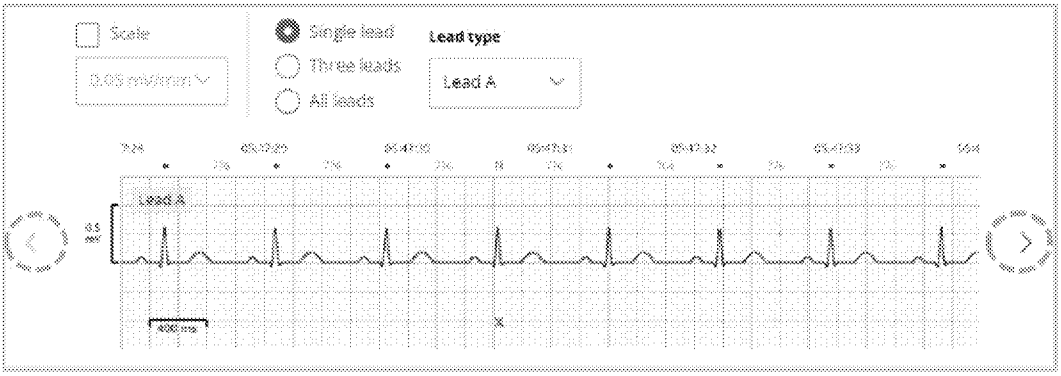
There are multiple ways to inspect the heartbeats belonging to a selected heartbeat cluster:

- Select the cluster to review
  - In the cluster screen, continue clicking on the selected heartbeat cluster to see each heartbeat in the ECG full disclosure and ECG preview strip
  - In the full disclosure ECG view (All complexes belonging to the cluster are displayed in the full disclosure view)
    - Click on any point to display that period of time in the rhythm strip view
    - Use the scroll bar on the right side of the screen to move through the ECG complexes

    NOTE: The beat highlighted in red on the full disclosure view is shown on the rhythm strip with the QRS complex beat annotation about the center of the strip.

OR

- On the rhythm strip, use the right/left arrow keys to move forward or go back in time



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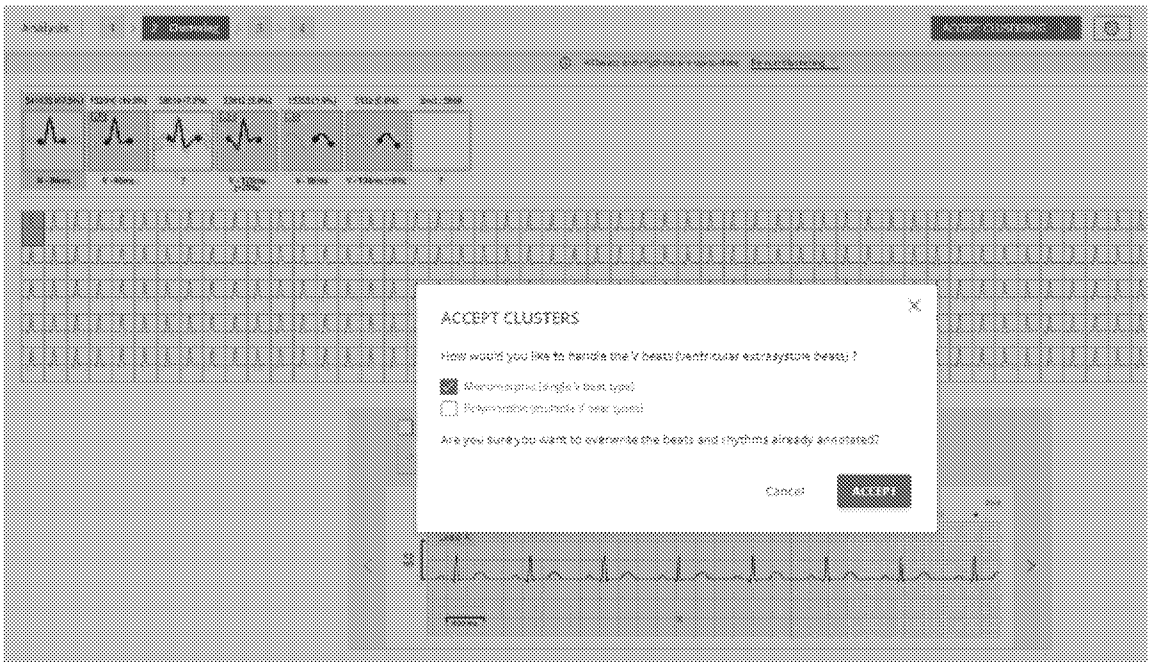
Accept Clustering

Select “ACCEPT CLUSTERING”.

In the “pop up” box, ACCEPT CLUSTERS choose how to handle the V beats (ventricular extrasystole beats)

- Monomorphic single (V beat type)- classify all V beats into one category/cluster
- Polymorphic multiple (V beat type)- classify V beats into more than one category/cluster



Step 3 Report selection

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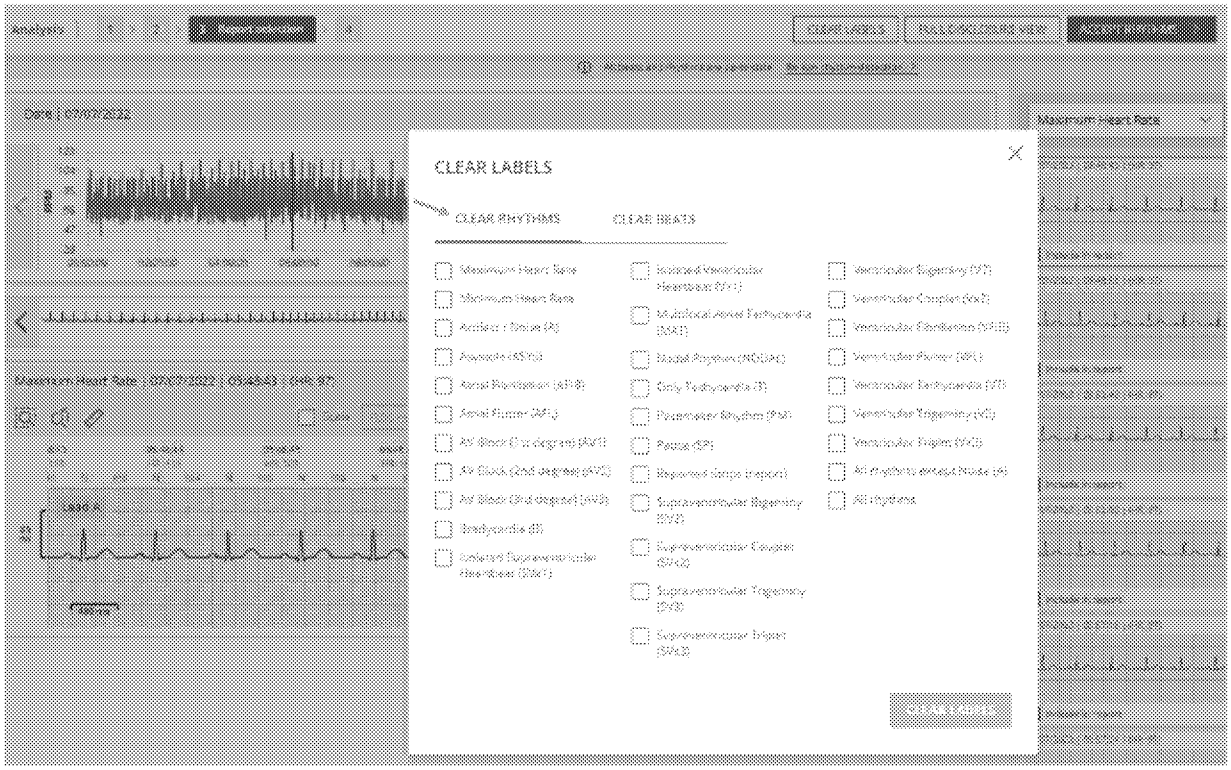
Rhythm detection can be repeated if needed. Select “Re-run rhythm detection” in the top middle of the screen.

Labels for rhythms and beats can be cleared by selecting “CLEAR LABELS” in the upper right corner.

In the pop-up box, select the item to delete which will be shaded in blue, then select “CLEAR LABELS”

CLEAR RHYTHMS



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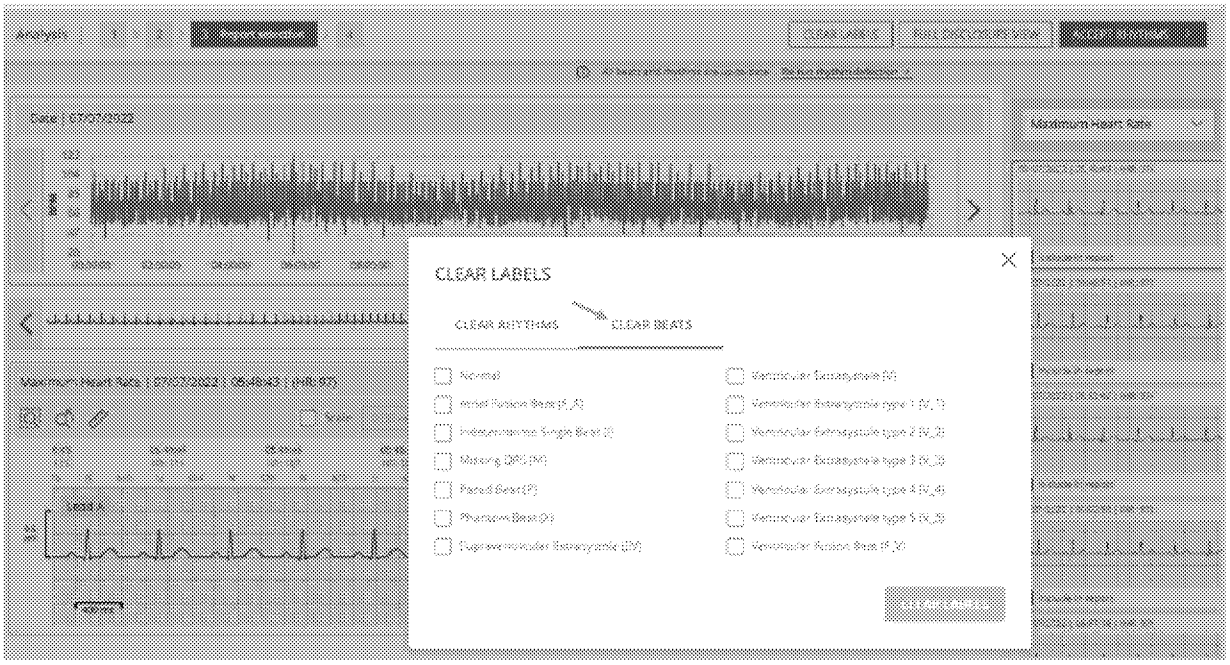
CLEAR BEATS



To view all available rhythms, use the scroll bar on the right side of the screen. In the various rhythm categories, there may be additional rhythms to view.

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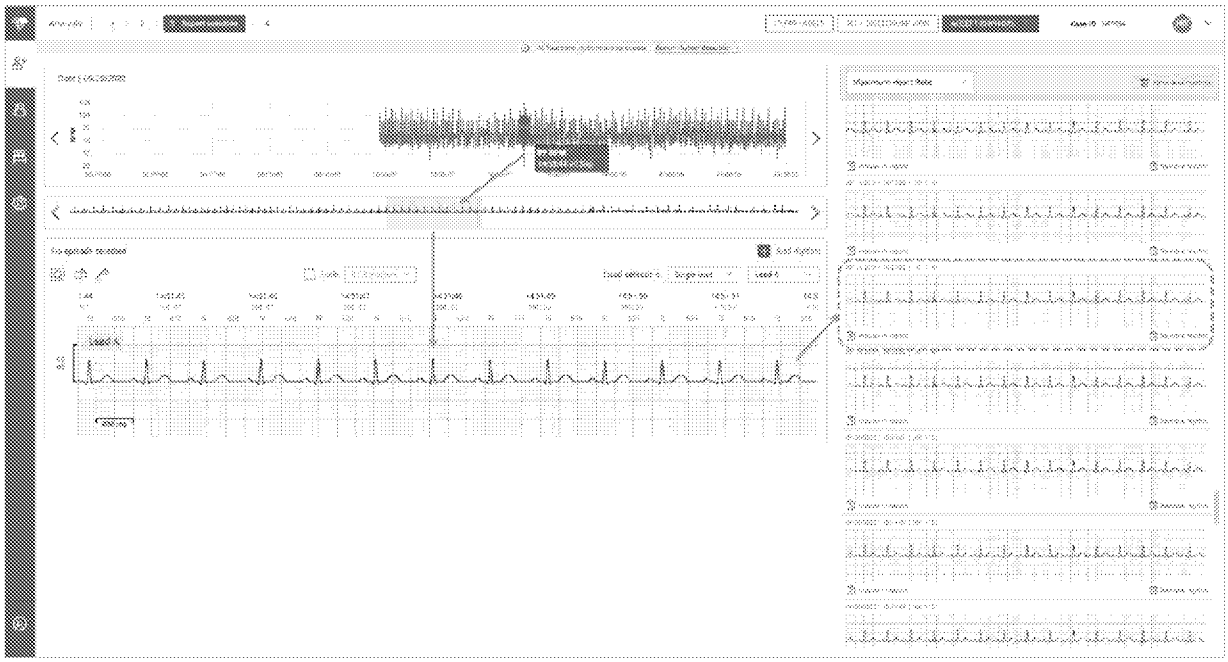

All rhythm strips can be removed from the report by selecting “Remove all rhythms”. Individual rhythm strips can be included or removed from the report using “Include in report” or “Remove rhythm”.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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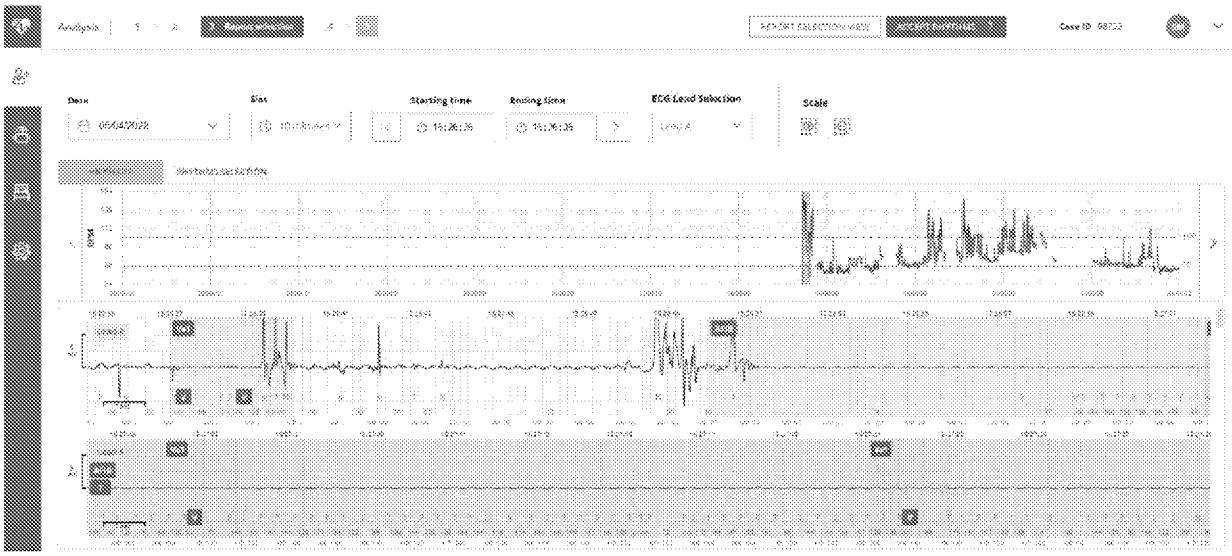
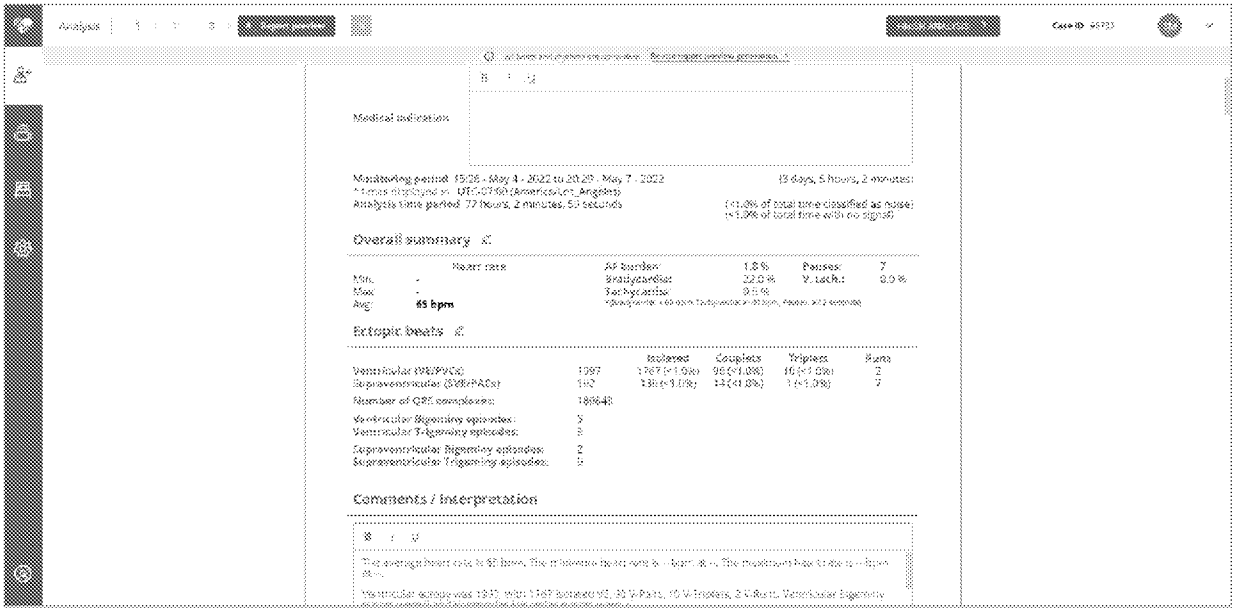
Full Disclosure View



When finished with review, select “ACCEPT RHYTHMS”

Step 4 Report preview

- The report is displayed, and you can scroll through all pages to review.
- Select “FINISH ANALYSIS”



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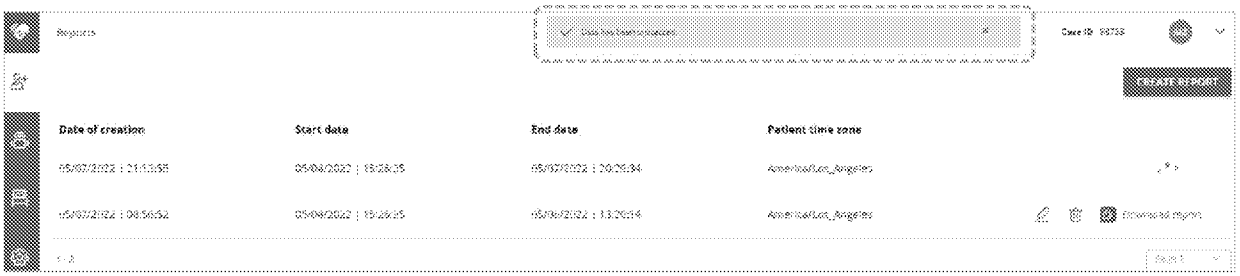
Step 5 Finished



Holter Report Preparation- Rapid Processing

Select “START RAPID PROCESSING” to begin analysis.

