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Produkte
Products

Prüfbericht - Nr.: *Test Report No.:*	(b)(4)
Auftraggeber: *Client:*	
Gegenstand der Prüfung: *Test Item:*	
Bezeichnung: *Identification:*	
Anlieferungszustand: *Delivery condition:*	
Prüfort: *Testing location:*	
Prüfgrundlage: *Test specification:*	
Prüfergebnis: *Test result:*	

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Article

Wearable Sensing of In-Ear Pressure for Heart Rate Monitoring with a Piezoelectric Sensor

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Abstract: In this study, we developed a novel heart rate (HR) monitoring approach in which we measure the pressure variance of the surface of the ear canal. A scissor-shaped apparatus equipped with a piezoelectric film sensor and a hardware circuit module was designed for high wearability and to obtain stable measurement. In the proposed device, the film sensor converts in-ear pulse waves (EPW) into electrical current, and the circuit module enhances the EPW and suppresses noise. A real-time algorithm embedded in the circuit module performs morphological conversions to make the EPW more distinct and knowledge-based rules are used to detect EPW peaks. In a clinical experiment conducted using a reference electrocardiogram (ECG) device, EPW and ECG were concurrently recorded from 58 healthy subjects. The EPW intervals between successive peaks and their corresponding ECG intervals were then compared to each other. Promising results were obtained from the samples, specifically, a sensitivity of 97.25%, positive predictive value of 97.17%, and mean absolute difference of 0.62. Thus, highly accurate HR was obtained from in-ear pressure variance. Consequently, we believe that our proposed approach could be used to monitor vital signs and also utilized in diverse applications in the near future.

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Keywords: wearable heart rate monitoring; in-ear pressure variance; piezoelectric sensor

1. Introduction

Cardiovascular disease (CVD), which includes hypertension, myocardial infarction, coronary artery diseases, and stroke, has become a serious problem and is currently one of the major causes of disability and death globally. In fact, more than 17 million people worldwide die each year because of CVD, and it accounts for about 30% of all deaths per year [1]. While many of the risk factors for CVD are known, such as tobacco use, physical inactivity, obesity, and diabetes, resting heart rate (HR) is one of the simplest cardiovascular parameters and an independent risk factor [2]. Resting HR has prognostic importance in that an elevated resting HR is strongly related with mortality in the general population, the elderly, and patients with myocardial infarction, congestive heart failure, diabetes, or hypertension [2]. Thus, frequent HR monitoring in everyday life is necessary to assess and prevent cardiovascular problems in advance.

Vital signs such as HR, respiration, and blood pressure were in the past possible to measure by medical systems in hospitals. However, recent technological advances in physiological sensors, processing capabilities, and wireless communications have enabled individuals to monitor their health status outside of hospitals via wearable biosensor systems [3]. Compared with previous medical devices, wearable sensor systems provide nonintrusive solutions for long-term monitoring without constraints on time and place. A further advantage is that such systems can offer real-time feedback about their health status to the patients themselves or even a professional physician at a hospital [4]. Therefore, wearable HR monitoring systems play an important role in the monitoring of cardiovascular exacerbations in the early stage, during catastrophes that may occur with high risk individuals, or during emergency situations [5].

Many technologies and methodologies have been introduced for wearable HR monitoring. Among these technologies, those that monitor photoplethysmogram (PPG), which is obtained by optical detection of blood volume changes in the microvascular bed of the tissue using light-emitting diodes and photodetectors, are the most widely utilized. PPG sensors have mainly been applied to fingers, earlobes, or wrists in the form of tweezers- or watch-shaped apparatuses [6]. Also, a customized ear mold equipped with a reflective PPG sensor has been applied to the ear channel [7]. Conventional measurement of electrocardiogram (ECG), which is the gold-standard method for HR monitoring, is not appropriate for wearable sensing because of the adhesive electrodes and wires utilized. However, recent studies have proposed and investigated T-shirts and band type wearable ECG systems that use conductive fabric, flexible printed circuit boards, or textile circuits [8]. In addition, stethoscopes that use a microphone to measure phonocardiography have also been proposed as wearable and portable devices [9].

However, despite significant progress in wearable systems, various issues that impede extensive application have been reported. These issues include bulky sensors, connections to additional hardware modules, skin irritation, and laundry [9]. In order to solve these problems, Teichmann *et al.* recently presented a bendable and flexible device that can be placed in a shirt pocket using noncontact sensor principles [10]. However, very few studies have presented a high acceptance rate by users, and there are still many challenges that have to be resolved in order for wearable systems to become accepted by

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normal people and patients [3,8]. For examples, existing methods have limitations to utilization in particular situations when the user is running or swimming in which hands and feet are excessively moving. The human head is rather the least moving and least affected part by strenuous exercise or movement according to circumstances. Thus, new methods or alternatives are required for vigorous follow-up studies and applications.

In this paper, we present our proposed wearable HR monitoring sensor device developed based on pressure variance in the ear canal surface. The ear is an excellent site for users to accept a wearable device. In addition, the ear canal is partially composed of cartilage and bone and located in the temporal bone, thus providing the proper conditions for anchoring the sensor apparatus [11]. The ensuing sections present the physiological principle that enables HR monitoring from the ear canal surface, the material comprising the sensor, design and implementation of the wearable sensor device, the verification process and the results obtained, and our conclusions.

2. Physiological Background and Piezoelectric Sensor

When the left ventricle of the heart rhythmically contracts, blood is ejected into the arterial system, and the elasticity of the arteries enable a pulse wave to be generated and propagated. The pulse wave observed in the arterial system is the summation of a forward (incident) wave and a backward wave [12]. The forward wave travels from the heart toward the periphery, whereas the backward wave is caused by the forward wave's reflection within the peripheral arterial system [12]. The characteristics of the arterial pulse wave differ slightly according to the sites at which the measurements are taken because of the complicated topology of the arteries. However, in general, all arterial pulse waves present the general function of the cardiovascular system: the systolic function of the left ventricle [13].

The carotid artery, which has diameter in the range 6.1 to 6.5 mm, originates along the aortic arch and travels upward to supply oxygenated blood to the brain. The carotid arterial pressure and diameter change linearly as blood flows, and the hemodynamic change generates the ascending aortic pressure waveform around the artery [14,15]. Ultrasound with the Doppler technique is the gold-standard method for observing volume changes in the carotid artery, whereas a tonometry attached to the subject's neck is also typically utilized to measure the pressure wave propagated to the skin surface [16].

As illustrated in the anatomical view depicted in Figure 1, the internal carotid artery, which arises from the carotid artery, is located near the ear. The internal carotid artery also has a similar characteristic; that is, it expands and propagates a pressure wave to the ear canal surface during the inrush of blood. Consequently, it has been hypothesized that pressure variance measured from the ear canal surface has a consistent pulse waveform, and the in-ear pulse wave (EPW) presents sharp upstrokes reflective of heartbeats.

The ear canal is approximately 2.5 cm long and has a diameter of about 0.7 cm. The surface of the skin in the ear canal is one of the most sensitive parts of the human body. Any sensor material that is intended to be utilized there therefore has to be small and soft, which are properties possessed by the piezoelectric sensor used in this application. The sensor used is flexible, lightweight, and is composed of mechanically durable plastic film with the unique ability of being configurable into various shapes and sizes. Piezoelectric materials convert strain or stress into electrical energy when they are mechanically deformed [17]. They operate over a wide temperature range and have a high frequency response.

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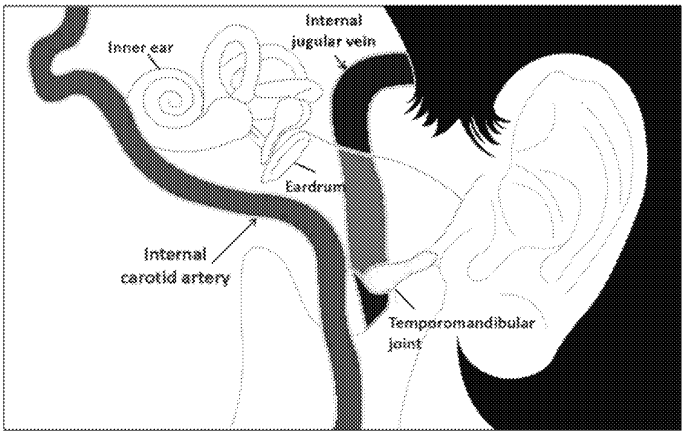


Figure 1. Anatomical view of the vessels around the ear.