Using Rapid Processing skips user interaction in Step 2 Clustering-Beat clustering analysis and takes you directly to Step 3 Report selection.

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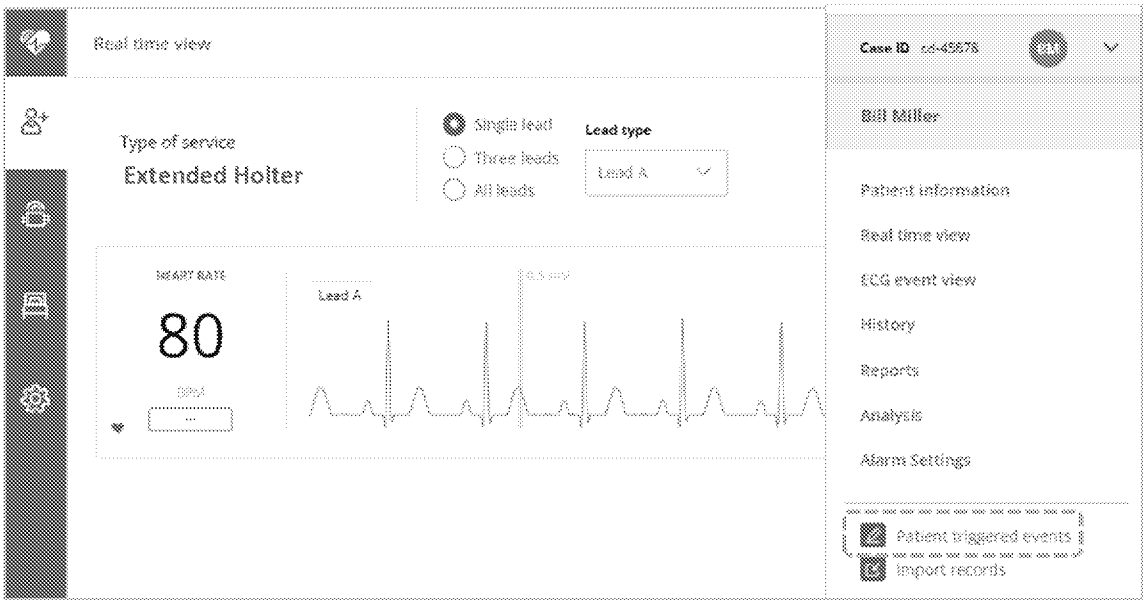
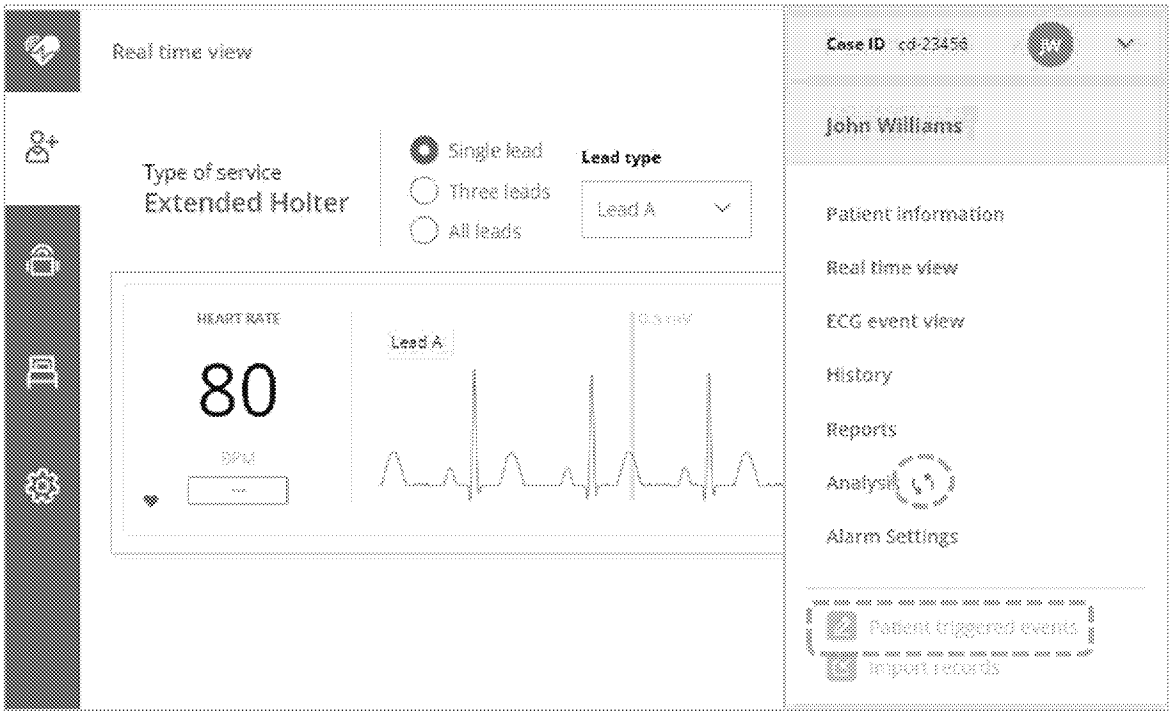
Patient Triggered Events

Patient triggered events can be reviewed from any individual patient page options (Patient information, Real time view, ECG event view, History, Reports, Analysis, and Alarm Settings).



If Analysis is in process “Patient triggered events” is not available and shaded in grey.



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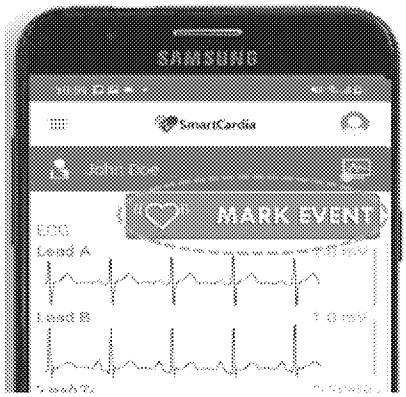
Patient triggered events can be added to the list by the patient or clinician

- The patient can select "MARK EVENT" on the SmartCardia *Phone* and select:
  - event duration
  - symptoms occurring

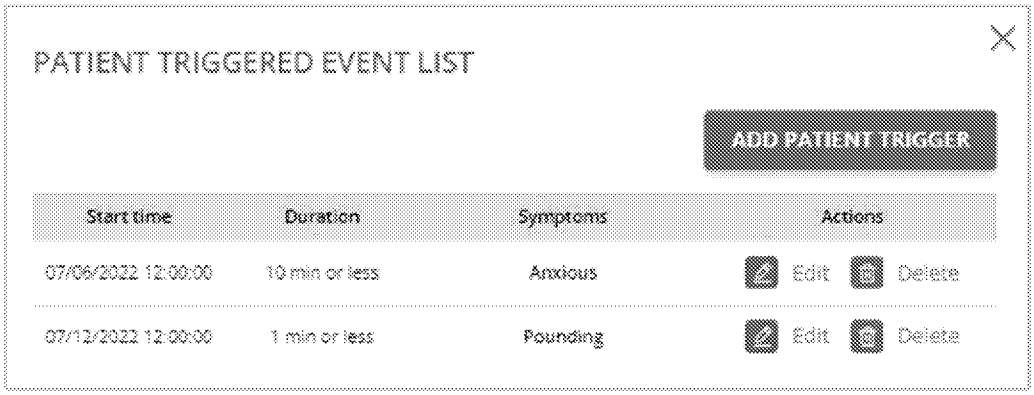


7L Web Browser

- This triggered event is automatically listed in "ACCEPTED EVENTS" in ECG event view
- All triggered events appear in the report

- Clinicians can manually add the patient triggered event information as shown in the two different patient triggered events list screens below

  - If the patient has triggered events, the event time, duration, and symptoms are listed. Triggered events on this event list can be edited or deleted.



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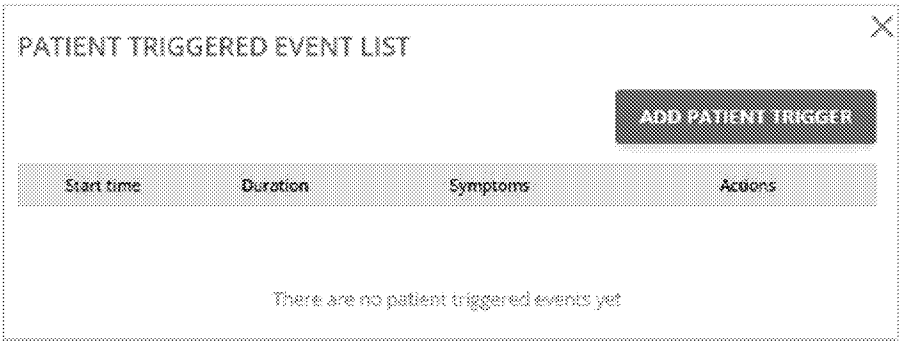
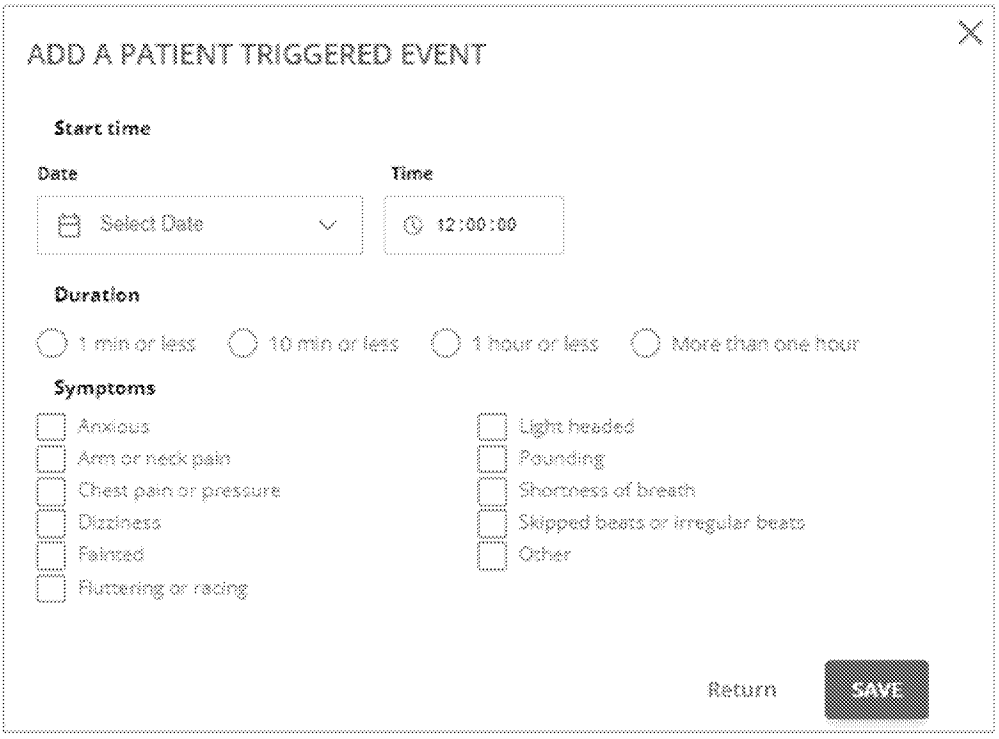
- If this patient has not marked any events or none have been added by the clinician, the list will be empty with the message “There are no patient triggered events yet”.



In both above situations if there are no patient triggered events yet or if events are listed, patient triggered events can be added.

Select “ADD PATIENT TRIGGER”

Enter all event information. Once the information is complete select “SAVE” and the event will be added to the list of triggered events for the patient.



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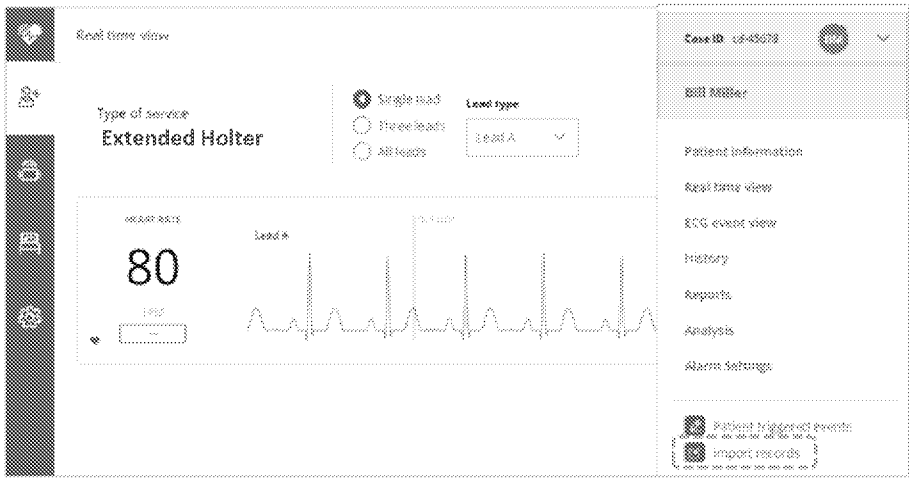
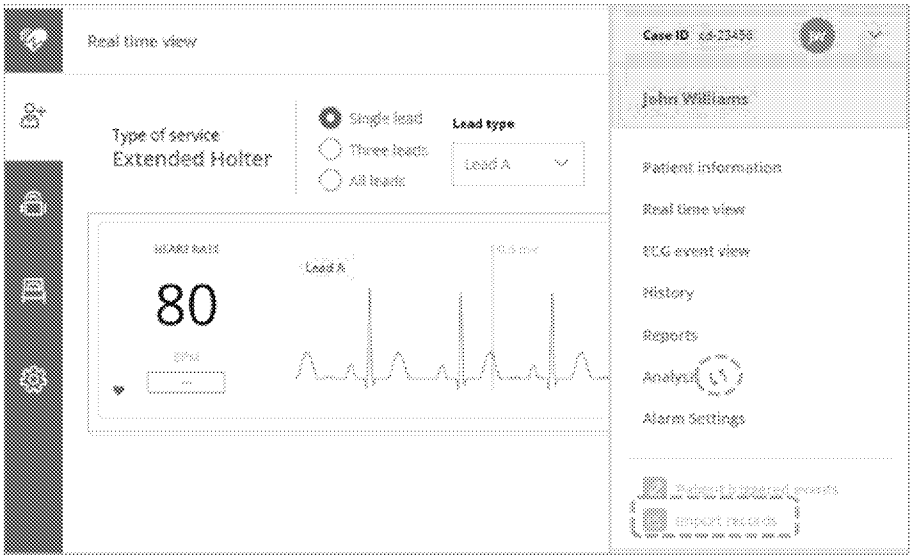
Import records

Import records can be done from any individual patient pages (Patient information, Real time view, ECG event view, History, Reports, Analysis, and Alarm Settings). Patient data can be added or combined with a record that already exists.



If Analysis is in process “Import records” is not available and shaded in grey.



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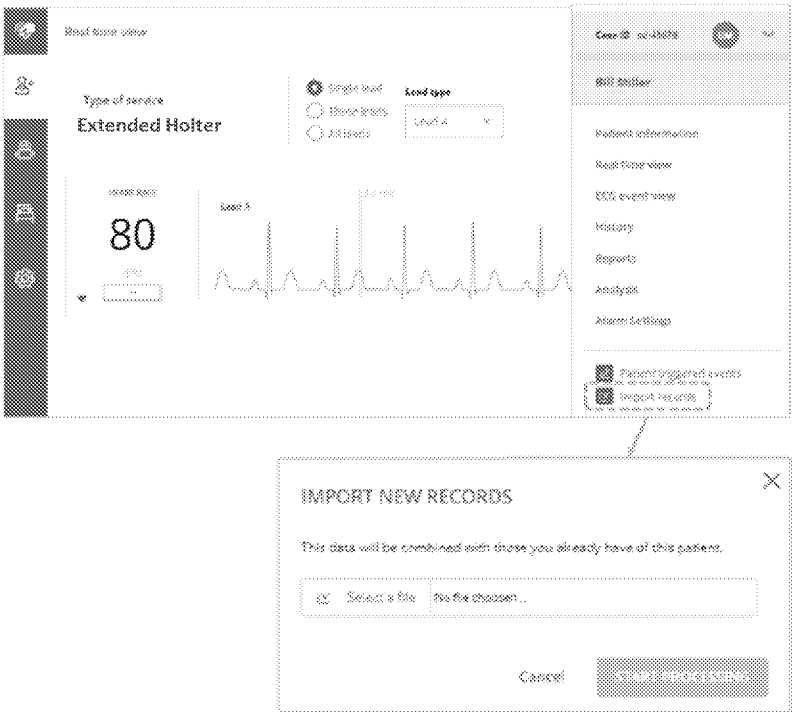
Select “Import records”



Click on the “Select a file” button to search for the file to add. **The file must have the extension “.sc”.** If a file is selected that does not have that extension, an error message is displayed.