Piezoelectric sensors are widely used in medical applications such as patient monitoring and human motion analysis. In particular, a piezoelectric sensor can be ideally utilized in harsh environments and is suitable for measuring tiny pressure variances under high static pressure [18]. This property raises the possibility of successful monitoring in our application, because the pressure for anchoring the film sensor to the ear canal surface is high and static, and the pressure variance from a heartbeat is relatively low. In this study, we utilized a customizable piezoelectric film sensor sheet manufactured by Measurement Specialties [19]. The film sensor sheet is metallized with silver ink which enables optimized applications where mechanical stress is being applied.

3. In-Ear Pressure Sensing Device

3.1. Apparatus Design Concepts

A specialized design is required for any apparatus specified to measure pressure variance from the ear canal surface accurately. High wearability should also be guaranteed to facilitate long-term use in everyday life. Further, to enable accurate measurement, the piezoelectric film sensor needs to be sufficiently adhered to the skin surface of the external ear canal. When these conditions are satisfied EPW can be consistently converted to electrical current and various noises, caused by the user's movements and activities, can be minimized. For a comfortable fit, the apparatus should also not cause the user any pain, and should be lightweight in order for the user to wear it for hours. Furthermore, it should not interfere with the user's hearing as an insert-type device in the ear. To meet these requirements and considerations, we designed a scissor-shaped apparatus with the structure illustrated in Figure 2.

We cut the piezoelectric film sheet into a 3.5 mm × 3.5 mm sized piece that can covers the head part of a longer stick. The outside surface (signal) and the inside surface (ground) of a piezoelectric sensor were wired with shielded cable respectively to protect EPW signal and minimize the noise. When the user wears the apparatus, the two sticks are inserted into the ear canal, and a spring enables proper extension between the sticks. Thus, the head parts of both sticks are able to remain adhered to opposite sides of the ear canal surface. The head positions that make contact with the ear canal surface can be changed by pushing and rotating buttons. Because the optimal point on the ear canal surface for EPW sensing varies slightly from individual to individual, the best point for a particular individual can be

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found by varying the stick positions. The hardware circuit module and coin-cell battery are located in the body of the apparatus. Figure 3 shows the appearance of a prototype manufactured according to the proposed design along with examples of it being worn.

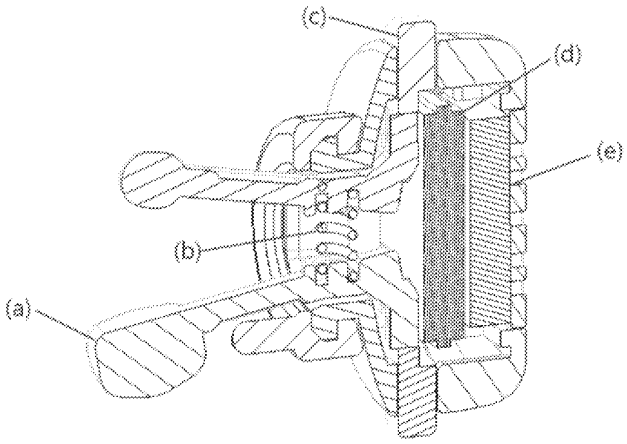


Figure 2. Structure of the in-ear pressure sensing device: (**a**) stick covered with piezoelectric film sensor; (**b**) spring to push both sticks in different directions; (**c**) button to control the position of both sticks; (**d**) hardware circuit module; (**e**) coin-cell battery.



Figure 3. (**a**) In-ear pressure sensing device prototype; (**b**) wearing example (lateral view); (**c**) wearing example (frontal view).

3.2. Hardware Circuit Module

Electrical current, generated from the piezoelectric sensor, is converted to voltage. Then, it is 3 dB pre-amplified and passed to a buffer to prevent loading effect. A second-order low-pass filter (LPF) with a cut-off frequency (*fc*) of 12 Hz is used to remove the high frequency noises [20]. The smoothed signal is then amplified to a maximum of 24 dB, and an offset control circuit adds DC voltage to the amplified signal. Consequently, the final output signal of the analog part has a voltage range of 0 to +3.3 V, which can be appropriately processed in the digital part (Figure 4).

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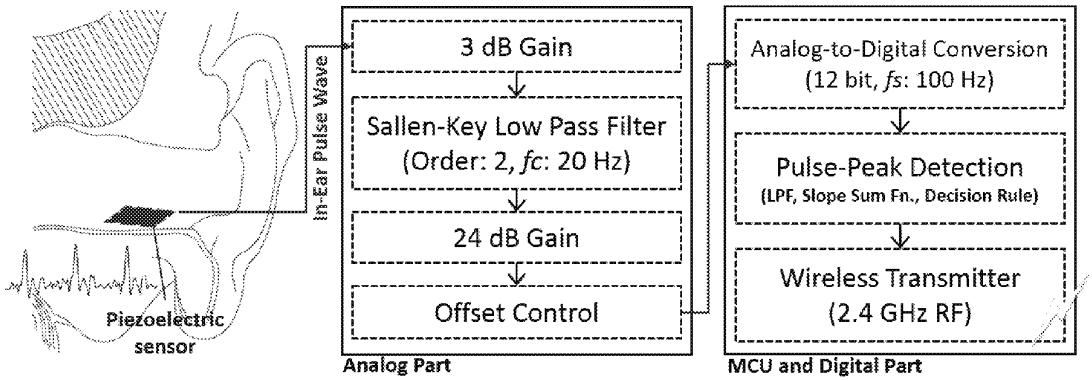


Figure 4. Circuit module and signal processing flow.

The digital circuit comprises a micro-controller unit (MCU) and a wireless communication module with an antenna. Analog EPW is converted to a 12-bit digital signal at a sampling frequency (*fs*) of 100 Hz by an analog-to-digital converter (ADC) module in the MCU. A software program embedded in the MCU detects pulse peaks in real time, and then the HR value is periodically transmitted to the host via a wireless communication module. The module utilizes radio frequency (RF) on the 2.4 GHz band, and the RF and antenna power output specifications are 0 dB and 0.5 dB, respectively (Figure 4). The complete circuit module is depicted in Figure 5. It is designed and implemented in the shape of a cross to utilize space efficiently and to have a minimal size to facilitate insertion into the proposed apparatus.

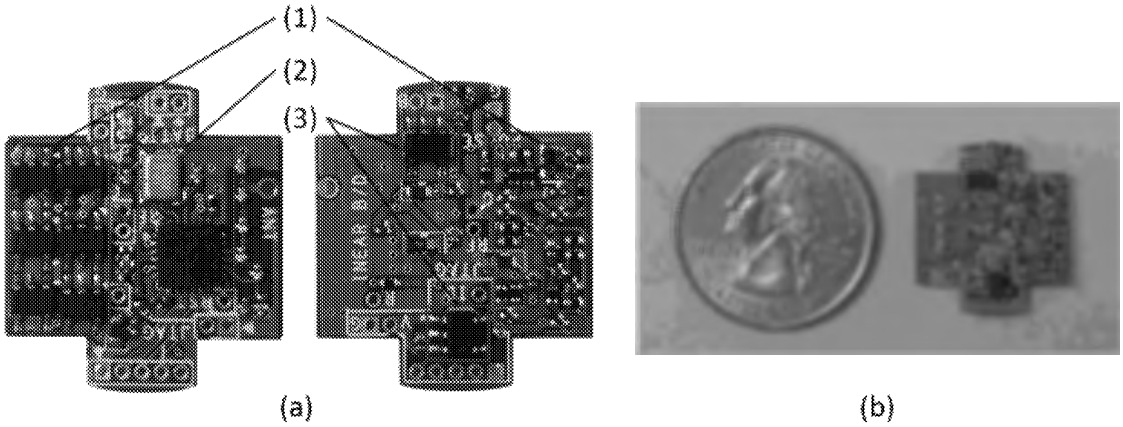


Figure 5. Circuit board (15 × 17 mm): (**a**) top and bottom views of circuit board, (1) analog part, (2) MCU and digital part, (3) power regulator; (**b**) circuit board size compared to 25 cent coin.

3.3. Pulse-Peak Detection

The pulse peak detection algorithm comprises two stages. The first stage is morphological conversion, in which the raw EPW is converted to a more robust signal that is impulsive and distinct [21]. The second stage is application of knowledge-based rules to detect pulse peaks. The algorithm is implemented in the C language in an embedded software environment, and runs in real time.

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The morphological conversion stage comprises three phases: (1) finite impulse response (FIR) LPF; (2) differentiation; and (3) slope sum function (SSF). An FIR filter is employed to suppress high frequency factors by muscle influence and 50/60 Hz noise interference. A constrained equiripple FIR filter (window size: 500 ms, *fc*: 8 Hz) was designed and applied. This filter guarantees that the stop-band of the filter begins at a specific frequency and provides the desired minimum stop-band attenuation [22]. Then, differentiation with half-rectification is applied to enhance the ascending part and suppress the descending part of the EPW. The SSF, a signal transformation scheme, is applied, for the same purpose as the differentiation process (Figure 6). Window size of the SSF is set as 128 ms because the ascending portion of a typical pulse wave is 128 ms [23].

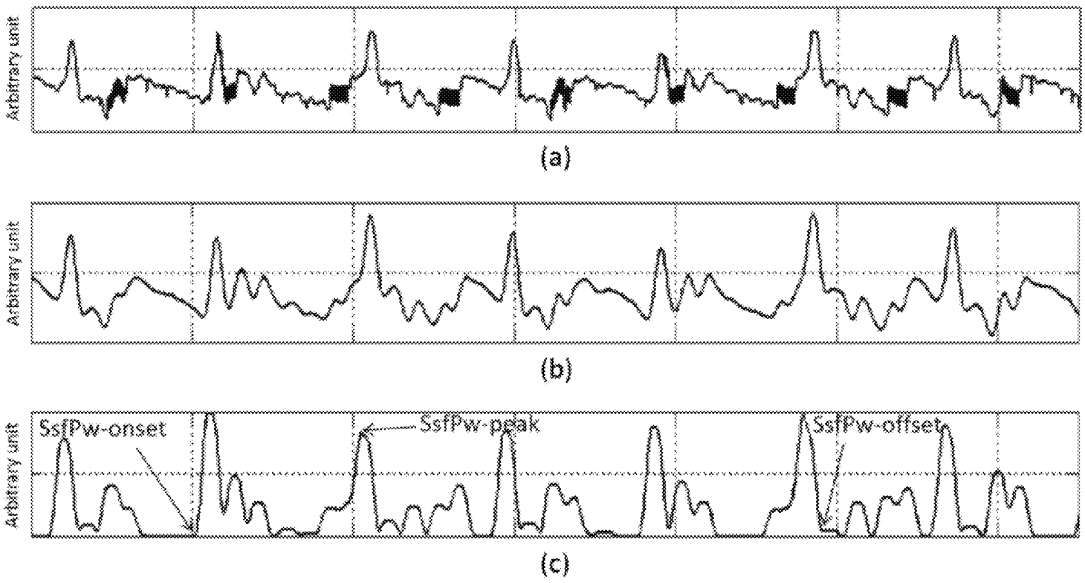


Figure 6. In-ear pulse wave recorded for 6.5 s: (**a**) raw EPW; (**b**) smoothed EPW; (**c**) converted (SSF) EPW.

The offset point of the EPW that passes the SSF (SsfPw) corresponds with the peak of the raw EPW. The decision rules therefore aim to detect the peak and offset point of SsfPw. Figure 7 and Table 1 describe the knowledge-based decision process used to detect EPW peak. An example of the peak detection result is shown in Figure 8.

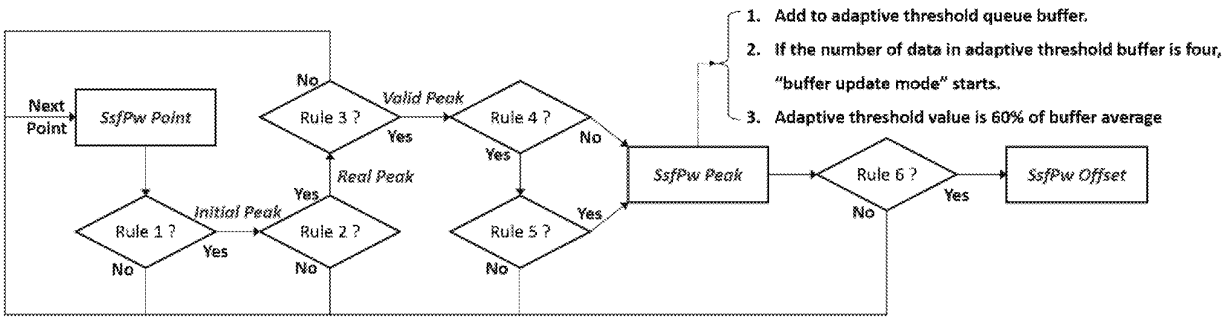


Figure 7. Decision flow of EPW peak detection.

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Table 1. Decision rules for SsfPw-offset detection.

Decision Rule	Description
# 1	Are both the previous and next points lower than the current point?
# 2	Is it continuously descending until 50% of the "*Initial Peak*" value?
# 3	Is the distance between any continuous "*Real Peaks*" further than 250 ms?
# 4	Is it in "update mode"?
# 5	Is "*Valid Peak*" higher than the adaptive threshold?
# 6	Find the minimum point from "*Valid Peak*" within 150 ms in the forward direction.

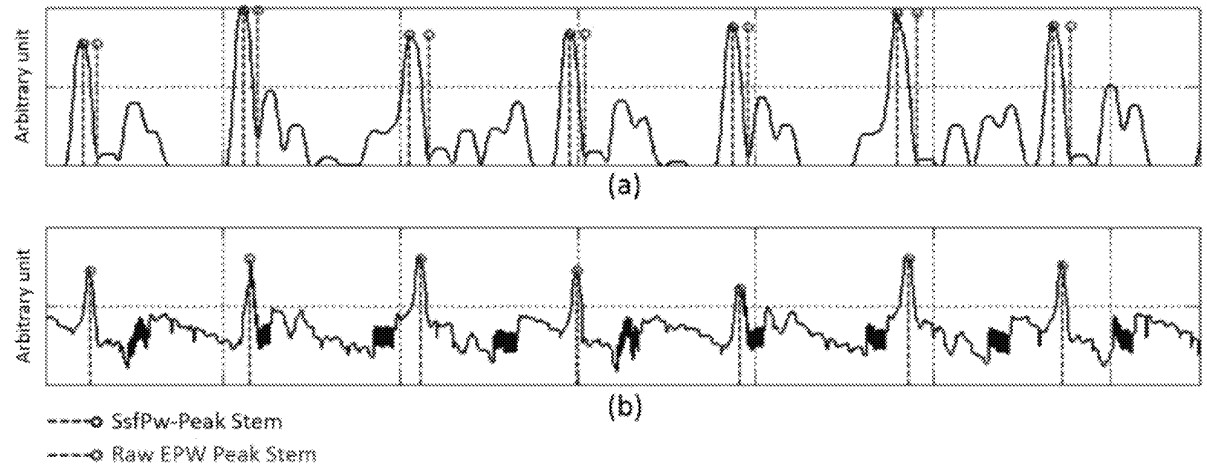


Figure 8. SsfPw peak and raw EPW peak detected via decision rules: (**a**) SsfPw with its peaks and offsets; (**b**) raw EPW with its peaks.

4. Validity Study

4.1. Study Design

To evaluate the validity of our developed monitoring device, a comparative analysis was performed based on clinical data with reference equipment. A total of 58 healthy volunteers aged 26–44 years participated in our clinical experiment (Table 2). Each subject was informed of the procedure and the purpose of clinical data acquisition prior to the experiment, and subsequently signed a participation agreement form. None of the participants had any self-reported cardiovascular disease such as hypertension, cardiac infarction, or arrhythmia.

Table 2. Participants' personal information.

	N	Age	Height (cm)	Weight (kg)
Male	43	36.3 ± 5.6	172.9 ± 4.9	72.5 ± 11.6
Female	15	31.7 ± 5.3	163.2 ± 3.7	53.5 ± 7.1
Total	58	35.3 ± 5.8	170.6 ± 6.3	67.8 ± 13.4

A commercial device (ECG-KIT V3.0, PhysioLab Co., Ltd, Busan, Korea) for the ECG measurement was utilized as reference equipment [24]. The device measures ECG using three wired leads in contact

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with the user's right arm, left arm, and right leg, respectively. ECG-KIT includes instrumentation amplifier and filters (LPF, HPF, and notch), and provides an analog waveform as a final output. We connected its analog output to the ADC input port of the MCU in our developed in-ear device for the experimental setting. Thus, both analog signals, EPW and ECG, were simultaneously converted to digital signals with the same *fs* (100 Hz) and ADC resolution (12 bit). This setting was intended to secure time-synchronized measurement between our targeted and reference signals.

Each subject wore the in-ear device and ECG electrodes while sitting in a relaxed position, and EPW and ECG were simultaneously measured. A rest time of 5 min was given before the measurement in order to induce a stable state in each subject. Data were recorded for 30 s from each subject.