Once the file is chosen, the file will begin uploading. The green line and digital information show the progress of the file upload.

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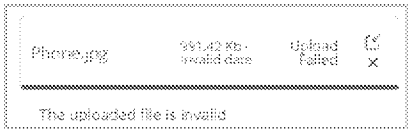
Steps when uploading the data file:

- Error
  A red message means there was an error in the operation with the message: “Upload Failed. The uploaded file is invalid.”
  NOTE: check file name and extension for correct format (.sc) See page 110.



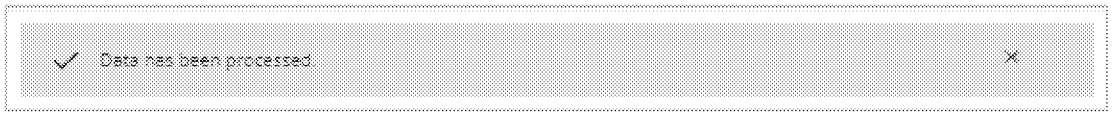
- Once upload is complete, record saved (name of record, file size/date/time, and complete with the option to delete) is displayed
- Select “START PROCESSING” Now ready to import additional new records

- In process

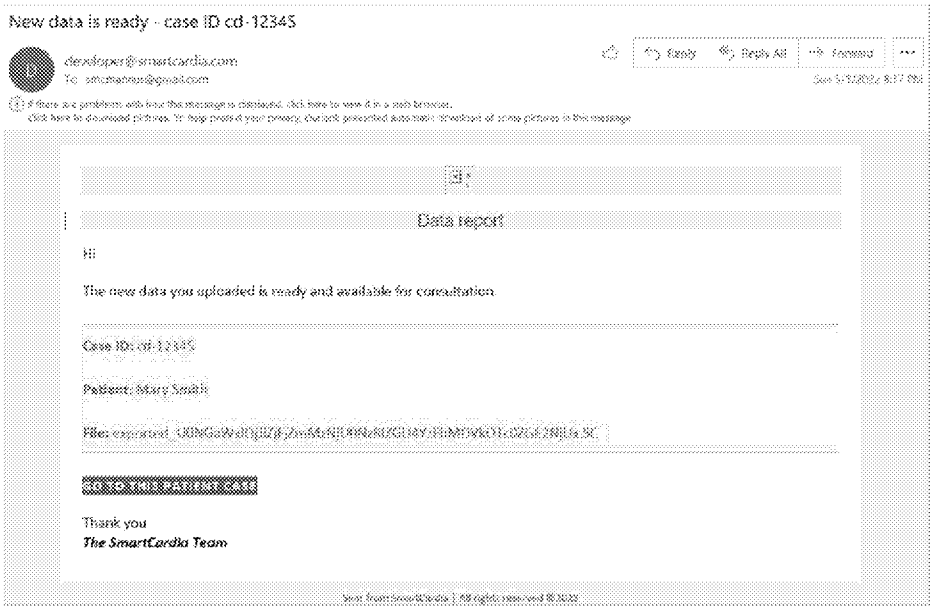
  The message in blue text, “Processing new data. Feel free to continue using the platform” indicates the operation is in process

- Successful import of record

  The message “Data has been processed” In the green box means the operation is successful



An email is sent to the clinician with notification the new data file is ready for import.



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Manage Devices

The Devices section of the *7L Web Browser* provides two functionalities for the clinician. They include review and editing the list of devices and to add a device.

List of Devices

This list has all *7L Sensors* currently in use or available to use for a new patient.

List of devices

The search bar allows the user to search for a device by MAC address or device name.

The following information is displayed and can be sorted:

- MAC address of the *7L Sensor*
- Name of the device
- Date of the last association with the patient
- Patient name which the device is assigned

Identification of the device location on the chest of the patient

The “Edit” button is used to change the name or MAC address of the *7L Sensor*

The “Delete” button removes the *7L Sensor* from the list of devices (only available for devices that are not assigned to a patient).

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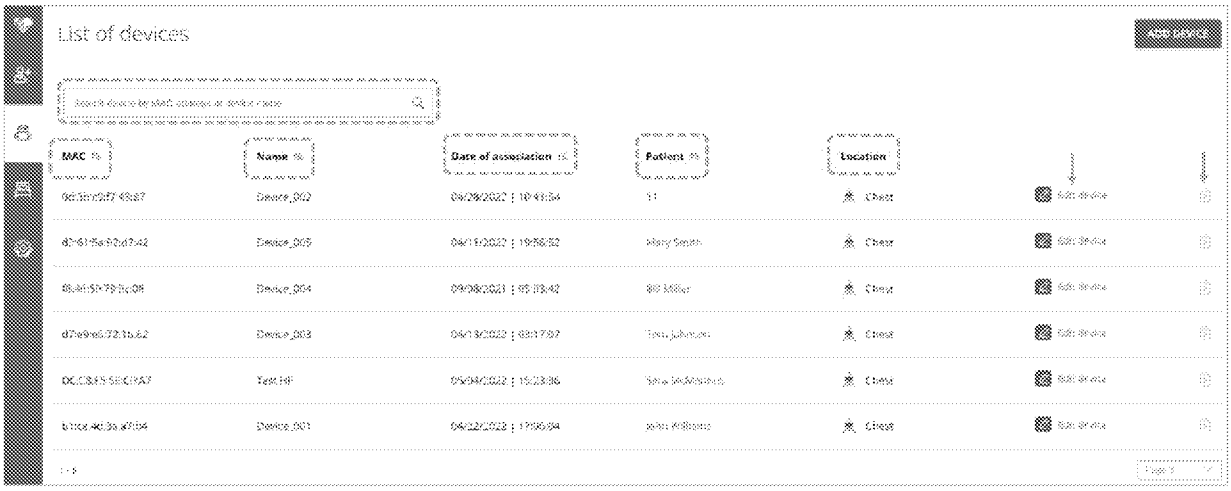
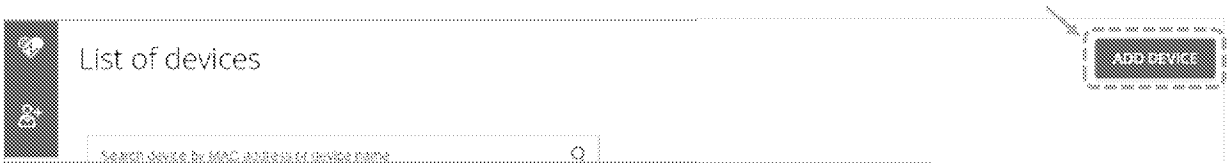


NOTE: To remove or add an association between a *7L Sensor* and a patient, the user must go the patient information page. Easily get there by selecting the patient's name on the list, select patient information and select "Assigned Devices" then "Unassign device" or "Assign device".

Add a New Device

If a new *7L Sensor* (device) needs to be added to the SmartCardia 7L Platform use the following process. Each *7L Sensor* has a unique MAC address that will be added along with the device name designated by your practice. For example, the device name could be CD01, CD02, etc.



Select the "ADD DEVICE" button in the upper right corner.

- Type the name for the new *7L Sensor* device (must not currently exist)
- Enter the MAC address that is found on the surface of the *7L Sensor* that is inserted into the *7L Patch*
- Select "SAVE"
- A notification is displayed with the message "Device added"
- The new device is now added to the list of devices and available for patient use

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Discontinuation of Monitoring

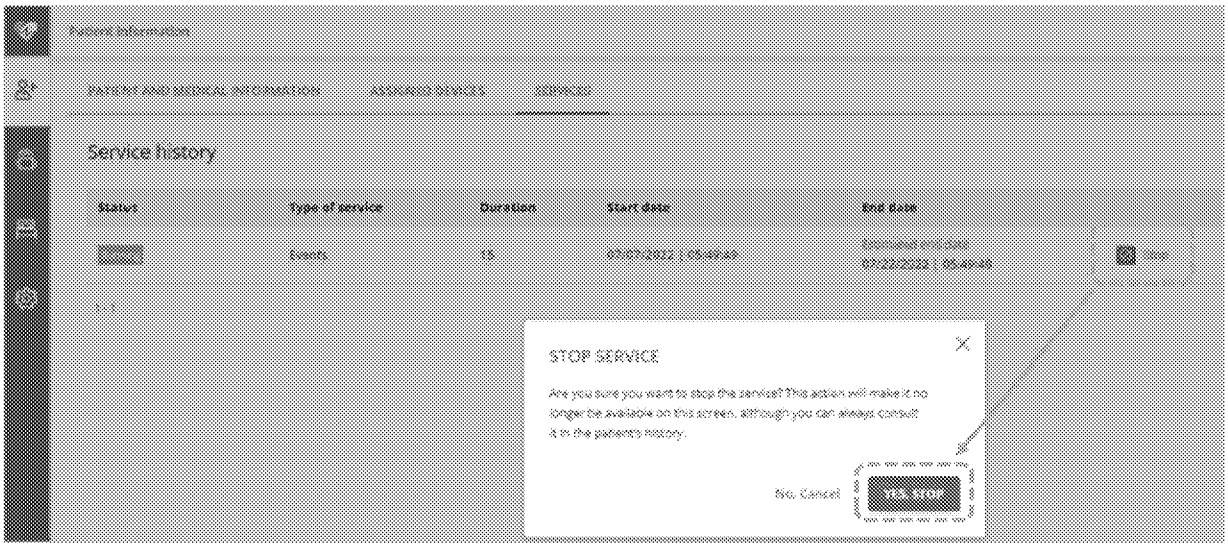
At the conclusion of the monitoring service, the patient returns the SmartCardia *7L Sensor*, *Phone*, and medical grade charger using the pre-addressed, pre-paid mailing envelope for reprocessing.

Follow the process of your practice to review, analyze, and prepare patient reports.

On the patient information page, select “SERVICES” tab.

Under Service history, for the current running service, select “Stop”.

In the confirmation pop-up box, select “YES, STOP”



The confirmation message, “Type of service has been stopped” is briefly displayed on the screen and status shows “Finished”.

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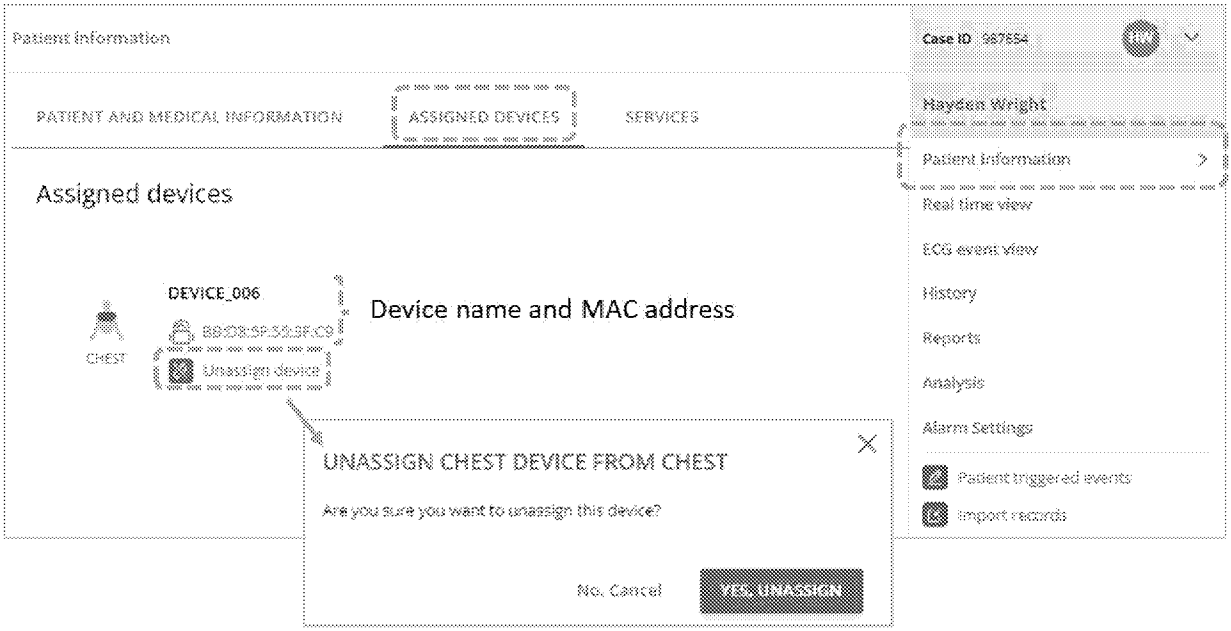
Next step is to unassign device.

On the patient information page, select “ASSIGNED DEVICES”, then select “Unassign device”.

In the pop-up box select “YES, UNASSIGN” to stop monitoring the patient.



A notification message is posted that the device was unassigned successfully.

NOTE: Monitoring is stopped for the patient. All patient information, data, and reports remain available in the practice data base.

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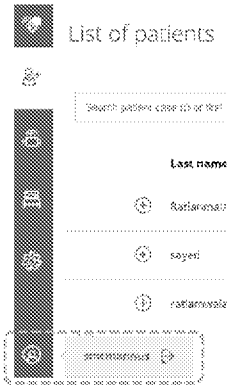
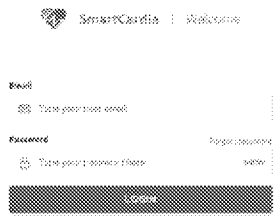
Clinician Logout

The last image of the main left navigation menu is the clinician logout option.



When “Logout” is selected the application closes and the SmartCardia Welcome LOGIN screen is displayed.



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Troubleshooting

7L Sensor, 7L Patch, and SmartCardia Phone

Problem	Cause	Correction
When logging into the SmartCardia *Phone* an error occurs	Unknown	Contact SmartCardia Customer Support
Problem	**Cause**	**Correction**
Related to the Bluetooth-ECG does not display on SmartCardia *Phone*	• *7L Patch* battery is low • *SmartCardia Phone is too far away from 7L Patch*	Always use new *7L Patch* (batteries are part of the *7L Patch*)
Problem	**Cause**	**Correction**
SmartCardia *Phone* is not connected to the SmartCardia backend server	• SmartCardia *Phone* lost its cellular connection or is out of range of cellular communication	Make sure the SmartCardia *Phone* has good cellular signal strength. Move location if necessary

7L Web Browser

Problem	Cause	Correction
Unable to login using the clinician's credentials (email and password)	• Clinician's account is not activated • Clinician's email is not correct • Clinician's password is not correct	Contact SmartCardia Customer Support team to: • Activate the account • Update the clinician's email • Set a new password
Problem	**Cause**	**Correction**
Invalid web certificate *7L Web Browser* says site is insecure, web certificate is invalid	The *7L Web Browser* has cached the old certificate	Remove the browser cache and reload the page

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Viewing Clinical Data

Problem	Cause	Correction
Missing functionality- Some of platform functions are not working properly. Artifacts are presented, problems with style, etc.	• User is not using supported Google Chrome browser (version 93 or higher) • Web browser has cached the old code	• Use Google Chrome version 93 or higher (do not use beta or alpha releases) • Remove browser cache and reload page
Problem	**Cause**	**Correction**
Real-time signals are not shown on clinical data page	• Patient is not connected to the server • Patient does not have the *7L Patch* on their chest	• Make sure the patient is connected and sending data to server • Confirm Bluetooth is activated on SmartCardia *Phone* • Verify no error is displayed on SmartCardia Mobile application • Put *7L Patch* on chest
Problem	**Cause**	**Correction**
Signal amplitude is too small, and signal cannot be visualized properly	Poorly positioned *7L Patch* High Body Mass Index (BMI)	• Reposition *7L Patch* • Manually change scale to smaller one so signal display will be higher amplitude
Problem	**Cause**	**Correction**
Text labels and controls overlap or appear partially	Screen size is too small, or resolution is too low	• *7L Web Browser* was designed to run in a system with minimum resolution of 1024x768 pixels • Use higher resolution in Operating System or use larger screen
Problem	**Cause**	**Correction**
Real-time signals are not shown on multi-patient view	Patient does not have the *7L Patch* on the chest	Put *7L Patch* on chest

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Reports

Problem	Cause	Correction
The generation of the reports never finishes	The server is processing other user's reports	Wait a few minutes until the server finishes processing the rest of the reports
Problem	**Cause**	**Correction**
Unable to download a PDF report	The browser is blocking the file downloads browser allows the file downloads	• Verify the report is being downloaded to a write-allowed location • Try to download the report to another location
Problem	**Cause**	**Correction**
Unable to open a PDF report	• PDF document is corrupted • User is trying to open document using a non-PDF reader application	• Open PDF report using PDF reader, like Adobe Acrobat Reader

Files

Problem	Cause	Correction
Unable to save a file	User does not have necessary write permissions	Make sure user has proper permissions to write to file and access directory where file is stored
Problem	**Cause**	**Correction**
Unable to upload a data file	The file does not have the extension ".sc". If a file is selected that does not have that extension, an error message is displayed.	Check file name and extension for correct format (.sc)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118
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Patient Use

Problem	Cause	Correction
Contact between skin and *7L Patch*- Quality of ECG signal is poor	• Skin was not cleaned well or *7L Patch* isn't attached correctly • Out-of-date *7L Patch* was used and no longer works well	Clean skin, clip or shave hair if needed, and attach new *7L Patch*
Problem	**Cause**	**Correction**
Quality of ECG signal is poor	Amplitude of ECG wave is small in Lead A, which is difficult for analysis	Reposition or replace *7L Patch*

We are here to help

Customer Support (800) 363-8151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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System Administrator Set-up for the Organization

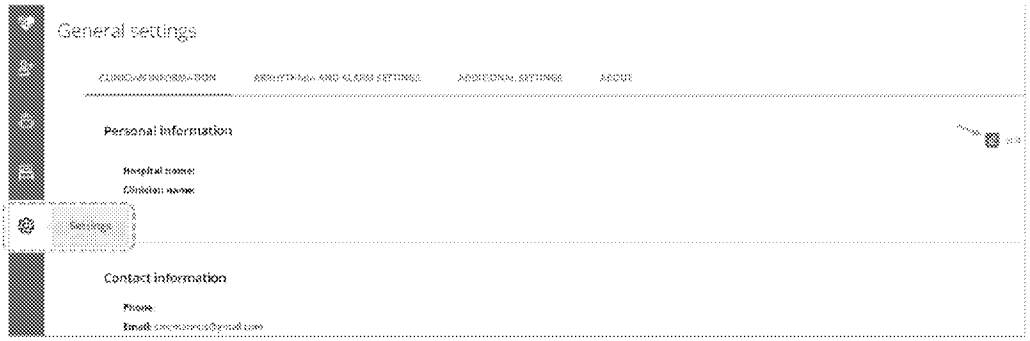
Initial Set-up for Clinician First Use

Registration of Clinicians on SmartCardia 7L Platform

- Contact SmartCardia Customer Support (800) 363-8151 to register clinicians to use the 7L Platform
- Viewing and report privileges for each clinician will be established

Settings

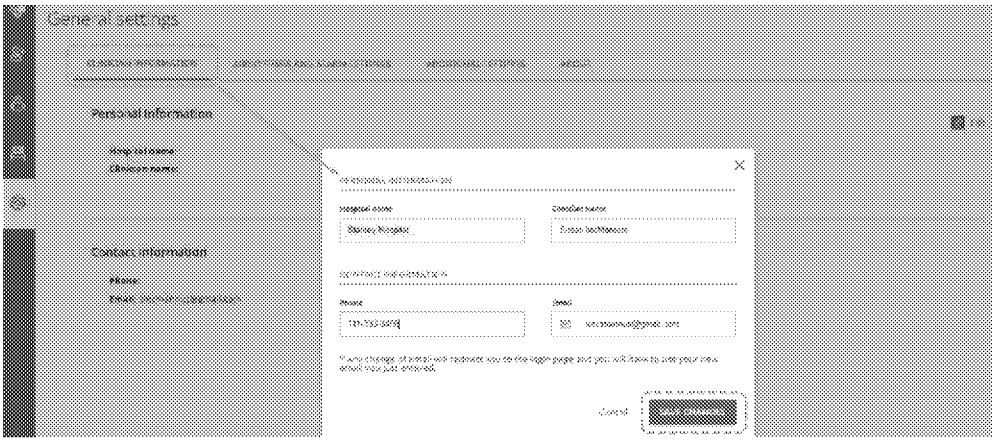
The administrator for each practice facility can edit the system general settings for their organization. On the left menu select the gear icon to access “Settings”.



Clinician Information

- Select the “Clinician Information” tab to edit clinician personal and contact information
- Select “Edit” on right side to make changes to hospital name, clinician name and phone
- Enter required information - Hospital name, Clinician name, and Phone. Email will be already entered. (Any change of email will redirect you to the login page and you will have to use your new email you just entered)
- Select “Save Changes” or “Cancel”

NOTE: To add new clinician, contact SmartCardia customer support at 800-363-8151



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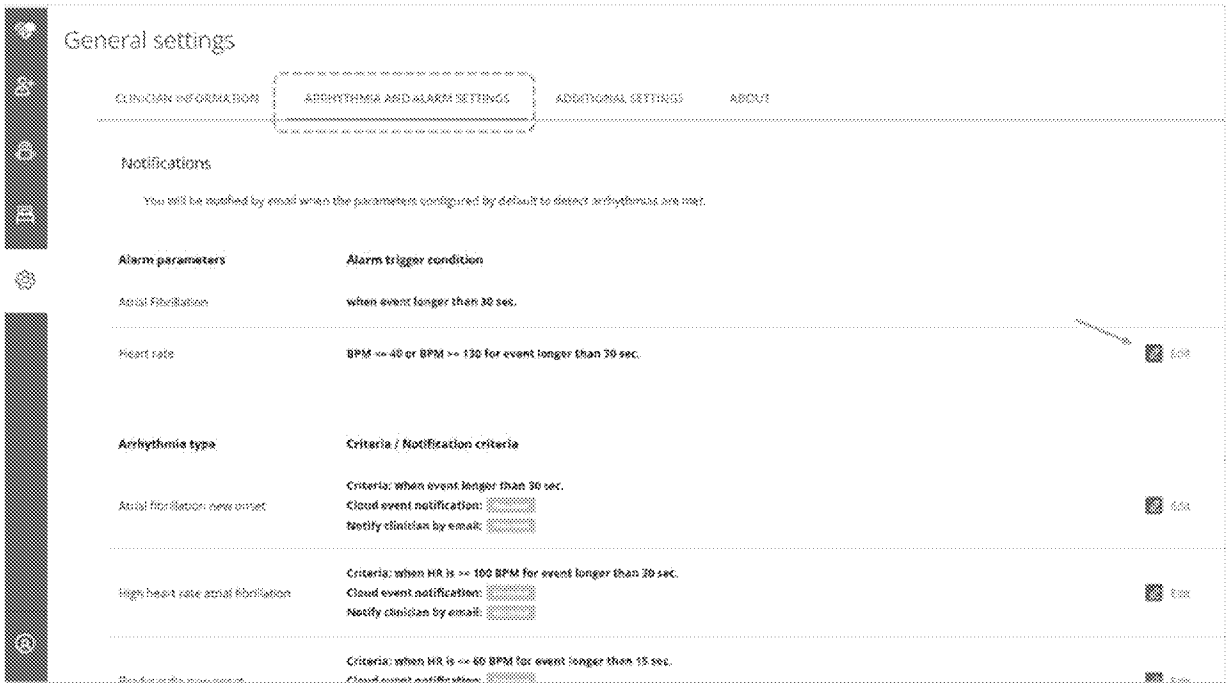
Configure Default Alarm and Arrhythmia Event Notification Settings for Organization

Alarms and arrhythmia event notifications are pre-set by the manufacturer and can be modified to meet the practice requirements. It is important to review settings and modify these to meet the practice requirements of the organization.

NOTE: Alarms and event notifications can be customized for individual patients based on their clinical condition and provider orders.

To set the hospital/practice alarm and notification settings:

- Select the "Arrhythmia and Alarm Settings" tab to adjust alarm, notification, and report settings
- See Alarms and Alarm Management page 35 and Arrhythmia Event Notification page 38 for detailed information



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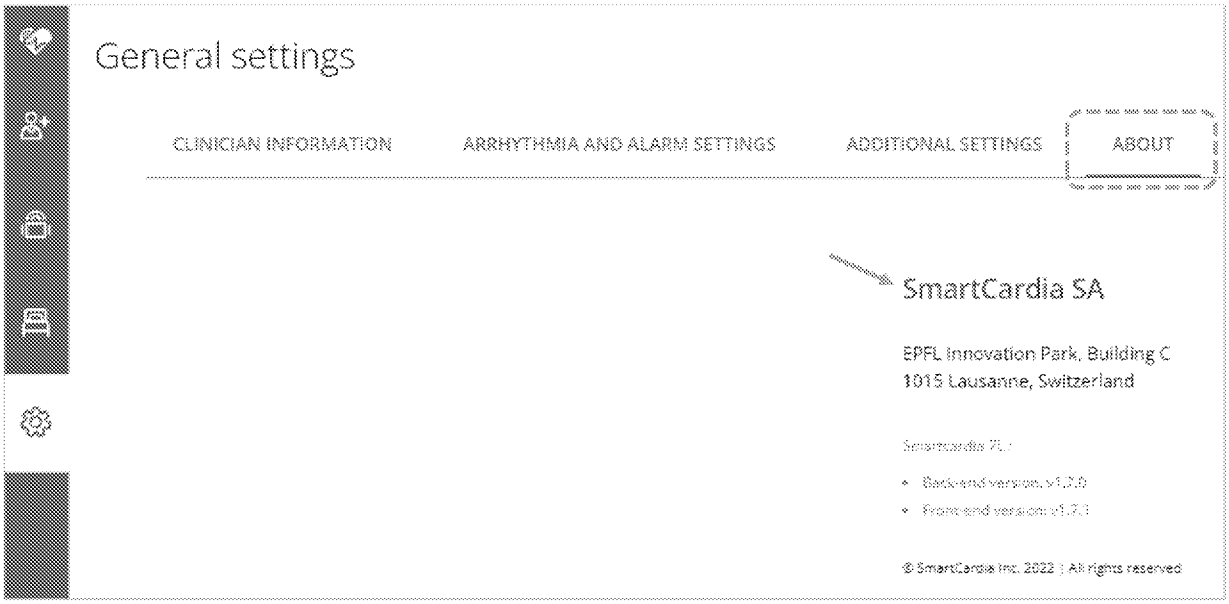
About

The About section provides SmartCardia SA corporate address and software version information.



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Product Specifications

Physical and Environmental

Physical and Environmental	
Size	7L Sensor: 1.97 x 1.18 x .39 inch; (50 x 30 x 10mm) 7L Patch (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14mm)
Weight	7L Sensor and 7L Patch: Less than 3.52oz. (100 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C)
	Operating: +41 to +104°F (+5 to + 45°C)
Humidity	Storage and transport: relative humidity up to 90%, non-condensing
	Operating: 10 to 95% at +41 to 95°F (+5 to +35°C) (non-condensing) / 700 – 1060 hPa
Safety	Type BF
Water Ingress	IPX7 (waterproof)
Battery Life	Up to 14 days, depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30 - 200	Beats per Minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Manufacturer Default Alarm Settings			
Parameter	Low Limit	High Limit	Alarm Delay
Heart Rate	40	130	0 seconds
Atrial Fibrillation	When event is longer than 30 sec.		NA

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Parameters

Body Measurements	Shown As	Range	Units	Accuracy	Comment
Heart Rate	HR	30 - 200	Beats per minute (BPM)	± 3 BPM	HR is computed every 2.048 seconds and the displayed value is updated every 2.048 seconds as the average of the last 6 beat-to-beat intervals
Atrial Fibrillation	AF	N/A	N/A	N/A	Computed every 10 seconds using last 30 seconds of ECG data

ECG Arrhythmia Definitions

Arrhythmia Definitions	
Normal Sinus Rhythm	Normal rhythm of the heart, originating in the sinoatrial (SA) node with a regular rhythm and heart rate of 60-100 beats per minute (BPM)
Bradycardia	Regular rhythm and heart rate below 60 BPM
Tachycardia	Regular rhythm and heart rate more than 100 BPM
Sinus Pause	SA node does not discharge an impulse for ≥ 2 seconds
Supraventricular Bigeminy	Every other beat is a premature supraventricular contraction
Supraventricular Trigeminy	Every other beat is a premature supraventricular contraction
Supraventricular Couplet	Two consecutive premature supraventricular beats
Supraventricular Triplet	Three consecutive premature supraventricular beats
Multi-focal Atrial Tachycardia (MAT)	Atrial tachycardia (heart rate greater than 100) originating in three or more different atrial ectopic pacemaker sites, P waves differ in size, shape, and direction
Nodal Rhythm	Regular rhythm arising from the atrioventricular (AV) node typically the QRS complexes are narrow
Atrial Fibrillation	Absence of P waves, with disorganized electrical activity in their place, and irregular R–R intervals due to irregular conduction of impulses to the ventricles.
Atrial Flutter	Absence of P waves, presence of characteristic "flutter waves". Individual flutter waves may be symmetrical, resembling p-waves, or maybe asymmetrical with a "sawtooth" shape.

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Ventricular Bigeminy	Every other beat is a premature ventricular contraction
Ventricular Trigeminy	Every third beat is a premature ventricular contraction
Ventricular Couplet	Two consecutive premature ventricular beats
Ventricular Triplet	Three consecutive premature ventricular beats
Ventricular Tachycardia	Originates in an ectopic pacemaker in the ventricles characterized as a wide complex (QRS duration greater than 120 milliseconds) and heart rate greater than 100 BPM
Monomorphic Ventricular Beat	QRS morphology is the same from beat to beat
Polymorphic Ventricular Beat	QRS morphology changes from beat to beat
Ventricular Flutter	Sinusoidal waveform without clear definition of QRS and T waves with loss of organized electrical activity with a rate over 250-350 BPM
Ventricular Fibrillation	Arrhythmia originating in multiple ectopic pacemakers in ventricles characterized by many fibrillatory waves and no QRS complexes
Asystole	Absence of any contractions
AV Block (First degree)	All normal P waves are followed by QRS complexes, but the PR interval is longer than normal (> 0.20 seconds)
AV Block (Second degree)	Some normal P waves are followed by QRS complexes, but some are not. Type I- PR interval progressively lengthens with each beat until atrial impulse is not conducted and QRS complex is dropped, AV nodal conduction resumes with next beat, and the sequence is repeated. Type II- PR interval remains constant with beats intermittently not conducted and QRS complexes dropped
AV Block (Third degree)	No relationship between P waves and QRS complexes (AV dissociation) the P wave rate is greater than the QRS rate
Pacemaker Rhythm	Arrythmia produced by an artificial pacemaker

Definitions from public source domain

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Attachment A: Alarm System Disclosures

Alarm System Description

The SmartCardia 7L Platform is a Distributed Information System (DIS) that communicates alarm conditions in real time for Heart Rate and Atrial Fibrillation. It provides alarm signals at a remote location but does not contain a mechanism for confirmation of receipt of the alarm signal.

	WARNING: The alarm system in the SmartCardia 7L Platform is a distributed information system and cannot be relied upon to indicate the clinician has received the alarm signals as there is no feedback mechanism for the clinician to acknowledge such receipt.

Alarm Conditions

The SmartCardia 7L Platform provides alarm signals for heart rate (upper and lower threshold violations) and Atrial Fibrillation. In addition, there are information signals for battery charge level and wireless communication status.

Alarm System Delay

The SmartCardia 7L Platform measures the ECG of a patient through a body worn sensor/patch (the source). The ECG waveform and heart rate are communicated via Bluetooth wireless communication to the SmartCardia Phone (the integrator) which acts as a gateway to the SmartCardia cloud-based backend server (the communicator). Alarm signals are communicated when the heart rate exceeds the alarm limit threshold (either upper or lower) or Atrial Fibrillation is detected for more than 30 seconds.

Delays from the 7L Sensor to the SmartCardia Phone to the SmartCardia backend and for presentation on the web browser are shown in Table 1. These were measured using a simulated signal and applying the alarm condition (High or Low HR, or Atrial Fibrillation) to the 7L Sensor and measuring the delay time to see the condition on the SmartCardia Phone, on the SmartCardia Backend server, and resultant display of the alarm signal on the SmartCardia Web Browser.

Table 1. Alarm Signal Delay

7L Sensor to SmartCardia Phone	SmartCardia Phone to SmartCardia Backend	SmartCardia Backend Server to Display on the SmartCardia Web Browser	Total Alarm Signal Delay (seconds)
Up to 100 msec.	Up to 1 sec.	User selectable 0, 4, 8 sec.	Based on user selection up to 9.1 sec.

Alarm signal delay is a user choice to reduce false alarm signals due to artifact or momentary violations of limit settings. Follow clinical practice guidelines for your institution when

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selecting an alarm delay. If no delay is desired, set to "0" and the alarm system delay will be approximately 1.1 seconds. However, this may result in multiple false alarm signals so take caution when making this selection.

Alarm System Presets

The SmartCardia 7L Platform contains one alarm preset for heart rate. This is set by the manufacturer to a lower heart rate value of 40 and an upper heart rate value of 130, either condition lasting longer than the user selectable alarm delay time of 0, 4, 8 seconds. The delay preset is at 0 seconds. . These alarm preset values are configured by the manufacturer and cannot be permanently modified.

These alarm preset values can only be changed by an operator with authorized credentials (username and password login) to ensure proper monitoring for a patient's clinical condition. These settings are automatically selected upon admitting a new patient.

Alarm Settings

In the event of a power failure or loss of power, whether momentarily or for up to 30 seconds, the alarm settings are not affected as these are stored in the SmartCardia cloud-based server. When power is restored to the viewing web browser computer, the alarm settings remain as they were prior to the power loss.

The SmartCardia 7L Platform does not continuously display the alarm limit settings but these are displayed through operation action by selecting "Patient Alarm Settings".
The SmartCardia 7L Platform does not incorporate "Intelligent Alarm System" as defined in the IEC 60601-1-8 standard, nor does it provide automatic setting of alarm limits. Customized alarm limit settings must be done through manual operator action.

To check the alarm system functionality, manually set an alarm limit below or above the current heart rate. The visual and auditory alarm signals should be present after the selected delay time.

Alarm Sounds

The SmartCardia 7L Platform provides alarm signals for heart rate (upper and lower threshold violations) and Atrial Fibrillation. Table 2 shows the alarm condition, alarm priority, alarm signal, and sound presented. The sound level is operator adjusted only, the SmartCardia 7L Platform does not incorporate dynamically algorithm-adjusted sound levels. The SmartCardia 7L Platform does not incorporate reminder signals as defined in the IEC 60601-8 Alarm Standard.