4.2. Comparative Parameter

Each dataset obtained comprised EPW and ECG data simultaneously recorded for 30 s. Thus, a total of 58 datasets were obtained through the clinical experiment with the 58 subjects. Physiologically, an EPW peak and an ECG R-peak cannot occur at the same time owing to the pulse transit time [25]. Therefore, peak-to-peak interval was chosen as the parameter to use for comparison of the EPW and ECG signals. Each interval was calculated as

$$Interval(n) = No.of\ data\ samples\ between\ successive\ peaks \quad (1)$$

and extracted from EPW and ECG, respectively (Figure 9). The EPW peak was automatically determined by the EPW peak detection algorithm outlined in Section 3.3. Conversely, the ECG R-peak was manually annotated by three examiners. Each examiner marked the ECG R-peak position (index) using MATLAB (Matrix Laboratory, USA) Ver. 2009, and unconformable peak positions were modified with the consent of all three examiners.

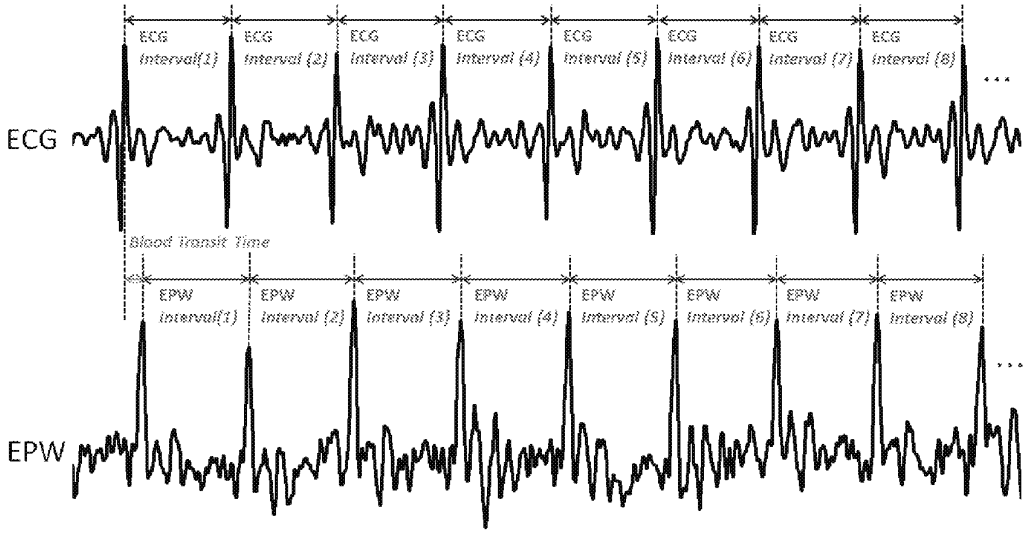


Figure 9. Concurrently recorded ECG and EPW signals, and their peak-to-peak intervals for comparative analysis.

An ECG R-peak occurs when the left ventricle contracts to pump blood out, whereas an EPW peak occurs when the pulse wave is generated in the internal carotid artery near the ear canal [25]. In that

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typical pulse transit time from heart to arteries near the ear, ranging from 10 to 20 ms [26], an EPW peak corresponding to an ECG R-peak occurs right after the ECG R-peak occurs in the concurrently recorded plot. In this way, intervals 20–23 numbers of $ECG_{Interval}(n)$ and their corresponding $EPW_{Interval}(n)$ were extracted from each dataset.

4.3. Evaluation

Interval differences between ECG and EPW were investigated to determine the validity of our proposed sensor device. To this end, four quantitative measures were utilized: sensitivity, positive predictive value (PPV), mean absolute difference (MAD), and normalized error rate (ER_{Norm}). These measures are defined in Equations (2) to (5), respectively.

$$Sensitivity\ (\%) = \frac{TP}{TP + FN} \times 100\ (\%) \tag{2}$$

$$PPV\ (\%) = \frac{TP}{TP + FP} \times 100\ (\%) \tag{3}$$

$$MAD\ (samples) = \frac{1}{N}\sum_{n=1}^{N} |ECG_{Interval}(n) - EPW_{Interval}(n)| \tag{4}$$

$$ER_{Norm}\ (\%) = \frac{\sum_{n=1}^{N} |ECG_{Interval}(n) - EPW_{Interval}(n)|}{\sum_{n=1}^{N} ECG_{Interval}(n)} \times 100\ (\%) \tag{5}$$

Peak-to-peak interval of ECG or PPG is used to HR monitoring or HRV (heart rate variability) analysis. In HR monitoring, 20 ms interval error possibly cause maximum error ranges of 0.85–3.23 bpm. However, HR is an integer value and calculated from the averaged interval. HR error is therefore much less than the maximum error range. In HRV analysis, an indicator that utilizes time delay is the pNN*x*; the percentage of NN intervals in a 24-h time series differing by more than *x* ms [27]. The pNN50 or pNN20 is typically utilized [27]. Thus, maximum interval error of 20 ms is allowed to HRV analysis in time domain. For these reasons, we defined true detection as the difference between $ECG_{Interval}(n)$ and its corresponding $EPW_{Interval}(n)$ being less than or equal to two samples (20 ms). Thereby, true positive (TP), false positive (FP), and false negative (FN) are defined as follows:

TP—the number of $EPW_{Interval}(n)$ that satisfy the true detection condition,
FP—the number of $EPW_{Interval}(n)$ that do not satisfy the true detection condition,
FN—the number of $ECG_{Interval}(n)$ that do not satisfy the true detection condition.

Accordingly, sensitivity represents the proportion of "the number of truly detected intervals" out of the "total number of $ECG_{Interval}(n)$," whereas PPV signifies the proportion of "the number of truly detected intervals" out of the "total number of $EPW_{Interval}(n)$." [28] MAD and ER_{Norm} represent the interval difference per unit interval and unit sample, respectively. In addition, we adopted the Bland-Altman analysis to assess the agreement of $EPW_{Interval}$ with $ECG_{Interval}$ [29]. We utilized SPSS (Statistical Package for the Social Science, Armonk, NY, USA) Ver. 22 for statistical data processing.

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5. Results and Discussion

Table 3 presents a summary of the acquired EPW data. Totals of 1297 of peaks, 1239 intervals, and 111,401 samples of interval length were detected from the 58 datasets, and their HR was 66.74 bpm on average. Average 22.36 ± 0.67 of peaks, 21.36 ± 0.67 of intervals, and 1920.71 ± 34.48 samples of interval length existed in each dataset, and its HR was 66.74 ± 1.82 on average. In general, the normal HR of an adult ranges from 60 to 100 bpm [30]. Thus, the HR of the subjects in this study was considered as relatively low, and presented in a narrow range: standard deviation (SD) of EPW-HR is 1.82. We surmise that this result was obtained because the subjects measured ECG and EPW in a very stable state, and belong to a similar age group.

Table 3. Summary of acquired EPW data.

	No. of Peaks	No. of Intervals	Interval Length (samples)	Heart Rate (bpm)
Dataset	22.36 ± 0.67	21.36 ± 0.67	1920.71 ± 34.48	66.74 ± 1.82
Total	1297	1239	111,401	66.74

Table 4 shows the performance evaluation results for the EPW device. TP, FP, and FN were 1204, 35, and 34, respectively. Sensitivity was 97.25%, and PPV was 97.18%. Even in the case where PPG and ECG were concurrently measured with standard devices and methods, the peak-to-peak interval of PPG was not perfectly in agreement with the corresponding peak-to-peak interval of ECG [31], because the physiological system of the human body has various, tiny and nonlinear effects on the blood flow [32]. We therefore regard our obtained sensitivity and the PPV as outstanding achievements, although two samples (20 ms) were set as allowable error.

Table 4. Performance evaluation results.

TP (No. of Intervals)	FP (No. of Intervals)		FN (No. of Intervals)
1204	35		34
Sensitivity (%)	PPV (%)	MAD (samples)	ER_{Norm} (%)
97.25	97.18	0.62	0.68

MAD was 0.62 samples, and ER_{Norm} was 0.68%. This means that EPW had on average 0.62 samples (6.2 ms) of error per unit interval, and on average 0.68% (68 μs) of error per unit sample, compared with ECG. These numerical values also support the accuracy and validity of our proposed device for HR monitoring.

As the allowable error (flaw size) increased, the sensitivity and the PPV naturally increased. Increasing curves are depicted in Figure 10 with increasing flaw size from two to nine. When the flaw size is greater than three, the sensitivity and the PPV are above 98%. When the flaw size is greater than eight, the sensitivity and the PPV are above 99%. In the case where the HR varies from 50 bpm to 100 bpm, flaw sizes two, three, and eight possibly cause maximum error ranges of 0.85–3.23 bpm, 1.28–4.76 bpm, and 3.83–11.76 bpm, respectively (*fs*: 100 Hz).