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Table 2. Alarm Signals and Sounds

Alarm Condition	Alarm Priority	Alarm Signal Displayed	Alarm Sound
Heart Rate lower than the low alarm limit setting	High	Patient tile outlined in red, Heart Rate numeric zone backfilled in Red and flashing, Heart Rate numeric in white text	High Priority pointer per IEC 60601-8 standard, Annex G, table G.3
Heart Rate higher than the high alarm limit setting	High	Patient tile outlined in red, Heart Rate numeric zone backfilled in Red and flashing, Heart Rate numeric in white text	High Priority pointer per IEC 60601-8 standard, Annex G, table G.3
Atrial Fibrillation detected for greater than 30 seconds	Medium	AF message displayed below the heart rate when in the single patient data view, below patient name in the multi-patient view. AF message is highlighted in yellow with 'AF' in white text and flashing.	Medium Priority pointer per IEC 60601-8 standard, Annex G, table G.3

The alarm signal auditory sound level is controlled by the speaker volume control on the personal computer that is presenting the SmartCardia *7L Web Browser*. Personal computers have the ability to turn the auditory sound completely OFF (Mute).

	WARNING: Do not try to turn the volume on the personal computer to OFF or Mute. Do not try to adjust the volume to such a low value that auditory alarm signals cannot be heard. The 7L Platform will indicate a waring on the display.

The SmartCardia 7L Platform enables auditory alarm sounds to be turned OFF for an individual patient for five minutes. At the expiration of the five minutes, the audio is turned ON automatically. This inactivation state only impacts the selected patient, other patient's audio remains ON unless they are individually inactivated.

This inactivation state is indicated in the patient tile using the audio off symbol.

Operator Position

For continuous monitoring, the operator should be located from one to four meters from the display of patient data to ensure they can identify alarm signals.

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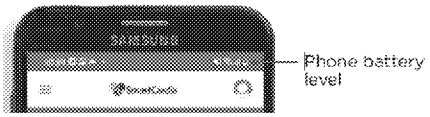
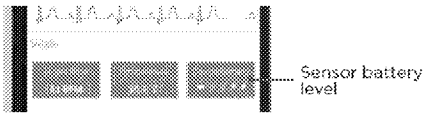
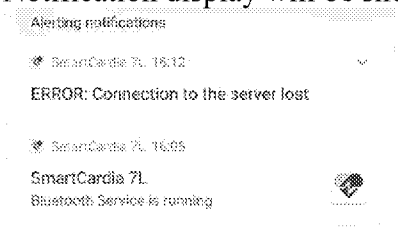
Information Signals

The SmartCardia 7L Platform displays information signals as shown in Table 3.

Table 3. Information Signals

Information Signal	**Meaning**	**Display**	**Sound**
Battery charge level in SmartCardia Phone	Charge level in SmartCardia Phone		Visual indicator
Battery charge level in the SmartCardia 7L Sensor green	Charge level at 100%, 75%, 50% 25%	 100% (4 green dots), 75% (3 green dots), 50% (2 green dots), 25% (1 green dot)	Visual indicator
Battery charge level in the SmartCardia 7L Sensor – red	Charge Level less than 10% remaining		Visual indicator
Bluetooth Connection	Bluetooth not connected between the SmartCardia 7L Sensor and the SmartCardia phone	Bluetooth ON icon located in the upper right of the top bar of the phone disappears, SmartCardia logo appears next to the time. In addition, a red banner "trying to re-connect Please wait" appears on mobile app display	Single notification sound
Cellular Connection	The SmartCardia Phone and the cloud service are not connected	The same SmartCardia logo will appear, and Wi-Fi icon will disappear. If you swipe down from top, the Alerting Notification display will be shown 	Single notification sound

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Alarm System Logging

The SmartCardia 7L Platform logs all alarm related data in a responsible organization log. There is no separate operator alarm system log. The alarm system log can only be accessed by SmartCardia authorized personnel. The alarm log is maintained in the SmartCardia cloud-based backend server. Powering down of the SmartCardia 7L Web Browser instance does not affect the alarm system log. The SmartCardia cloud-based server is maintained by Amazon Web Services and is redundant and automatically backed up. The alarm system will not experience a total loss of power; therefore, the alarm system log is not impacted.

The alarm system log is stored on the SmartCardia cloud-based backend server and has an unlimited capacity. In the event the log reaches maximum capacity, the oldest data stored are deleted and the newest data are saved.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118

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Attachment B Electromagnetic Compatibility

FCC ID: XOYNINAAB30
Medical electrical equipment can generate or receive electromagnetic energy or interference. This product has been evaluated for electromagnetic compatibility (EMC) with the appropriate accessories according to IEC 60601-1-2:2020, the international standard for EMC for medical electrical equipment. This IEC standard has been adopted in the European Union as the European Norm, EN 60601-1-2:2015.
Product Essential Performance specified for EMC:

1. The Wireless EEG System shall not change operating modes, settings, or modify stored data during EMC immunity testing.
2. Within 30 s after exposure to transient electromagnetic phenomena, the device shall resume normal operation without operator intervention. The resumption to normal operation shall be without loss of any operator settings or stored data

Radio frequency (RF) interference from nearby transmitting devices can degrade performance of the product. Electromagnetic compatibility with surrounding devices should be assessed prior to and when using the product.
Fixed, portable, and mobile radio frequency communications equipment can also affect the performance of electrical medical equipment. If this device does cause harmful interference to other devices, you may need to do one of the following:
• Reorient or relocate the other device,
• Move the devices farther apart,
• Contact the device manufacturer for assistance.
Your service provider for RF communications equipment may have a minimum recommended separation distance between that equipment and the product.
Compliance is only claimed for sensors and accessories that are listed in documentation accompanying the product.

Warnings and Cautions

- The use of accessories, sensors, and cables other than those specified in the technical and user documentation can result in increased electromagnetic emissions or decreased immunity of the product.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Short-range radio communication is subject to interruption that may be caused by interference from other radio sources in the vicinity. This can include microwaves (microwave ovens), other Bluetooth devices, and cellular phones. Outside of the operating frequency and 5% above and below is the exclusion band according to IEC

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60601-1-2. The short-range radio connection is immune up to 10 V/m in the frequency range from 80MHz to 2.7 GHz. If the strength and duration of the radio interference is strong, the interruption may occur for an extended period.

- Always inspect the product before use. If the product appears damaged or out of sorts, do not use.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The SmartCardia 7L Platform is equipped with a wireless communication interface and intentionally receives RF electromagnetic energy for the purpose of its operation. Therefore, other equipment may cause interference, even if that other equipment complies with CISPR emission requirements.
- These guidelines may not apply in all situations. Electromagnetic energy is affected by the type of structures, objects, and people in the vicinity of the product.
- The SmartCardia 7L Platform should not be used in an aircraft.

To Reduce Electromagnetic Interference

The SmartCardia System and associated accessories can be susceptible to interference from other RF energy sources and continuous, repetitive, power line bursts.

Examples of other sources of RF interference are other medical electrical devices, cellular phone products, information technology equipment, microwave ovens, and radio/television transmission. If interference is encountered, as demonstrated by excessive artifact on the ECG or a sudden and dramatic change in measurement values, you should attempt to locate the source.

• Is the interference due to a misplaced or poorly applied SmartCardia 7L Sensor/7L Patch? If this is the case, check the installation to ensure it is properly installed or positioned and located correctly per the user instructions.

• Does the interference come and go or is it always present?

• Does the interference happen only when the SmartCardia 7L Sensor/7L Patch is in a specific place?

• Does the interference occur only when the SmartCardia 7L Sensor/7L Patch are near other medical or electrical equipment?

The first thing to do when the interference source is located is to reduce the interference as much as possible by moving as far from the source as possible. Do this prior to contacting your service representative to ensure you have taken necessary precautions.

Restrictions for Use

Artifact on ECG and other physiological waveforms caused by electromagnetic interference should be evaluated by a physician or physician-authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

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The SmartCardia 7L Platform environment of use is in a physician office, outpatient facility, or in the patient's home.

Electromagnetic Compatibility (EMC) Specifications
Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your equipment according to the EMC information provided in this manual. Portable and mobile radiofrequency (RF) communications equipment can affect medical electrical equipment.
Accessories Compliant with EMC Standards
Only accessories listed as accessories for the SmartCardia system comply, with the requirements of IEC 60601-1-2:2014.

Electromagnetic Emissions
Specification
The SmartCardia 7L Platform uses Bluetooth LE version 5 and includes an RF transmitter for Bluetooth Low Energy that transmits data in the 2.4 GHz frequency band (2.400 to 2.4835GHz)
using data rates of 2 Mbps

Guidance and manufacturers declaration – electromagnetic emissions		
The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Avoiding Electromagnetic Interference**
Radio Frequency (RF) emissions	Group 1	The SmartCardia System uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The SmartCardia System is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Not Applicable	Device is powered by disposable battery only
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Not Applicable	Device is powered by disposable battery only

Electromagnetic Immunity

Guidance and manufacturers declaration – electromagnetic immunity

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The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Comments**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2kV, ± 4kV, ±8kV, ±15kV air	± 8 kV contact ± 2kV, ± 4kV, ±8kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC61000-4-4 EFT/burst immunity	± 2 kV, 100 kHz burst frequency, coupling duration ≥ 60s, positive and negative polarity	± 2 kV, 100 kHz burst frequency, coupling duration ≥ 60s, positive and negative polarity	
IEC61000-4-5 Surge Immunity	± 0.5 kV, ± 1 kV differential mode source impedance, positive and negative polarity, phase angle at 0°, 90°, 180°, 270°, 60 sec repetition rate, 5 surges at each position	± 0.5 kV, ± 1 kV differential mode source impedance, positive and negative polarity, phase angle at 0°, 90°, 180°, 270°, 60 sec repetition rate, 5 surges at each position	AC Power Line Cable, unshielded, active status, 0.3 m in length
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz 60 s each axis (X, Y, Z)	30 A/m 50 Hz or 60 Hz 60 s each axis (X, Y, Z)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, home, and/or healthcare environment
IEC61000-4-11 Voltage dips	100% dip; 0.5 period, phase angle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 3 interruptions, 15s repetition	100% dip; 0.5 period, phase angle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°, 3 interruptions, 15s repetition	

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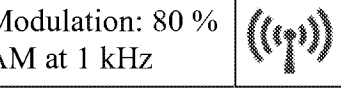
	100% dip; 1 period, phase angle at 180°, 3 interruptions, 15s repetition	100% dip; 1 period, phase angle at 180°, 3 interruptions, 15s repetition	
	30% dip; 30 periods (60 Hz), 180°, 3 interruptions, 15s repetition	30% dip; 30 periods (60 Hz), 180°, 3 interruptions, 15s repetition	
	100% dip; 300 periods (60 Hz), 180°, 3 interruptions, 15s repetition	100% dip; 300 periods (60 Hz), 180°, 3 interruptions, 15s repetition	
IEC61000-4-39 Immunity - Proximity Magnetic Fields	30 kHz, CW Modulation, 5 cm distance, 8 A/m	30 kHz, CW Modulation, 5 cm distance, 8 A/m	
	134.2 kHz, PM Modulation, 5 cm distance, 65 A/m	134.2 kHz, PM Modulation, 5 cm distance, 65 A/m	
	13.56 MHz, PM Modulation, 5 cm distance, 7.5 A/m	13.56 MHz, PM Modulation, 5 cm distance, 7.5 A/m	

Guidance and manufacturers declaration – RF Immunity

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform may use it in such an environment.

Immunity Test	**Immunity Test Levels**	**Compliance Levels**	**Electromagnetic Environment Guidance**
IEC 61000-4-6 Conducted Disturbances, Induced by RF Fields AC Power Line Cable, unshielded, active status, 0.3 m in length	3 Vrms 0.15 MHz – 80 MHz, 6 Vrms in ISM bands between 0.15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	3 Vrms 0.15 MHz – 80 MHz, 6 Vrms in ISM bands between 0.15 MHz and 80 MHz Modulation: 80 % AM at 1 kHz	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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IEC 61000-4-3 Radiated RF	10 V/m, Antenna Separation 2.5 m, 80 MHz – 1000 MHz, 1.0 GHz - 2.7 GHz, 80 % AM modulation at 1 kHz, 1% frequency step @ 3s dwell time	10 V/m, Antenna Separation 2.5 m, 80 MHz – 1000 MHz, 1.0 GHz - 2.7 GHz, 80 % AM modulation at 1 kHz, 1% frequency step @ 3s dwell time	
NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SmartCardia 7L Platform is used exceeds the applicable RF compliance level above, the SmartCardia 7L Platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended Separation Distances

Guidance and manufacturers declaration – recommended separation distances between portable and mobile RF communications equipment and the SmartCardia 7L Platform

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter - W	**Separation distance according to frequency of transmitter m**		

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	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	d = 1.2√P	**d = 1.2√P**	**d = 2.3√P**
	Minimum Separation distance	**Minimum Separation distance**	**Minimum Separation distance**
0.01 W	0.1 m	0.1 m	0.2 m
0.1 W	0.4 m	0.4 m	0.7 m
1 W	1.2 m	1.3 m	2.3 m
10 W	3.8 m	3.8 m	7.3 m
100 W	12.0 m	12.0 m	23.0 m
Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).			

Portable and mobile RF communications equipment should be used no closer to any part of the SmartCardia System, than these recommended separation distances that are calculated from the equation appropriate for the frequency of the transmission.

Enclosure Port Immunity

Guidance and manufacturers declaration – Proximity Fields from RF Wireless Communications Equipment

The SmartCardia 7L Sensor, 7L Patch, and SmartCardia Phone is intended for use in the electromagnetic environment specified below. The customer or the user of the SmartCardia 7L Platform should assure that it is used in such an environment.

Band (MHz)	Test frequency (Mhz)	Modulation	Maximum Power (W)	Distance (m)	Immunity Test level (V/m)
380 – 390	385	Pulse modulation 18 Hz	1.8	0.3	27
430 – 470	450	Pulse modulation 18 Hz	2	0.3	28
704 – 787	710	Pulse modulation 217 Hz	0.2	0.3	9
	745	Pulse modulation 217 Hz	0.2	0.3	9
	780	Pulse modulation 217 Hz	0.2	0.3	9
800 – 960	810	Pulse modulation 18 Hz	2.0	0.3	28

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	870	Pulse modulation 18 Hz	2.0	0.3	28
	930	Pulse modulation 18 Hz	2.0	0.3	28
1700 – 1990	1720	Pulse modulation 217 Hz	2.0	0.3	28
	1845	Pulse modulation 217 Hz	2.0	0.3	28
	1970	Pulse modulation 217 Hz	2.0	0.3	28
2400 – 2570	2450	Pulse modulation 217 Hz	2.0	0.3	28
5100 – 5800	5240	Pulse modulation 217 Hz	0.2	0.3	9
	5500	Pulse modulation 217 Hz	0.2	0.3	9
	5785	Pulse modulation 217 Hz	0.2	0.3	9

Note:

1. For some services, only the uplink frequencies are included.
2. The carrier shall be modulated using a 50% duty cycle square wave signal.
3. As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case

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Attachment C: Wireless Communications Specifications

The SmartCardia 7L Platform consists of two wireless links: a Bluetooth link between the 7L Sensor and the SmartCardia smartphone and a cellular link between the SmartCardia smartphone and the internet.

Link	Standard	Frequency	Power output / modulation
BLE link between sensor and phone	IEEE 802.15.4 Bluetooth V 5.0	2.4 Ghz Gaussian	8 dBm Frequency spread spectrum with PSK modulation Gaussian frequency shift
Cellular link between phone and server	Cellular network	746-757 MHz & 776-787 MHz	up to 3 Watts 4G. CDMA-less B2/B3/B4/B5/B7/B12/B13/B20/B66

Operating characteristics:

BLE link

The BLE link is preconfigured by SmartCardia at the time of manufacturing. BLE version 4.0 or greater is implemented. The link is configured such that only SmartCardia sensors will be recognized by the SmartCardia smartphone. No other BL or BLE devices will be recognized. The operating range is within 3 meters. The patient IFU includes a note to keep the 7L Sensor within 10 ft. of the smartphone at all times. Quality of Service and Cybersecurity requirements are managed through the configuration of the sensor and phone by authorized SmartCardia personnel. All data originating in the phone is encrypted at rest and during transport.

Cellular phone link

The cellular phone link is determined by the phone platform, the Samsung Galaxy A12 Smartphone. The phone is configured by SmartCardia authorized personnel and placed in a kiosk mode. The SmartCardia phone hosts no other applications other than the SmartCardia application. The audio telephone operation is disabled. The phone UI includes a cellular signal strength bar. When connectivity is lost the signal strength bar indicated no bars and a notification message is sent to the clinician viewer. When connectivity is restored all data (up to 14 days) stored in the sensor and phone are forwarded to the SmartCardia Server. Quality of Service requirements are managed by SmartCardia when the phone is configured in the kiosk mode. The cellular link is unburdened by all other cellular data allowing only SmartCardia packets to communicate with the SmartCardia server.

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Network Access

Network access is managed only by authorized SmartCardia personnel. All devices are preconfigured during the provisioning process. Users have no access to network administrative functions.

Warnings and Cautions regarding wireless links

Warnings and cautions associated with wireless communications are found in the patient IFU, Clinician IFU and the EMC section of this IFU.

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Attachment D: Cybersecurity Disclosure

SmartCardia is certified to ISO 27001; 2013 Information technology- Security techniques- Information security management systems- Requirements. As continued post-market activities, SmartCardia conducts an annual audit to this standard.

SmartCardia employs a risk-based approach per the ISO 14971 standard to design and develop products with the appropriate cybersecurity protections for the intended use. Hazards are identified early in the project development lifecycle and updated at each phase of development to ensure existing risks are mitigated and any new risk are identified and addressed prior to commercialization. This process ensures the proper maintenance and continuity of device safety and essential performance as well as the continued safety and effectiveness.

The SmartCardia 7L Platform cybersecurity includes:

- **Identification and Protection of Device Assets and Functionality**
    - The SC System is designed to protect assets and functionality to reduce risk of multi-patient harm due to the loss of authenticity, availability, integrity, and confidentiality. Protection mechanisms are established that prevents all unauthorized use (through all interfaces) to ensure code, data, and execution integrity (subversion of system functionality/safety/security features) and protect confidentiality of data (insofar as its release could be leveraged) to effect multi-patient harm.
    - Appropriate protections are in place regarding the SC System that prevents sensitive information from being read by unauthorized parties either in storage or in transmission through the following (Encryption is used)
- **Limit Access to Trusted Users & Devices Only**
    - Access to the SC System is through the authentication of users via:
        - Email and password (for clinicians).
        - Device MAC and patient's date of birth (for patients)
    - Automated time methods will be used to terminate sessions when appropriate.
- **Passwords will be unique for each user and no public access will be given.**
    - During new patient provisioning, a device is assigned to the patient and a monitoring service is configured. The new patient will receive a kit with a device and a phone, with the SmartCardia app already installed. The patient will login using the device MAC and his/her date of birth. This identifies the patient and the specific sensor(s) connected to the mobile App. This authentication is encrypted and stored in an isolated repository with no public access.
    - Administrative access is controlled by a unique Name and Password.

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Cybersecurity Bills of Material (CBOM)

Manufacturer	Manufacturer Reference	Revision	Purpose
Google	Android	10	Mobile Gateway to cloud based server
	com.android.support:support-V4	v4:27.1.1	Support Library
	com.android.support:support-V13	V13:27.1.1	Support Library
	com.android.volley:volley:1.1.0	1.1.0	HTTP request Library
	com.rabbitmq:amqp-client:	4.6.0	AMQP Client for publish/subscribe
	org.greenrobot:eventbus:	3.1	Event bus for inter-module communications
	com.andrognito.flashbar:flashbar:	1.0.3	Customizable alert and notification Library
Google	Chrome Web Browser	93	Web browser Operating system
Ubuntu Server	Linux	18.04 LTS	Server Operating System

Cybersecurity - 7L Sensor:

- The sensor is a sealed unit with no external ports published to an end user.
- There are no software of unknown provenance (SOUP) in the sensor firmware.
- All firmware and software are controlled internally with no access allowed by end users.
- The sensor hardware manufacturer is certified to ISO 13485. The software load is only for a minimum number of functions. Cyclic redundancy checks (CRC) ensure uncorrupted load of data.
- Firmware is loaded after the sensor is completely encapsulated with CRC checks to ensure uncorrupted loading. The sensor is not serviceable.
- Firmware updates are performed over the BLE link using BLE DMU profile. An over-the-air update can only be performed under the control of SmartCardia. Updating sensor software requires acknowledgement of a private key embedded in the sensor firmware. This key is known only to trained authorized SmartCardia personnel.
- The BLE link data is encrypted during transport in normal operation.

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Cybersecurity - Mobile Gateway:

- The Android smartphone mobile gateway is configured and provided by SmartCardia authorized personnel.
- The Android OS is placed in kiosk mode with only necessary functions enabled to support the SmartCardia App. The end user is not allowed to add Apps.
- The USB-C port is disabled of all functionality except battery charging.
- WWAN link is encrypted during transport.
- All data stored by the SmartCardia App is encrypted.
- SW updates are performed only by trained authorized SmartCardia personnel over a secure https link.

Cybersecurity - Backend AWS

- The Amazon Web Service instance is configured and managed by SmartCardia authorized personnel.
- The Amazon Web Service is configured with automatic backup service such that the database can be restored as required by authorized SmartCardia personnel.
- Two factor authentication is required by SmartCardia personnel in order to access administrative functions.
- PHI is separated from physiologic data in the AWS database.
- All data is encrypted at rest and in transport.
- AWS provides routine period scans for the detection of intrusion and malware.

Cybersecurity - Remote Viewing Station

- Access to SmartCardia remote viewing is only through a secured browser.
- All communication between the remote viewing station and backend AWS is encrypted over a https link.

Cybersecurity - Notification to User

In the event of a security breach, users are notified by SmartCardia as soon as the breach becomes noticed. The notification method may be via email or other direct communication.

Forensic Investigation

AWS captures and stores forensic evidence for investigation and resolution.

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Attachment E: Reprocessing

Reprovisioning Process

The patient is instructed to return the SmartCardia *7L Sensor*, SmartCardia *Phone*, medical grade charger, and phone cable using the pre-addressed, pre-paid mailing envelope for reprocessing. They should dispose of all unused *7L Patches*.

NOTE: The *7L Sensor* may be returned inside of the used *7L Patch* if there is difficulty removing the *7L Sensor* after use.

The provider organization reprocesses their own patient returned devices or an approved reprocessing center. Both situations follow the same reprocessing steps.

The reprocessing process shall take place at room temperature and humidity on a clean surface that is separated from all other activities.

Individuals performing this process shall be trained and documented in the appropriate training record.

Service life is not adversely impacted by the number of reprocessing cycles.

Receipt of *7L Sensor*, *Phone*, medical grade charger, and phone cable

- Record the date and time they are received for reprocessing.

NOTE: If any unused *7L Patches* are received, discard.

7L Web Browser

- Verify the *7L Sensor* is listed as an available device on the *7L Web Browser* page assigned to the responsible organization. If not, "Unassign" it from the previous patient.

Clean and Disinfect

1. Using protective gloves, inspect the *7L Sensor*, SmartCardia *Phone*, medical grade charger, and phone cable for physical damage including label integrity.

   NOTE: If the used *7L Patch* is returned with the *7L Sensor* still inside, carefully remove the *7L Sensor* and properly dispose of the *7L Patch*.

   NOTE: Do not immerse the *Phone* in water or other liquid.

2. Remove any debris, damaged labels, adhesive, etc. from surfaces with a damp cloth using a mild detergent.
3. Disinfect the *7L Sensor* with PDI Super Sani-Cloth® Germicidal Disposable Wipe for five minutes following the instructions on the package.
4. Wipe Phone with disinfectant wipes per instructions on the disinfectant package.
5. Wipe devices with clean cloth to remove any residual disinfectant.
6. Set devices aside and covered for two minutes with a clean disposable towel to maximize drying time.

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Testing of Components

1. Check if there is any damage on the *7L Sensor* or labels. If you find any damage, stop using it, and contact SmartCardia Customer Support.
2. Insert *7L Sensor* into a test *7L Patch* to verify it works (LED lights turn on)
3. Turn Phone on and test for wireless link. (Verify BLE link between *Phone* and *7L Sensor* is connected)
4. Using the *7L Mobile Application*, scan for the *7L Sensor*
5. Verify the MAC address of the *7L Sensor* is recognized
6. Record testing of *7L Sensor*, MAC address, and *Phone*
7. Store cleaned and disinfected *7L Sensor*, *Phone*, medical grade charger, and phone cable (keep the *7L Sensor* and SmartCardia *Phone* together as they are paired)

Provision 7L Sensor and Phone for new patient admission

1. "Add Patient" on the *7L Web Browser*
2. Enter patient information
3. Select the *7L Sensor* device and *Phone* that are going to be used by the new patient
4. Insert the selected *7L Sensor* into an unused *7L Patch* (confirm LED lights turn on)
5. Turn on the Phone (confirm that it is fully charged)

NOTE: If "Error occurred while logging you in"

- Select CANCEL at the bottom of the screen
- For password, enter 0111, select "OK".
- Scan
- Select S7L with the MAC address of the *7L Sensor* in use
- Once connection successful, select OK to pair *7L Sensor* and *Phone*

Verification *Sensor* and *Phone* are ready to send patient

1. Verify that the *Phone* screen shows Welcome with the new patient's name asking them to enter their date of birth
2. Turn off *Phone* and remove *7L Sensor* from *7L Patch* used for testing

Preparation of SmartCardia Kit for shipping

Insert the following components into the kit box insert

- *7L Sensor placed in sensor box*
- *Phone*, phone cable, and *Phone* instructions placed in phone box
- Medical grade charger

Place on top of the assembled components listed above

- Small envelope for phone return to put into larger pre-addressed, pre-paid mailing envelope for return following monitoring service

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- *7L Patch* (two packages)
- Guide card, “let’s get started assembling and positioning patch”
- Patient User Guide

Reference: ISO 17664-1:2021(E) Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices

Software License Agreement and Warranty

Contact SmartCardia Customer Support for information about the software license agreement and warranty.

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UDI	Unique Device Identifier(s) 7L Sensor 7640375610058 7L Patch 7640375610041
	SmartCardia Inc. EPFL Innovation Park, Building C 1015 Lausanne, Switzerland Customer Support: 800-363-8151
REF	PL-08 SmartCardia 7L™ Platform – Patient Guide
	July 15, 2023
Rx ONLY	Prescription Only
	Consult Instructions for Use or User Manual
	Type BF
	See Warnings and Cautions
EC REP	SmartCardia Inc. EPFL Innovation Park, Building C 1015 Lausanne, Switzerland
FCC	This device complies with Part 15 of the FCC Rules. Operation and is subject to the following two conditions. 1. These devices may not cause harmful interference, and 2. These devices must accept any interference received, including interference that may cause undesired operation.
FCC ID:	XPYNINAAB30
	Non-ionizing electromagnetic radiation

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SmartCardia SA
EPFL Innovation Park, Building C
1015 Lausanne, Switzerland
info@smartcardia.com
Customer Support 800-363-8151

Questions? Contact FDA/CDRH/OCE/DID at CDRH-EQUESTAT@fda.hhs.gov or 301-796-8118
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· PL-10 SmartCardia 7L Clinician QRG

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We are here to help 800-363-8151

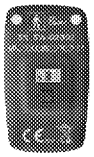
System Description

The SmartCardia 7L™ Platform is a system comprising of a wireless sensor component (the *7L Sensor*), an adhesive patch (the *7L Patch*) that the *7L Sensor* connects to, a mobile component (the SmartCardia *Phone*), and a backend server cloud platform (SmartCardia *7L Web Browser*) used to access the patient data.

SmartCardia *7L Sensor*

A reusable Sensor (NOT Disposable)

- Inserts into *7L Patch*
- Sends patient ECG data to SmartCardia Phone
- Waterproof (IPX7) in *7L Patch*



SmartCardia *7L Patch*

A single-use Patch (Disposable)

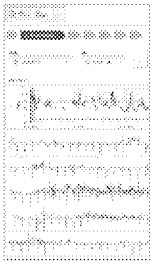
- Includes batteries
- Holds reusable *7L Sensor*
- Medical adhesive to skin on chest

SmartCardia *Phone*

- Mobile gateway for SmartCardia data
- Must always be kept close to SmartCardia *7L Sensor*
- Charge daily (or more often)

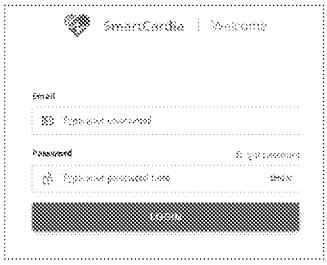
SmartCardia *7L Web Browser*

- Service mode choices (Holter, Extended Holter, Event)
- View patient data, manage alarms, perform Holter analysis, create reports



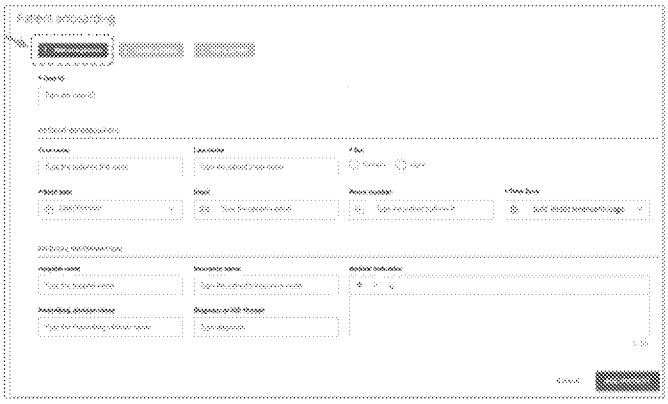
Clinician LOGIN

- Enter your user email and password
- Click LOGIN to show list of patients



Admit a Patient

- On “List of patients” screen in upper right corner select “ADD PATIENT”
- The “Patient onboarding” screen opens with the “Add new patient” screen
- Enter all patient information
- Select “ADD PATIENT” at the bottom right of screen to advance to next step in onboarding process to assign a device



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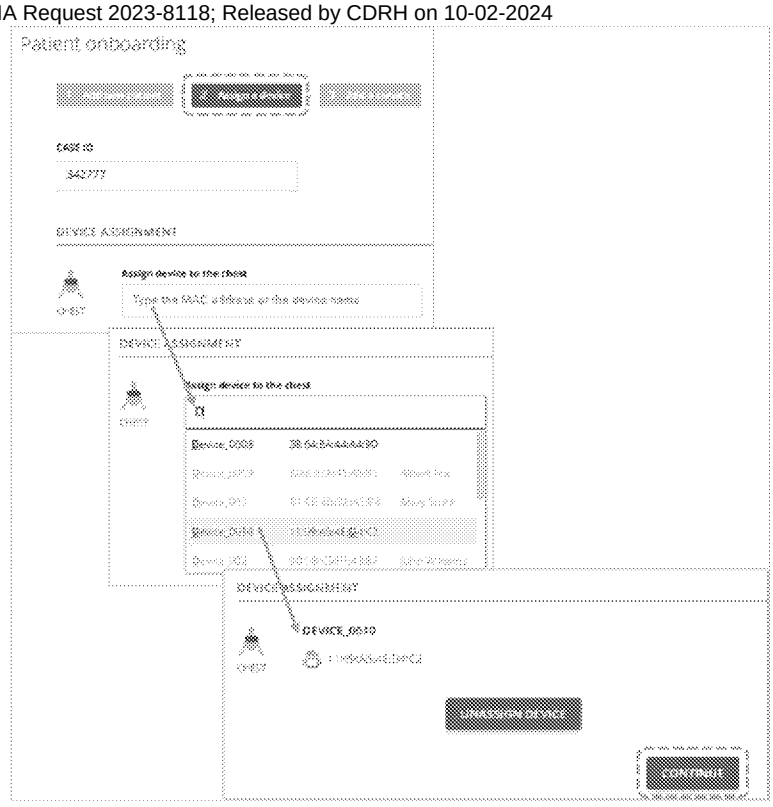
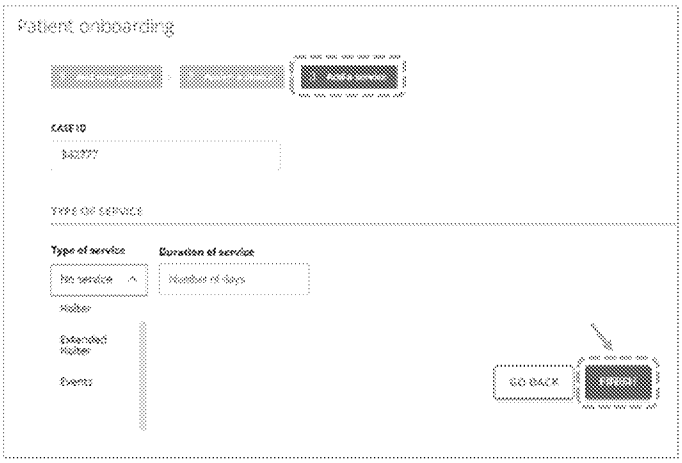
- On the next screen "Assign a device"
- Type MAC address or device name. As information is typed, a box below begins to populate with device, then select it from list of options, next select "CONTINUE" to associate *7L Sensor* to the patient (MAC address is found on surface of *7L Sensor* that is inserted into *7L Patch*)
- This advances you to the next step in onboarding process to "ADD A SERVICE"



- From drop-down menu, select type of service
- Enter number of days duration of service
- Select "FINISH"
- This new patient is now added to the patient list and displayed on Multi-Patient View



NOTE: Service begins once *7L Sensor* is on patient's body and connected to *7L Mobile Application*.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display. Consult Technical Manual.

Service type options and features

	Features				
Service Type	Measurements	Event Capture	Real Time View	Duration	Report Editing and Creation
Holter	7 lead ECG, Atrial Fibrillation	Yes	Optional	<48 hrs	Yes
Extended Holter	7 lead ECG, Atrial Fibrillation	Yes	Optional	>48 hrs	Yes
Event	7 lead ECG, Atrial Fibrillation	Yes	Optional	As ordered	Yes

Note: the maximum duration for a single SmartCardia 7L Patch is 14 days.

Type of service for monitoring is listed as ordered by the physician. Status is “Running”, “Not Started”, or “Finished”. Service can be changed or stopped at any time as ordered by the physician.

Select “Stop” to change the type of monitoring service and/or number of days.

Select “Stop” at the completion of monitoring and continue to “Unassign” *7L Sensor* device.

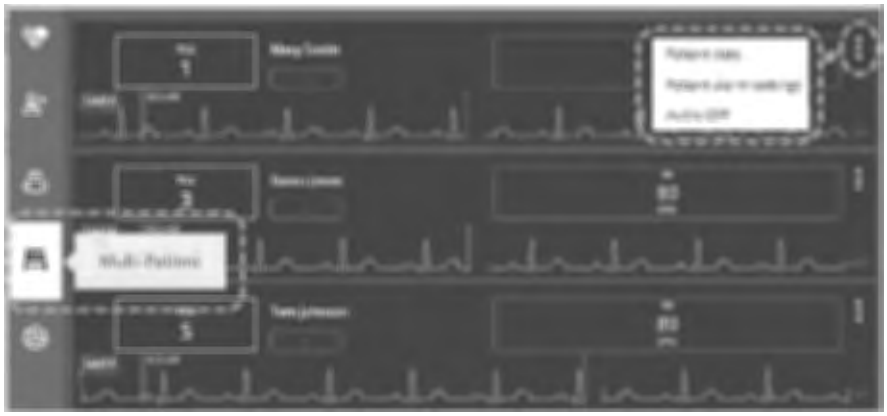
Customizing Heart Rate Alarm and Event Notification Settings for Individual Patients

Alarms and event notifications are pre-set by manufacturer, can be modified to meet practice requirements, customized for patient clinical condition, and provider orders.