We examined two different plots: plot of identity and the Bland-Altman plot (Figure 11). In the plot of identity, the $ECG_{Intervals}$ is plotted along the Y axis, and the $EPW_{Intervals}$ is plotted along the X axis. The identity line is presented as a reference to compare two different intervals, which are desired to be

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identical under ideal conditions [29]. In the Bland-Altman plot, we created two variables: the average between $ECG_{Intervals}$ and $EPW_{Intervals}$, and the difference between two intervals. The difference is plotted along the Y axis, and the average is plotted along the X axis. Then, we drew 95% limits of agreement (average ± 1.96 SD of the difference) for comparison [29,33].

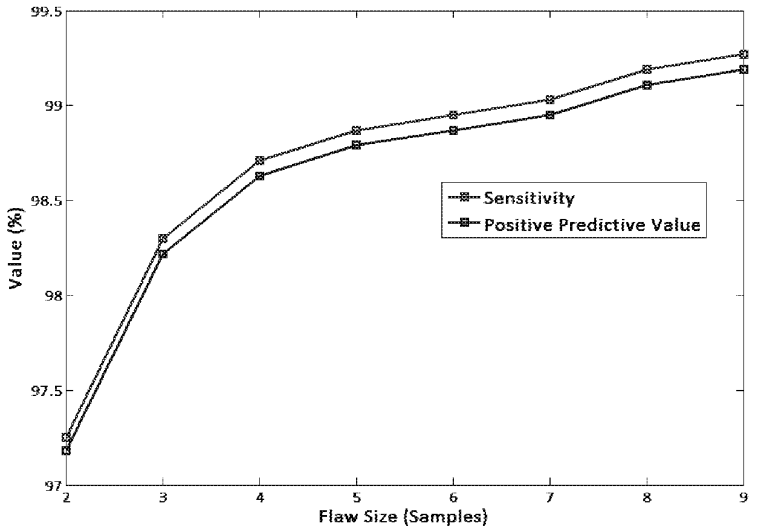


Figure 10. Sensitivity and PPV curves of the in-ear device.

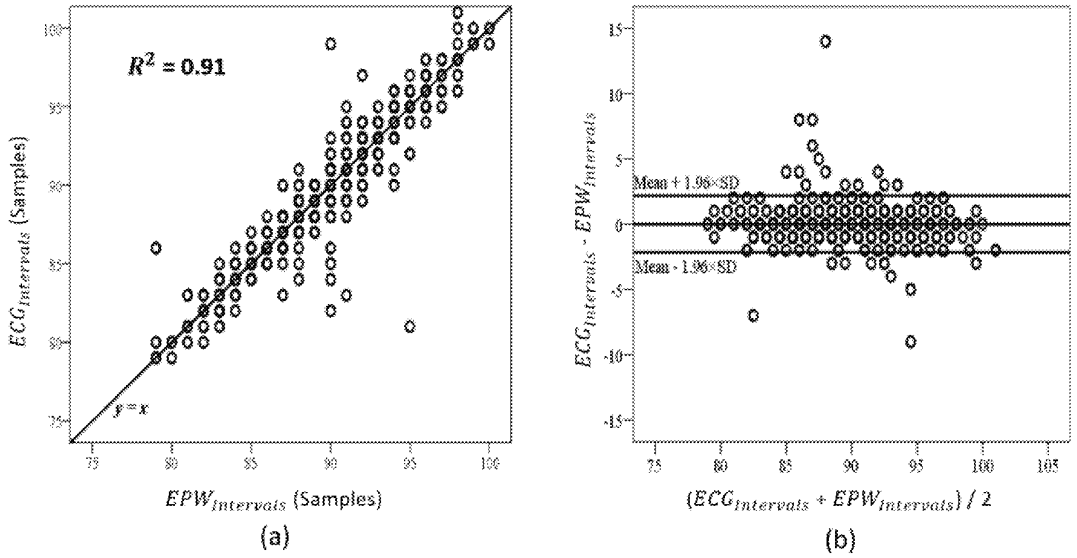


Figure 11. Agreement analysis results: (**a**) plot of identity; (**b**) Bland-Altman plot.

The identity line in Figure 11a is $y = x$; it represents a high level of agreement between $EPW_{Intervals}$ and $ECG_{Intervals}$. In the Bland-Altman plot (Figure 11b), the mean difference is 0.0065, the SD of the differences is 1.1011, and the 95% limits of agreement are −2.15 and 2.16. This figure shows that the difference does not have an increasing or decreasing trend, as the average increases. The estimated bias (mean difference) is very close to zero, and the random fluctuations (SD) around the bias are also narrow; thus, $EPW_{Intervals}$ can be considered as being in high agreement with $ECG_{Intervals}$.

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6. Limitations

Despite the fact that our approach exhibits a competent performance, it has a drawback—this method is quite sensitive to the user's motion. Because the piezoelectric sensor measures the pressure variance of the ear canal surface, if the user's motions or activities become substantial, the pressure variance is affected and EPW peaks then become less distinct. Accordingly, our proposed method is limited to monitoring HR temporarily in the user's stable status.

However, as can be seen in Figure 12, which depicts examples of EPW waveforms that occur when the user is walking, running, and chewing gum, rough EPW peak signals for heartbeats are still recognizable. Thus, we believe that a more sophisticated and improved algorithm to detect EPW peaks will be required for continuous monitoring in normal daily life. Additional circuits or sensor devices will also be necessary to compensate for the user's motion artifacts for more simple processing and extensive operation.

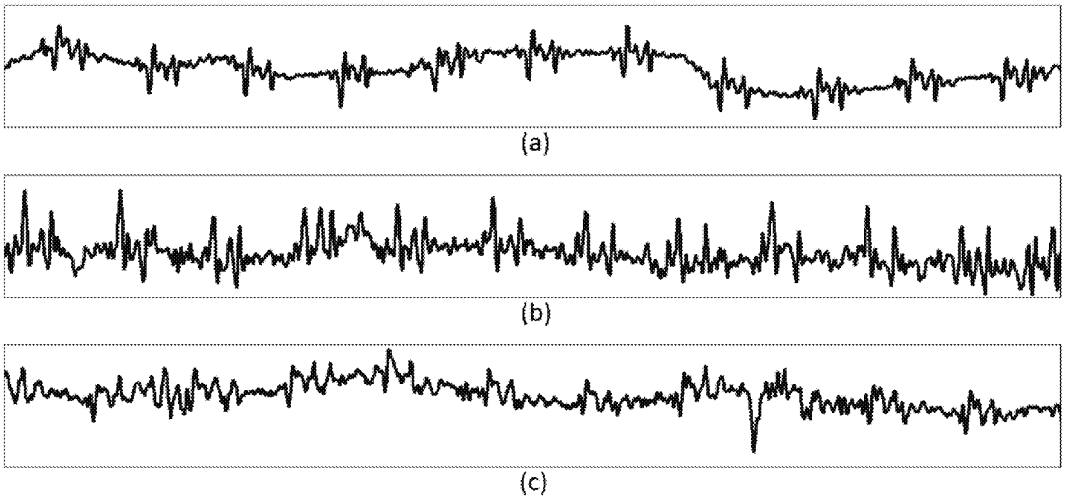


Figure 12. Examples of EPW waveform when the user is (**a**) walking, (**b**) running, (**c**) chewing gum.

7. Conclusions

In this study, a novel approach was proposed for monitoring HR: the development of a wearable sensing device that is both highly accurate and comfortable to measure EPW. The scissor-shaped apparatus developed facilitates utilization of a small piezoelectric sensor and measurement of in-ear pressure variance with high wearability. The piezoelectric sensor was sufficiently sensitive to detect pressure waveforms from the ear canal surface. The hardware circuit module efficiently amplified EPW and filtered various noises, and the embedded algorithm properly detected EPW peaks via knowledge-based rules.

Among the new findings obtained in this study are the following: (1) HR can be accurately detected from the pressure variance of the ear canal surface; and (2) a piezoelectric sensor enables measurement as a part of a wearable sensor device. In addition, the validity study presented very promising results that prove that our approach is accurate and performs well.

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We believe that this method could be used to monitor HR, and may also be utilized in diverse applications in the near future. One such instance could be to combine this method with a hearing aid. Hearing aids are already one of the most popular in-ear devices. The hearing impaired population, including the elderly, would be able to receive transparent and seamless vital sign monitoring benefits. There has been no known previous effort to produce this product, but reduction in the size and shape of the apparatus, and the circuit board could provide the key for the success of such a product as this.

Author Contributions

Jang-Ho Park performed overall work (design, implementation, and verification of sensor device) and wrote the paper. Dae-Geun Jang developed the signal detection algorithm, performed statistical analysis for the validity study, and revised the manuscript. Jung-Wook Park designed the sensor apparatus, developed hardware circuit modules, and carried out clinical data acquisition. Se-Kyoung Youm participated in apparatus design, clinical data processing, and manuscript revision. All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare no conflict of interest.

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Part 1: General requirements for basic safety and essential performance

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Hi Megan,

Here is the first email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

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Records processed under FOIA Request 2023-1091 Released by CDRH on 07-09-2024

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TEST REPORT

IEC 60601-1-2

Medical Electrical Equipment
PART 1-2: General Requirements for Basic Safety and Essential Performance
Collateral Standard: Electromagnetic Compatibility

Report Reference Number ..... : Project Reference Number ..... :	(b)(4)
Approved by(+signature)	(b)(4)
Date of issue:	
Total number of pages:	99
Name of Testing Laboratory preparing the Report ..... :	(b)(4)
Applicant's name ..... :	Accurate Meditech Inc.
Address ..... :	8F-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406, Taiwan
Test specification: Standard ..... : Test procedure ..... : Non-standard test method ..... :	(b)(4)
Test Report Form No. ..... : Test Report Form(s) Originator .... : Master TRF ..... :	

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Hi Megan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

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If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

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Accurate Meditech Inc.-May 2023 Response

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Description

Document Number: (b)(4)

Version: (b)(4)

2022/09/01

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2022-09-01

Kuan Jen, Wang (General Manager)

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Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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Photoplethysmogram Intensity Ratio: A Potential Indicator for Improving the Accuracy of PTT-Based Cuffless Blood Pressure Estimation

Xiao-Rong Ding, *Student Member, IEEE*, Yuan-Ting Zhang*, *Fellow, IEEE*

Abstract— **The most commonly used method for cuffless blood pressure (BP) measurement is using pulse transit time (PTT), which is based on Moens-Korteweg (M-K) equation underlying the assumption that arterial geometries such as the arterial diameter keep unchanged. However, the arterial diameter is dynamic which varies over the cardiac cycle, and it is regulated through the contraction or relaxation of the vascular smooth muscle innervated primarily by the sympathetic nervous system. This may be one of the main reasons that impair the BP estimation accuracy. In this paper, we propose a novel indicator, the photoplethysmogram (PPG) intensity ratio (PIR), to evaluate the arterial diameter change. The deep breathing (DB) maneuver and Valsalva maneuver (VM) were performed on five healthy subjects for assessing parasympathetic and sympathetic nervous activities, respectively. Heart rate (HR), PTT, PIR and BP were measured from the simultaneously recorded electrocardiogram (ECG), PPG, and continuous BP. It was found that PIR increased significantly from inspiration to expiration during DB, whilst BP dipped correspondingly. Nevertheless, PIR changed positively with BP during VM. In addition, the spectral analysis revealed that the dominant frequency component of PIR, HR and SBP, shifted significantly from high frequency (HF) to low frequency (LF), but not obvious in that of PTT. These results demonstrated that PIR can be potentially used to evaluate the smooth muscle tone which modulates arterial BP in the LF range. The PTT-based BP measurement that take into account the PIR could therefore improve its estimation accuracy.**

I. Introduction

Blood pressure (BP) is an intrinsically variable hemodynamic phenomenon. It fluctuates spontaneously in response to stress, emotion and physical effort, and also varies over days, months and seasons, through the regulation of the nervous and endocrine system [1]. BP variability (BPV), has shown to be a significant prognostic predictor for hypertension—the major risk factor for cardiovascular disease [2]. Therefore, it is crucial to monitor the long-term continuous BP with high accuracy so as for prevention, detection, evaluation, and treatment of hypertension and its related cardiovascular diseases. The continuous BP monitoring methods should better be unsupervised, without inflatable cuff, noninvasive and unobtrusive for home healthcare and long-term use. Continuous cuffless BP measurement methods are therefore highly valuable.

Currently, there are a few solutions for continuous noninvasive measurement of BP [3, 4], such as the volume clamp technique, arterial tonometry, and pulse transit time (PTT) method. Because of its advantage over volume clamp and tonometry as a "cuffless" technique, PTT method has gained considerable attention in recent years [5-7], and could be the most widely used method for unobtrusive cuff-less BP measurement in the future [3]. The PTT-based technique is based on the principle of pulse wave velocity (PWV) through the Moens-Korteweg (M-K) equation [8]:

$$PWV = \sqrt{Eh/\rho d} \tag{1}$$

The M-K equation models the relationship between PWV and the elastic modulus of arterial wall E given constant ratio of wall thickness h to arterial diameter d, where E can be exponentially correlated with BP [5, 9], i.e.,

$$E = E_0 e^{\gamma P} \tag{2}$$

Accordingly, indirect BP measurement can be achieved through the translation of PWV to BP after a calibration procedure. This method can be realized through the measurement of PTT at two specific sites. In practice, PTT can be derived from the time interval between the R-wave of electrocardiogram (ECG) and the characteristic point of photoplethysmogram (PPG).

Though PTT-based method overcomes the inherent problem existed in the cuff-based monitoring methods, there are still several issues to be resolved for its clinical application. Especially, the accuracy issue is the main bottlenecks blocking its widespread clinical usage [10]. One of the main reasons for the finite precision is that in the M-K equation, the variation of the arterial diameter is ignored. This may not be true since arterial diameter varies with arterial BP, with the diameter increases from the minimal level during diastole to the maximal level during systole over one cardiac cycle [11]. As a matter of fact, arterial BP is regulated by the contraction or relaxation of vascular smooth muscle that innervated by sympathetic nervous system through regulation the diameters of the blood vessels to change the volume of blood vessels and the local BP, where the smooth muscle tone is especially pronounced among peripheral arteries. In other words, the primary aspect of blood vessels that affects the flow and distribution of blood thereby regulating BP is their caliber, i.e., their arterial diameter [12]. As a result, the accuracy of estimated BP will be affected when ignoring the diameter variation [13]. Therefore, considering the factor of arterial diameter variations could improve the accuracy of the

This work was supported in part by the Guangdong Innovation Research Team Fund for Low-cost Healthcare Technologies in China, the External Cooperation Program of the Chinese Academy of Sciences (Grant GJHZ1212). Asterisk indicates corresponding author.

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PTT-based BP estimation. In this study, we propose a novel physiological indicator that can reflect the diameter change of blood vessel, with the attempt to examine its relationship with BP during autonomic nervous tests. Besides, since the smooth muscle tone is associated with the regulation of arterial diameter, it is expected that this indicator can interpret the influence of sympathetic nervous system activity on BP, thereby improving the accuracy of PTT-based BP measurement when this indicator is integrated into the BP estimation model.

II. Methodology

A. Photoplethysmogram Intensity Ratio (PIR) Derivation

Figure 1 shows a typical systolic-diastolic variation of arterial BP corresponding to systolic-diastolic variation of arterial diameter. It can be seen that arterial diameter varies with BP over the cardiac cycle, changing from Dd in diastole to Ds in systole.

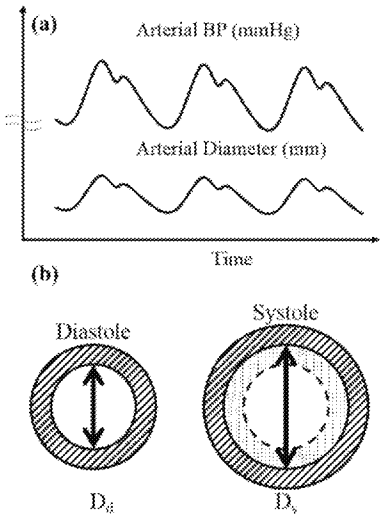


Figure 1. (a) The relationship between the arterial BP and diameter; (b) arterial diameter variation in diastole and systole

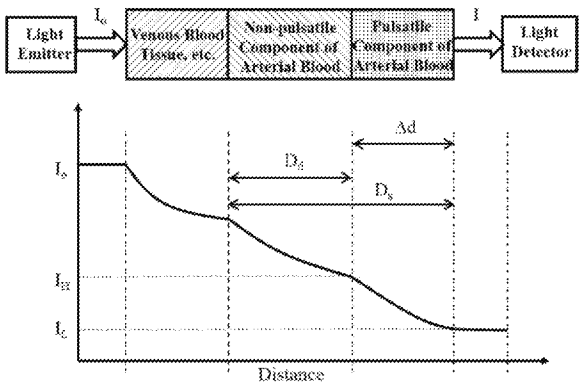


Figure 2. Light absorption variation through different distance

With PPG collected from a peripheral artery as shown in Figure 2, the incident light intensity I_0 of the light emitter will become I collected by the light detector after transmission through the tissue, venous blood, and arterial blood. It should be noted that the arterial blood contains non-pulsatile component as well as pulsatile component. During diastole, the arterial diameter at its minimal level Dd, and the transmitted light intensity will be at the highest level I_H accordingly. On the contrary, the transmitted light intensity will decrease to the minimal level I_L during systole as a result of the increase of arterial diameter to Ds. During one cardiac cycle, the change of the optical path is corresponding to the diameter change Δd. Therefore, the diameter change can be derived from the peak and valley intensity of PPG.