- Select patient by clicking on the “Patients” icon on left menu to see list of patients
- Click on patient’s name to adjust their heart rate alarm and arrhythmia event notification settings
- On right navigation menu, select “Alarm Settings” to review and edit heart rate alarm and arrhythmia event notification settings

Access alarm and arrhythmia event notification settings when in “Multi-Patient” view

- Click on ‘Three Dots’ on upper right side of patient tile of your selected patient
- In pop-up window menu, select “Patient alarm settings” to review heart rate alarm and arrhythmia event notification settings and edit settings



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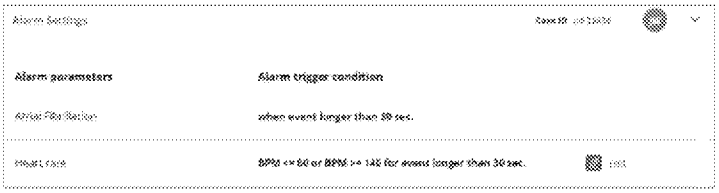
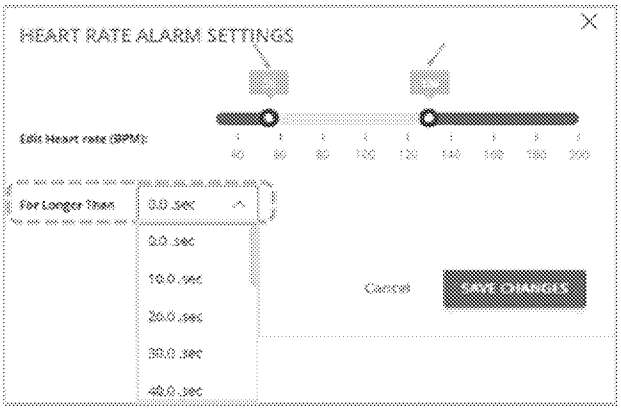
Alarm Settings screen:

Heart Rate Alarm parameters: Customize the alarm trigger condition for heart rate

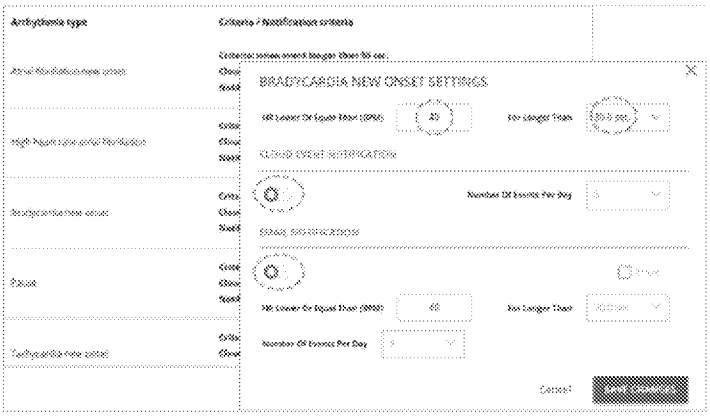
- Select "Edit" to change heart rate alarm setting values
- Slide each circle above scale to the left or right to adjust alarm settings (options in increments of 5 BPM)
- Using drop-down menu you can change length of time (0 – 120 seconds) for this alarm setting (i.e. when heart rate setting is less than 60 or greater than 140 BPM for longer than 30 seconds means an alarm will be triggered when the heart rate is outside of those limits for more than 30 seconds)
- Select "SAVE CHANGES" or "Cancel" if you choose to not make any changes





Arrhythmia Event Notification: Notification criteria and settings can be customized for arrhythmia type

- Select "Edit" to customize arrhythmia event notifications
- Enter numerical value for heart rate limit and select number of seconds duration for length before notification
- Cloud (*7L Web Browser*) Event Notification- use radio button to turn Off/On this arrhythmia event notification to be sent to the *7L Web Browser* and you can set how many of these arrhythmia events per day are sent when this function is enabled
- Email Notification- use radio button to turn Off/On for email to be sent to the patient's clinician listed in their profile and enter numerical value, select number of seconds duration of delay, and number of events per day are emailed when enabled
- Select "SAVE CHANGES" or "Cancel" if you choose to not make any changes



WARNING: Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a skilled clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.

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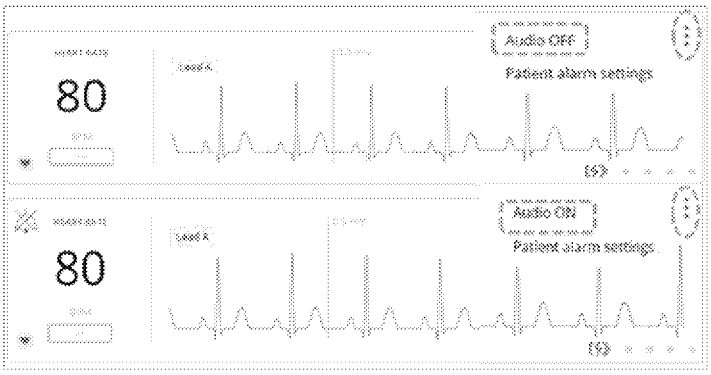
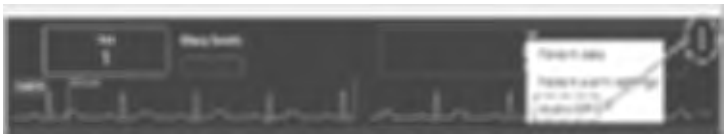
Turning Alarm Audio OFF and Audio ON

- Click on 'Three Dots' on upper right side of patient tile of your selected patient
- When you select "Audio OFF" for the selected patient, all auditory alarm sounds for that patient are turned off for five minutes (indicated by a red "crossed bell" in the upper left corner of patient tile)
- After five minutes of audio OFF, alarm audio turns ON automatically
- When Audio OFF is selected, the next time that menu is opened within the five-minute time period, Audio ON is displayed as option to turn on auditory sound for alarms
- Turning alarm Audio OFF and Audio ON can also be done when using Multi-Patient view in the same way

Individual Patient View



Multi-Patient View



WARNING: Do not try to turn the volume on the personal computer to OFF or Mute. Do not try to adjust the volume to such a low value that auditory alarm signals cannot be heard. The 7L Platform will indicate a warning on the display.

Multi-Patient View

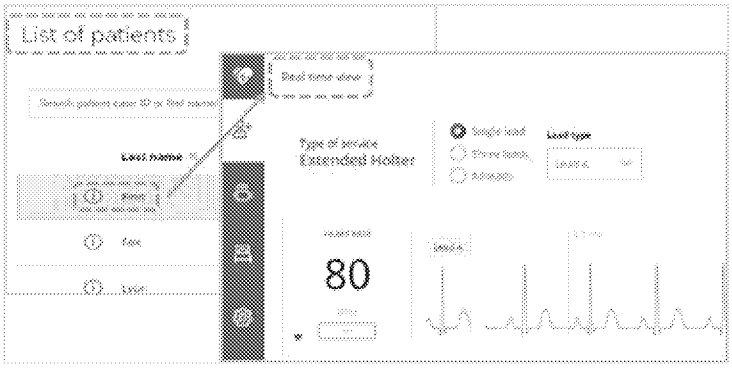
- Select "Multi-Patient" icon on left navigation menu to display all monitored patients
- When a new patient is added they are automatically placed in a patient tile.
- When monitoring more than 12 patients, ensure all patients are viewed at all times by opening another instance of the 7L Web Browser on additional displays.

NOTE: If more than 12 patients are monitored, you must open another instance of *7L Web Browser* on an additional display.

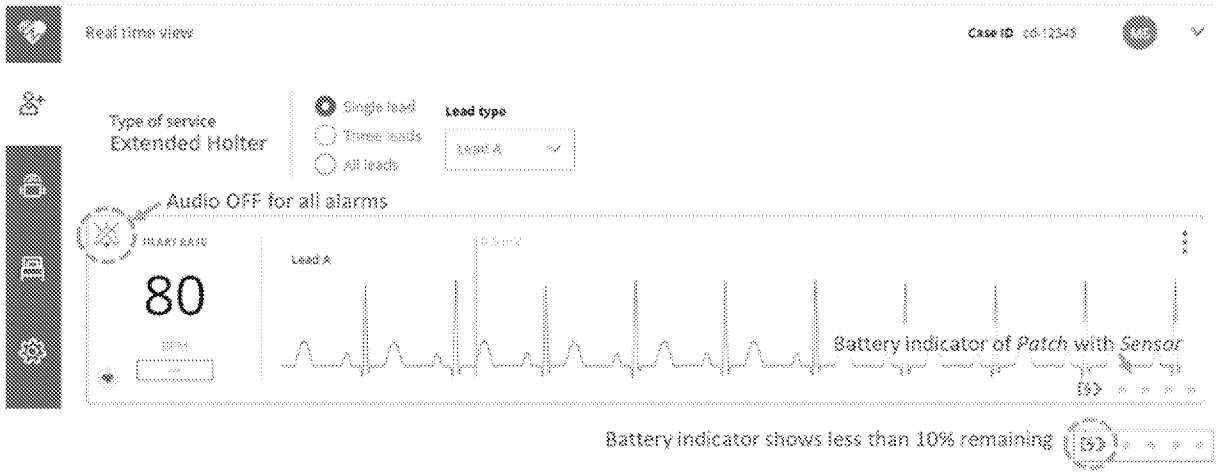
WARNING: When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.

Viewing Patient Data

- Select patient by clicking on "Patients" icon on left navigation menu to see list of patients
- Click on patient's name to view their real time ECG and heart rate.

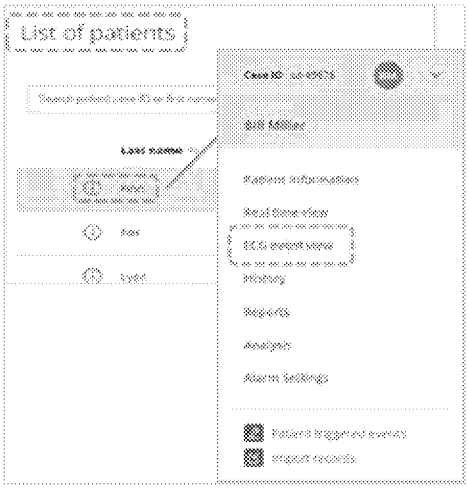


Real Time View screen



Review of Alarm Condition- "ECG event view"

- Select patient by clicking on "Patients" icon on left navigation menu to see list of patients
- Click on patient's name to view their real time streaming ECG and heart rate
- On top right navigation menu select "ECG event view"
- Select date to review



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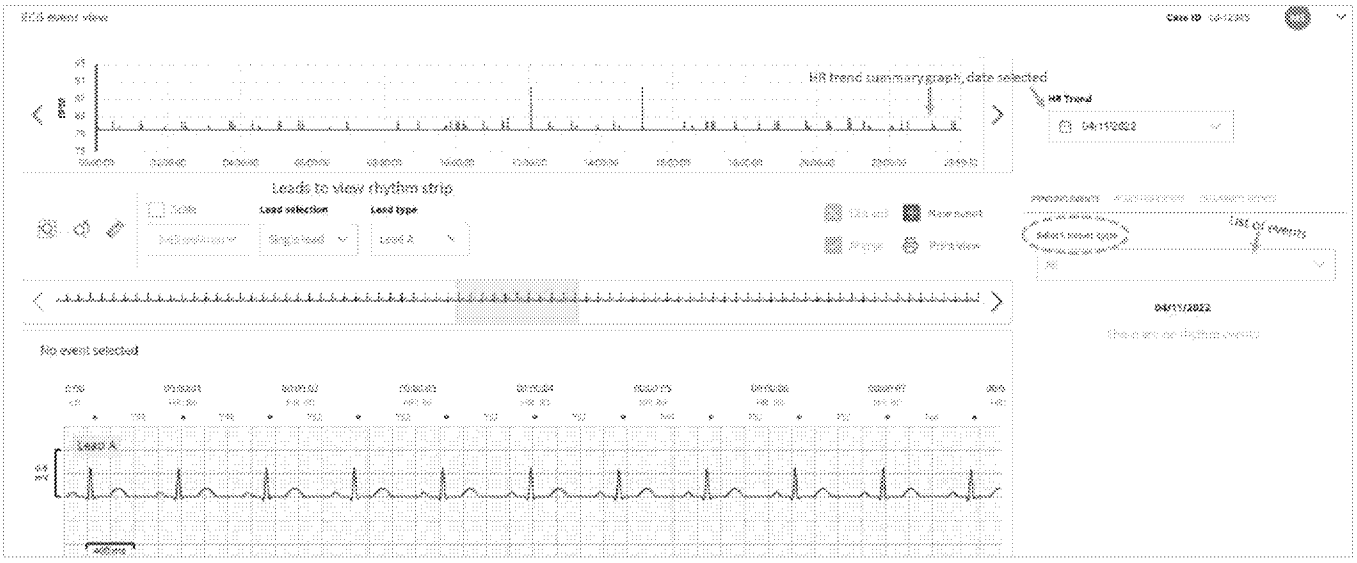
ECG event view



- Use arrows to move through summary graph for data you want to review in detail. Each click shifts ECG by one hour
- ECG shown represents highlighted section on compressed ECG, slide highlighted section left or right to view other ECG segments
- When events are listed, review can be done looking at pending, accepted, and discarded events
- Sorting can be done by event type
- A “New event” can be added, you can Accept, or Discard captured events

WARNING: The 7L Platform™ is not an emergency response system. If the patient has alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.

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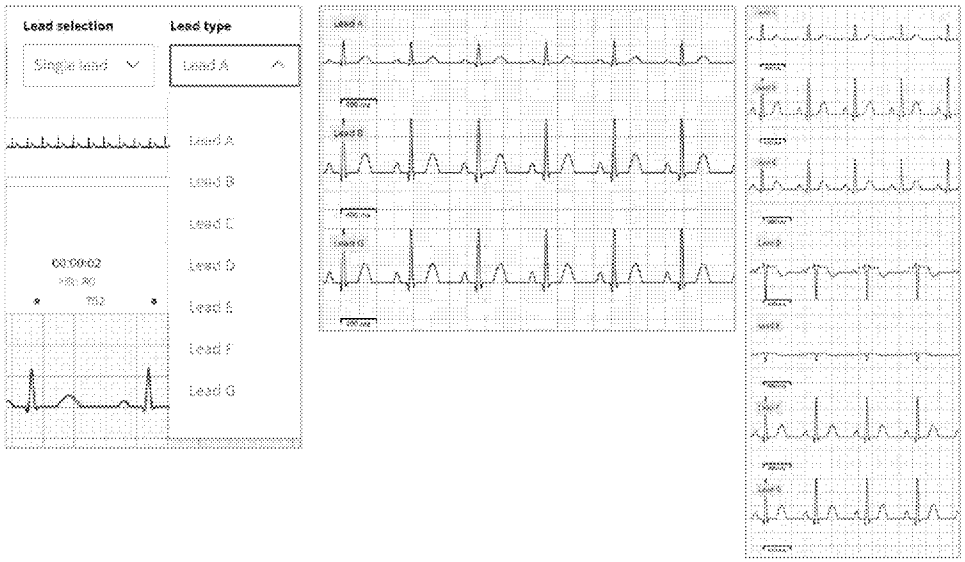
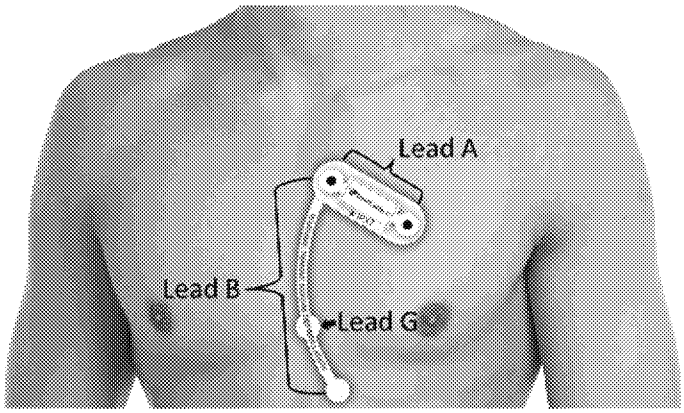
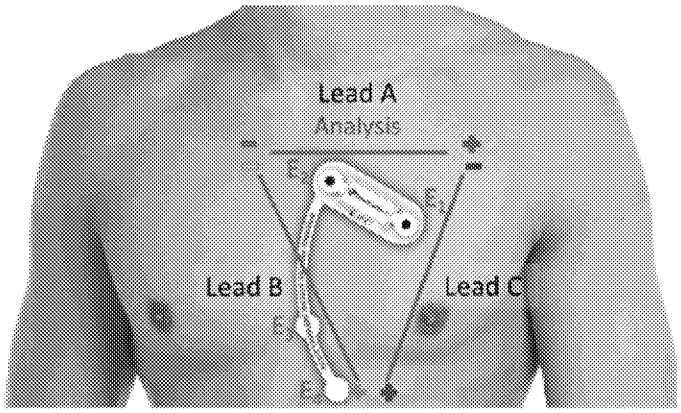
- Rhythm strip can be viewed in one lead, three leads, or seven leads (Leads A, B, C, D, E, F, G)





ECG Channels Transmitted



ECG Electrode Identification (E_x) and Polarity Measurements

NOTE: Analysis is done on Lead A only

WARNING: The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia 7L Patch and 7L Sensor before external defibrillation.

Editing and analyzing patient historical data (Refer to Clinician User Guide for details)

What the patient needs to do (Refer to the Patient User Guide and Kit)

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Specifications

Physical and Environmental	
Size	7L Sensor: 1.97 x 1.18 x .39 inch; (50 x 30 x 10mm) 7L Patch (without 'tail'): 5 x 2.2 x .55 inch; (128 x 55 x 14mm)
Weight	7L Sensor: Less than 3.52oz. (100 g) 7L Patch: <1.0 oz. (28.4 g)
Temperature	Storage and transport: -13 to +95°F (-25 to +35°C) Operating: +41 to +104°F (+5 to + 45°C)
Humidity	Storage and transport: relative humidity up to 90%, non-condensing Operating: 10 to 95% at +41 to 95°F (+5 to +35°C) (non-condensing) / 700 – 1060 hPa
Safety	Type BF
Water Ingress	IPX7 (waterproof)
Battery Life	Up to 14 days, depending on wireless connectivity of 7L Sensor
Biocompatibility	Compliant to ISO 10993-5, ISO 10993-10, ISO 10993-12 for cytotoxicity, skin irritation, skin sensitivity

Body Measurements	Shown As	Range	Units	Accuracy
Heart Rate	HR	30 - 200	Beats per Minute (BPM)	± 3 BPM
Atrial Fibrillation	AF	None	None	None

Manufacturer Default Alarm Settings			
Parameter	Low Limit	High Limit	Alarm Delay
Heart Rate	40	130	9.1 sec. max
Atrial Fibrillation	When event is longer than 30 sec.		NA

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Warnings

- **The 7L Platform™ is not an emergency response system. If the patient has an alarm condition or experiences a symptom that you feel is a medical emergency, immediately call 911 or check the patient and call 911 for emergency medical attention.**
- **The SmartCardia 7L Platform is not defibrillation-proof. Remove the SmartCardia 7L Patch and 7L Sensor before external defibrillation.**
- **Alarm conditions must be set to ON for a notification to be presented at the remote viewing station.**
- **When using the Multi-Patient view format, if a patient is not assigned to a patient tile and an alarm condition occurs, there is no audio or visual notification. Ensure all patients are viewed at all times by opening another 7L Web Browser on additional displays.**
- **Make sure that parameter limit settings are appropriate for the clinical condition of the patient being monitored - do not set parameter limit settings outside the physiological range for the patient.**
- **Alarm limits are patient or facility specific. The clinician must set and verify alarm limits appropriate for each patient. Failure to set alarm limits properly can lead to false alarms or failure to alarm.**
- **If a patient has severe skin irritation or burning feeling, they should remove 7L Patch right away and contact their doctor.**
- **Do not use this device in an MRI.**
- No computerized interpretation of patient data can correctly detect and classify a medical condition 100% of the time. Use sound clinical judgment when monitoring your patients.
- Audio on the PC used to view the *7L Web Browser* must be ON and sufficiently loud enough.
- When Audio is OFF, there is no auditory sound for this patient and an alarm condition could be missed.
- Do not turn OFF the audible notifications without providing continuous observation of the patient.
- Check notification volume periodically! If the volume is too low, it could result in the inability to hear a notification.
- In certain circumstances the pacemaker pulse may be detected as a heartbeat. Verify heartbeat with an alternative method such as auscultation, radial artery palpation, or viewing ECG.
- Make sure that proper patient preparation and settings are in place to avoid sensitivity to excessive artifact which can result in inaccurate notifications.
- Alarms are not automatically generated for ventricular fibrillation and ventricular tachycardia. When a clinician views the event, they should follow their practice guidelines and manually document the event in the patient record.
- The alarms provided on the SmartCardia 7L Platform should be properly assessed by medically trained or relevant qualified and accredited personnel.
- It is the responsibility of the clinician or care provider to respond to alarms consistent with their practice license.
- The SmartCardia 7L Platform should not be used in an aircraft.

Cautions

- The 7L Platform is used for adults over the age of 18 years.
- Install the 7L Platform and use as instructed. Do not attempt to connect it to another piece of equipment.
- Do not try to service the 7L Platform. It is not field repairable and there are no replaceable components.
- The 7L Platform is to be used by adequately trained personnel.
- Do not use with other devices, which have high-level electromagnetic radiation.

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Cautions (continued)

- The 7L Platform is not intended to record the activity of an implanted pacemaker onto the ECG waveform. The 7L Platform is designed to operate in the presence of pacemaker pulses. Caution should be used to not locate the *7L Patch* with the *7L Sensor* on top of a pacemaker.
- The 7L Platform is not designated for use in the operating room or operating theater.
- Make sure to have a good internet connection and sufficient bandwidth.
- The *7L Patch* is single use for a single patient. Do not reuse.
- Follow the instructions to use correctly.
- Make sure the *7L Sensor* is installed correctly and is firmly sealed in the *7L Patch*.
- Care should be taken by the patient if showering. Caution should always be taken when wearing in a wet location.
- Follow the instructions for the correct cleaning solution and process.
- Do not place the *7L Patch* on open wounds.
- The patient must keep the SmartCardia *Phone* within 10 ft of the *7L Sensor* at all times.
- Make sure the SmartCardia *Phone* is fully charged. It is best to charge the phone at night.
- If the Bluetooth on the SmartCardia *Phone* Is OFF, contact SmartCardia customer support.
- Only use the charger provided with the SmartCardia *Phone*.
- It is very important to have a good internet connection.
- For best results, the patient's skin where the *7L Patch* is applied should be cleaned and hair clipped or shaved to reduce artifact and prevent a noisy signal.
- Do not use the *7L Patch* if date of manufacture is more than two years. Refer to the *7L Patch* labeling.
- Keep username and login in a safe place and do not share them with anyone.
- Do not access the cloud platform from a shared computer.
- Make sure to set the correct mode of monitoring operation for the patient (Holter, Extended Holter, Event).
- Measured vital sign values should be reviewed and verified by alternate means if measurements are suspected to be inaccurate.
- When remote monitoring a patient, remember they may not have a caregiver or helper nearby and they may not be able to respond to communications. Always know how to provide aid for each patient.
- Receipt of alarms is not confirmed.
- Remote clinician notification of arrhythmia conditions is only done by email when configured in that manner.
- If the wireless connection from the *7L Sensor* and *7L Patch* to the *Phone* or the *Phone* to the internet/ cloud application is broken, a notification will show on the display. Periodically check to make sure the connection is intact.

Please refer to Clinician User Guide for the complete list of warnings and cautions.

Customer Support
(800) 363-8151

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SmartCardia 7L™

monitoring the fabric of life™

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info@smartcardia.com
Customer Support 800-363-8151

Questions? Contact FDA/CDRH/OCE/DD at CDRH-EQ|STATUS@fda.hhs.gov or 301-796-8118

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· PL-17 SmartCardia 7L Platform Technical Manual

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: steurerbob@gmail.com <steurerbob@gmail.com>

Sent: Wednesday, August 30, 2023 12:16 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov>

Cc: Francisco Rincon <francisco.rincon@smartcardia.com>; Srini Murali <srinivasan.murali@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; James Welch <jwelch@arcbiomed.com>

Subject: [EXTERNAL] Revision History, (b)(4)

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Hi Vincent,

(b)(4)

Thank you,

Bob

Best Regards,

Bob Steurer

[cid:image001.png@01D9DB32.F8F82500]Steurer Consulting Group

http://www.scgconsulting.net<http://secure-web.cisco.com/1uUweTdBzrTkvEvNfoBtNDHuyMhRbvGxBSZq0nwUFa_EIeglEZNNGkGVb2q2l2GNppg1fypDs5iP0l1P1m775HaEdbO4e-wwoklRvhmsHxoH6GfegmTiWj2hG7IeM9kjdrK_udrmGYy3gtZYBvCsUZRawkxfTlzjFBcWdJN7EtB-JZy_hfRFR63lW_lc2hQSq2Lm0uGDSYbd7bvjaPHdrHA/http%3A%2F%2Fwww.scgconsulting.net%2F>

m: +1 425-358-1072

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0511 Expiration Date: October 31, 2024. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

SmartCardia SA
Building C
EPFL Innovation Park
Lausanne
CH
1015
CH

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Srinivasan Murali
2.1 E-MAIL ADDRESS
srinivasan.murali@smartcardia.com
2.2 TELEPHONE NUMBER (include Area code)
7887-50864
2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: (b)(4)

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 01-May-2023

Form FDA 3601 (07/22)

"Close Window" Print Cover sheet

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August 30, 2023

SmartCardia SA
% Robert Steurer
Consultant
Steurer Consulting Group LLC
800 Blue Quail Rd
Keller, Texas 76248

Re: K231276
Trade/Device Name: SmartCardia 7L Platform
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter And Receiver
Regulatory Class: Class II
Product Code: DRG, DSI
Dated: July 28, 2023
Received: July 28, 2023

Dear Robert Steurer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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May 18, 2023</br></br>

Review Assignment Notification

I am the lead reviewer assigned to your submission K231276. Your file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 A. The first line supervisor is the Assistant Director of External Heart Rhythm and Rate Devices.

I will contact you should any additional information be required during the course of the review of your submission. You may contact me at any point during the review if you have questions or concerns. FDA aims to apply the least burdensome principles when requesting additional information.

You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Thursday, August 24, 2023 3:01 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Attached is our response to your Interactive Information Request 2.

This will be sent as two emails since the IFU and other files are too large.

(b)(4)

If you need anything else, please let me know.

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Wednesday, August 23, 2023 8:16 AM
To: steurerbob@gmail.com
Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Hi Bob,

That is correct. You can send the responses to me.

Please do not hesitate to let me know if you have any questions.

Thank you,

Vincent

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Wednesday, August 23, 2023 8:51 AM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Subject: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

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Hi Vincent,

We will be responding as soon as we can, and I will let you know if we need any additional clarification.

I assume all of the responses can be done via email, correct?

Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: Do, Vincent <Vincent.Do@fda.hhs.gov>
Sent: Tuesday, August 22, 2023 4:21 PM
To: steurerbob@gmail.com
Subject: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Hi Bob,

For further evaluation of your submission, we would like to request additional details. Please provide a response to the following comments by COB Thursday 08/24:

(b)(4)

Please let me know if you have any questions.

Thank you,

Vincent
Vincent Do
Lead Reviewer

Cardiac Ablation, Mapping and Imaging Devices Team
Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
Tel: (240) 402-4584
Email Address: Vincent.Do@fda.hhs.gov

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received: *Here*

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

From: steurerbob@gmail.com <steurerbob@gmail.com>
Sent: Wednesday, August 30, 2023 12:16 PM
To: Do, Vincent <Vincent.Do@fda.hhs.gov>
Cc: Francisco Rincon <francisco.rincon@smartcardia.com>; Srini Murali <srinivasan.murali@smartcardia.com>; 'Brodie Pedersen' <brodiecp@borderlessmd.com>; James Welch <jwelch@arcbiomed.com>
Subject: [EXTERNAL] Revision History (b)(4)

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Hi Vincent,

(b)(4)

Thank you,
Bob
Best Regards,
Bob Steurer

Steurer Consulting Group
http://www.scgconsulting.net

m: +1 425-358-1072

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2564
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
240-402-4584

Premarket Notification 510(k) Review

Date: August 30, 2023

Reviewer: Vincent Do

510(k)# K231276/S001 Subject: Traditional

Applicant: SmartCardia SA	**Device Trade Name:** SmartCardia 7L Platform
Contact Name: Robert Steurer	**Contact Title:** Consultant
Correspondent Firm: Steurer Consulting Group LLC	**Phone:** (425) 358-1072 **Email:** steurerbob@gmail.com
Received Date: July 28, 2023	**Due Date:** August 30, 2023
Pro Code(s): DRG **Class:** II **Reg #:** 870.2910	**Reg Name:** Radiofrequency Physiological Signal Transmitter And Receiver
Pro Code(s): DSI Class: II Reg #: 870.1025	Reg Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192757	DRG, DSI, MHX	VitalPatch 5D Biosensor - single, VitalPatch 7D Biosensor - single, VitalPatch 5D Biosensor – bag of 20, VitalPatch 7D Biosensor – bag of 20	VitalConnect, Inc.
K160064	DSI	MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System	Infobionic, Inc.

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(5)

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Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

(b)(5)

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SmartCardia

EPFL Innovation Park
Building
1015, Lausanne, Switzerland

contact@smartcardia.com

FDA/CDRH/DCC
JUL 28 2023
RECEIVED

May 1, 2023

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation Document
Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Traditional 510(k) Notification

Dear Sir or Madam:

In accordance with section 510(k) of the Federal Food, Drug and Cosmetic Act and 21 CFR §807, SmartCardia SA, hereby submits this 510(k) Premarket Notification for the ***SmartCardia 7L Platform***. This 510(k) is submitted to obtain clearance from FDA to commercially distribute this device.

(b)(4)

Attachment 1 to this cover letter is the Administrative Information content recommended by Appendix A of the FDA guidance document "*Guidance for Industry and FDA Staff – Format for Traditional and Abbreviated 510(k)s, 13 September 2019*".

This submission is provided as an electronic eSTAR copy.

SmartCardia trusts the contents of this submission completes the requirements for the 510(k) and looks forward to a favorable response from FDA. If any additional information is required, please contact the Application Correspondent, Mr. Robert Steurer, directly at (425) 358-1072, or via email at steurerbob@gmail.com.

Kindest regards,

(b)(6)

Srinivasan Murali, CEO
SmartCardia SA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

Attachment 1: Administrative Information

Confidentiality:	SmartCardia SA considers the existence of this submittal confidential
Type of submission:	**Traditional 510(k)**
Submitter Correspondent:	SmartCardia SA EPFL Innovation Park Building C 1015, Lausanne, Switzerland Mr. Srinivasan Murali Phone: +41 7887 50864 Email: srinivasan.murali@smartcardia.com
Application Correspondent:	Steurer Consulting Group 800 Blue Quail Rd Keller, TX 76248 Mr. Robert Steurer Phone: (425) 358-1072 Email: steurerbob@gmail.com
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency
Common Name:	SmartCardia 7LPlatform
Primary Classification Regulation:	21 CFR ¶870.2910
Primary Product Code:	DRG
Secondary Classification Regulation:	21 CFR ¶870.1025
Secondary Product Code:	DSI
Secondary Classification Name:	Detector and alarm, Arrhythmia
Product Class:	Class II
Classification Panel:	Cardiovascular Devices (OHT2)
Predicate Device	VitalConnect Biosensor (K192757)
Predicate/Reference Device	InfoBionic MoMe Kardia (K60064)

Basis for Submission:

Submission:	New Device
Prior FDA Documents:	(b)(4)

Design and Use of the Device:

Is the device intended for prescription use (21 CFR 801 Subpart D)?	Yes
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	No
Does the device contain components derived from a tissue or other biologic source?	No
Is the device provided sterile?	No
Is the device intended for single use?	No
If yes, does this device type require reprocessed validation data?	No
Does the device contain a drug?	No
Does the device contain a biologic?	No
Does the device use software?	Yes
Does the submission include clinical information?	No
Is the device implanted?	No

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2: Pre-Submission Correspondence & Previous Regulator Interaction

(b)(4)

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August 30, 2023</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Vincent Do.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: steurerbob@gmail.com <steurerbob@gmail.com>

Sent: Thursday, August 24, 2023 3:04 PM

To: Do, Vincent <Vincent.Do@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

Attached is our response to your Interactive Information Request 2.

(b)(4)

If you need anything else, please let me know.

Best Regards,

Bob Steurer

[cid:image001.png@01D9D693.8FC66220]Steurer Consulting Group

http://www.scgconsulting.net<http://www.scgconsulting.net/>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Wednesday, August 23, 2023 8:16 AM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Subject: RE: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Hi Bob,

That is correct. You can send the responses to me.

Please do not hesitate to let me know if you have any questions.

Thank you,

Vincent

From: steurerbob@gmail.com<mailto:steurerbob@gmail.com> <steurerbob@gmail.com<mailto:steurerbob@gmail.com>>

Sent: Wednesday, August 23, 2023 8:51 AM

To: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Vincent,

We will be responding as soon as we can, and I will let you know if we need any additional clarification.

I assume all of the responses can be done via email, correct?

Best Regards,

Bob Steurer

[cid:image001.png@01D9D693.8FC66220]Steurer Consulting Group

http://www.scgconsulting.net<http://www.scgconsulting.net/>

m: +1 425-358-1072

From: Do, Vincent <Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>>

Sent: Tuesday, August 22, 2023 4:21 PM

To: steurerbob@gmail.com<mailto:steurerbob@gmail.com>

Subject: K231276/S001 - SmartCardia 7L Platform - Interactive Information Request 2

Hi Bob,

For further evaluation of your submission, we would like to request additional details. Please provide a response to the following comments by COB Thursday 08/24:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118, Released by CDRH on 10-02-2024

(b)(4)

Please let me know if you have any questions.

Thank you,

Vincent

Vincent Do

Lead Reviewer

Cardiac Ablation, Mapping and Imaging Devices Team

Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: (240) 402-4584

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2023-8118; Released by CDRH on 10-02-2024
Email Address: Vincent.Do@fda.hhs.gov<mailto:Vincent.Do@fda.hhs.gov>

[cid:image002.png@01D9D693.8FC66220]<http://www.fda.gov/>

[cid:image003.jpg@01D9D693.8FC66220]<https://www.facebook.com/FDA>
[cid:image004.jpg@01D9D693.8FC66220] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D9D693.8FC66220] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image006.jpg@01D9D693.8FC66220] <http://www.flickr.com/photos/fdaphotos/>
[cid:image007.jpg@01D9D693.8FC66220]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

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