The detected PPG signal consists of DC component mainly due to the light absorption of tissue, venous blood and non-pulsatile blood, and the alternating component because of the pulsatile blood. According to the Beer-Lambert law, we have:

$$I_L = I_0 \cdot e^{-\alpha_{DC} \cdot d_{DC}} \cdot e^{-\alpha \cdot D_s} \tag{3}$$

$$I_H = I_0 \cdot e^{-\alpha_{DC} \cdot d_{DC}} \cdot e^{-\alpha \cdot D_d} \tag{4}$$

where $\alpha_{DC} = \varepsilon \cdot c$ is the multiply of absorbance coefficient and material concentration, d_{DC} the optical path of the DC component, Ds and Dd the systolic diameter and diastolic diameter, respectively. Taking the ratio of the Eqn. (3) and Eqn. (4), the diameter change can be derived as below.

$$\Delta d = D_s - D_d = \frac{1}{\alpha} \cdot \ln \frac{I_H}{I_L} \tag{5}$$

Therefore the arterial diameter change can be obtained in terms of PIR, which is the ratio of PPG peak intensity I_H to valley intensity I_L, under the assumption that the characteristic parameter α keeps constant.

B. Experiment

To investigate whether the arterial diameter can reflect the sympathetic nervous activity, and its relationship with arterial BP, the commonly used cardiovascular autonomic function tests such as deep breathing (DB) maneuver and Valsalva maneuver (VM) were performed on five healthy subjects. DB maneuver was used to test cardiac parasympathetic functions. It was performed with controlled breath rate, i.e., six breaths per min, with 30 s inspiration and 30 s expiration in each breath cycle. While the VM was applied to provide a measure of sympathetic activity. It was performed with a maximal forced expiratory pressure against a closed airway for 20 s. Subjects were asked to refrain from caffeinated beverages, alcohol, and smoking on the day of testing. All tests were conducted in an air-conditioned room at 23°C. ECG, PPG, continuous BP using Finometer® (FMS, Amsterdam, Netherlands), and respiratory movement were recorded throughout the testing. All subjects volunteered to participate and gave their informed consent prior to the experiment, and the study was approved by the University Ethics Committee.

C. Data Analysis

Cardiovagal functions during DB were evaluated by the heart rate (HR) responses, and sympathetic functions were measured by BP responses to VM [14]. Before the maneuver, BP was recorded and averaged for 30 beats, and mean resting HR, PTT, PIR were similarly calculated. For DB, the maximal and minimum HR, which is corresponding to inspiration and expiration stages, were measured during each breathing cycle;

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PTT, PIR and BP were calculated at the same time. During VM, indicators of baseline, phase II minimum, phase II end, and phase IV were measured. Data was expressed as mean ± SD (standard deviation) and significance was accepted at $p < 0.05$. The influence of nervous autonomic system activity is evaluated in frequency domain by analyzing the very low frequency (VLF, 0.01-0.04 Hz), low frequency (LF, 0.04-0.15 Hz), and high frequency (HF, 0.15-0.40 Hz) component of relevant physiological parameters, i.e., HR, PTT, PIR and BP. The LF reflects contributions directly from the sympathetic nervous system, and the HF band represents the effects of parasympathetic modulation on HR and also mechanical effects of respiration on cardiac filling and BP. The LF:HF ratio of HR, PTT, PIR and BP during rest and VM were calculated to represent overall sympathovagal balance [15].

III. Results

Effect of DB and VM on the response of physiological parameters, i.e., HR, PTT, PIR, and SBP, were analyzed in time domain and frequency domain. Figure 3 depicts the overall variations of the parameters during DB and VM. It was observed that during DB from inspiration to expiration, SBP was significantly decreased from 130.3±6.1 mmHg to 109.3±5.4 mmHg ($p<0.05$) with the increase of PTT, whilst HR was slowed down, and PIR elevated from 1.05±0.03 to 1.07±0.04 ($p<0.05$). A typical VM usually consists of four phases, in which SBP increases in Phase I, then declines in early Phase II, following with an increase at the end of Phase II, drops in Phase III, and elevates in Phase IV, finally recovers. The result in this study was well consistent with the reported studies [14], with SBP dropped to the minimal level at the end of early Phase II, then rose at the end of Phase II, and a further higher level at Phase IV, with a typical variation of HR. Meanwhile, PTT changed reversely with SBP, but it is noteworthy that PIR varied in the same direction with SBP, rather than negative relationship as displayed in DB.

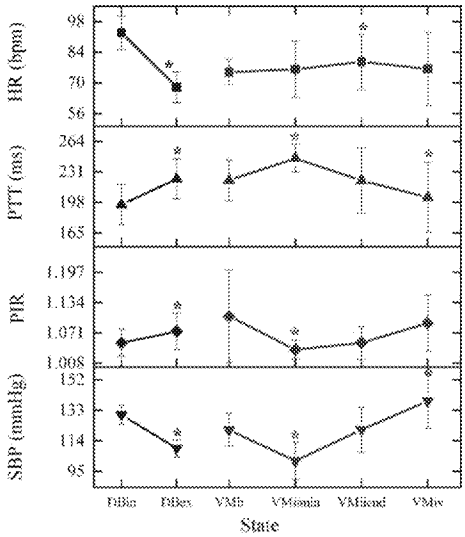


Figure 3. Parameters variations during DB and VM, where DBin and DBex presents the inspiration and expiration stage of DB, while VMb, VMiimin, VMiiend, and VMiv presents the stages of baseline, minimum of Phase II, end of Phase II, and Phase IV, respectively.

Moreover, the power spectral density (PSD) of HR, PTT, PIR, and SBP were analyzed during DB and VM, which is illustrated in Figure 4. It is obvious that during DB, there was a spectral peak at 0.1 Hz for all the parameters, which was exactly the controlled breathing rate. And as expected, during VM, the dominant frequency components shifted from the HF to the LF range, which was especially pronounced in PIR and SBP, whereas HR and PTT had both low and high spectral components. The LF:HF ratio of those parameters were calculated for rest state and VM, as shown in Figure 5. We can see that, except for PTT, all the other parameters, i.e., HR, PIR and SBP had a significant higher LF:HF ratio (PIR: 11.52±6.66, SBP: 10.24±7.04) during VM than that at rest (PIR: 3.17±1.87, SBP: 3.69±2.24).

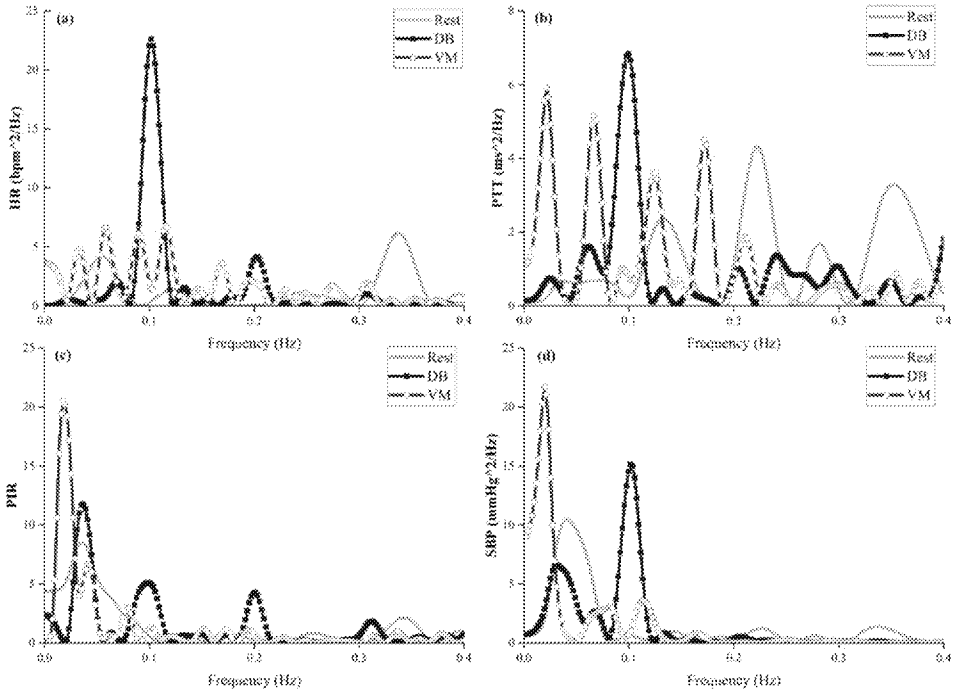


Figure 4. PSD of (a) HR, (b) PTT, (c) PIR and (d) SBP at rest (green solid), DB (blue solid square), and VM (red empty circle)

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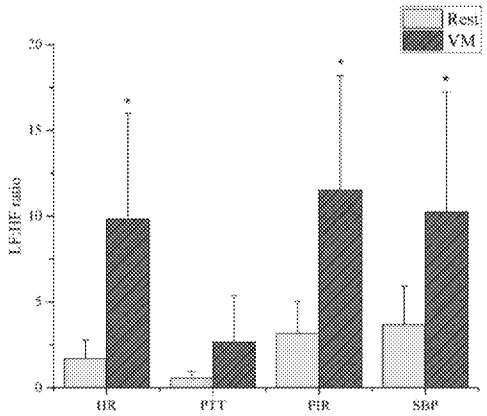


Figure 5. LF: HF ratio of HR, PTT, PIR and SBP with the comparison between rest and VM

IV. Discussion and Conclusion

Many previous reports have documented the effectiveness of using PTT for the cuffless continuous BP measurement; B. McCarthy [10], for example, compared two most cited papers on PTT-based BP estimation approaches, and found PTT can track BP with a reasonable accuracy in a certain period. However, most of studies were based on M-K equation which ignores the underlying condition that arterial geometries such as arterial diameter is dynamic rather than constant. The relationship between changes in arterial diameter and those in BP depends on the mechanical properties of the artery, with larger arterial diameter change for more compliant artery and vice versa. In this study we proposed a novel indicator, the PIR that can reflect the arterial diameter change during cardiac cycle, and tested the variations of PIR and BP in response to autonomic nervous system activities induced by DB and VM.

We found that the variations of PIR were associated with those of SBP during DB and VM, with PIR changed negatively with SBP during DB but positively during VM. This could be explained by the fact that the stiffness of peripheral arteries is modulated by the vasomotor tone, which depends on the sympathetic nervous system [11]. During DB, parasympathetic activity is increased with decreased sympathetic activity, as a result, the HR reduced with lower BP, and the activity of sympathetic nerve fibers is decreased thus leads to the relaxation of vascular smooth muscle, and further the increased arterial diameter and elevated PIR accordingly. Consequently, the arterial distensibility $D=(2\Delta d/D_d)/\Delta P$ increases. Nevertheless, the sympathetic nervous activity is increased during VM which improved the arterial stiffness and thus reduced distensibility. That could explain why PIR changed positively with SBP, though SBP changed more significantly than PIR. Furthermore, the spectral analysis as well as the LF:HF ratio of PIR and SBP showed that the dominant frequency components shifted from HF range to LF and VLF from the rest state to VM, which may reflect that the sympathetic nervous system activity enhanced during VM compared with resting state. Our findings therefore imply the influence of arterial diameter that evaluated by PIR on BP regulation especially in LF range. The results demonstrated the important potential of PIR for improving the accuracy of PTT-based BP measurement. However, some limitations are worth noting: the sample size was not large enough; how PIR approximates arterial diameter change should be addressed compared to sonomicrometry, the gold standard for arterial diameter measurement [16]; and the quantitative relationship between PIR and BP remains to be further studied. Future research should be directed toward the development of BP estimation model using both PTT and PIR for the improvement of accuracy.

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An Arterial Compliance Sensor for Cuffless Blood Pressure Estimation Based on Piezoelectric and Optical Signals

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Abstract: Objective: Blood pressure (BP) data can influence therapeutic decisions for some patients, while non-invasive devices that continuously monitor BP can provide patients with a more comprehensive BP assessment. Therefore, this study proposes a multi-sensor-based small cuffless BP monitoring device that integrates a piezoelectric sensor array and an optical sensor, which can monitor the patient's physiological signals from the radial artery. Method: Based on the Moens–Korteweg (MK) equation of the hemodynamic model, pulse wave velocity (PWV) can be correlated with arterial compliance and BP can be estimated. Therefore, the novel method proposed in this study involves using a piezoelectric sensor array to measure the PWV and an optical sensor to measure the photoplethysmography (PPG) intensity ratio (PIR) signal to estimate the participant's arterial parameters. The parameters measured by multiple sensors were combined to estimate BP based on the P–β model derived from the MK equation. Result: We recruited 20 participants for the BP monitoring experiment to compare the performance of the BP estimation method with the regression model and the P–β model method with arterial compliance. We then compared the estimated BP with a reference device for validation. The results are presented as the error mean ± standard deviation (SD). Based on the regression model method, systolic blood pressure (SBP) was 0.32 ± 5.94, diastolic blood pressure (DBP) was 2.17 ± 6.22, and mean arterial pressure (MAP) was 1.55 ± 5.83. The results of the P–β model method were as follows: SBP was 0.75 ± 3.9, DBP was 1.1 ± 3.12, and MAP was 0.49 ± 2.82. Conclusion: According to the results of our proposed small cuffless BP monitoring device, both methods of estimating BP conform to ANSI/AAMI/ISO 81060-2:20181_5.2.4.1.2 criterion 1 and 2, and using arterial parameters to calibrate the MK equation model can improve BP estimate accuracy. In the future, our proposed device can provide patients with a convenient and comfortable BP monitoring solution. Since the device is small, it can be used in a public place without attracting other people's attention, thereby effectively improving the patient's right to privacy, and increasing their willingness to use it.

Keywords: Moens–Korteweg; pulse wave velocity; photoplethysmography; systolic blood pressure; diastolic blood pressure

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1. Introduction

Blood pressure (BP) is an important physiological parameter affecting patients' treatment decisions. When the body's BP deviates from the normal range, it may lead to many diseases, such as hypertension, which can lead to chronic kidney disease, heart disease, and other health problems [1]. For monitoring BP abnormality in the clinical setting, non-invasive ambulatory blood pressure monitoring (ABPM) represents a current useful tool. Monitoring the patient's 24 h BP changes provides an accurate basis for the diagnosis of hypertension. It also allows patients to manage their treatment better [2]. However, ABPM requires intermittently inflating cuffs that can interrupt the patient's daily life, resulting in

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discomfort and reduced treatment compliance with BP monitoring [3]. Therefore, in recent years, many researchers have developed various technologies for cuffless BP monitoring. According to the definition of a cuffless BP monitor in the Institute of Electrical and Electronics Engineers (IEEE) standard, a cuffless BP monitor is a BP monitor without an occluding cuff [4]. This implies that the difference between a cuffless BP monitor and a traditional BP monitor is that there is no need to pressurize the patient's arteries, thereby reducing the discomfort caused by measurement. In the early days, popular cuffless BP monitoring technologies used electrocardiography (ECG) and PPG to measure the pulse arrival time (PAT) by calculating the time difference between the two [5,6]. Since PAT is correlated with arterial compliance in the description of hemodynamics, BP can be estimated under calibration by regression methods [7]. However, in recent studies, researchers found that the regression method cannot accurately estimate BP due to the influence of the pre-ejection period (PEP) on PAT [8]. Pulse transit time (PTT) is the time difference between pulse waves at two positions on the local artery. The speed of pulse wave transmission is faster than the speed of blood movement. Notably, measuring the PTT of an arterial segment can reflect the correlation of intra-arterial pressure [9]. However, PTT does not have the problem of PAT being affected by PEP and, thus, can avoid the problem of PAT being unable to accurately estimate BP. At present, related studies are using PTT to estimate BP. Piezoelectric sensors are used to measure the time difference between the wrist and fingers due to the pulse wave generated by the cardiac cycle [10]. In this method, an optical sensor array is placed on the finger to measure the change in arterial blood volume and calculate the time difference after taking the derivative of the alternating current (AC) signal generated [11]. The BP sensing patch integrates a flexible piezoresistive sensor (FPS) and epidermal electrocardiogram (ECG) sensor [12]. A sensor measures the carotid pulse wave by using the tissue movement generated by the pulse wave to change the magnetic field [13]. A probe integrates two ultrasonic transducers to measure the time difference between the echo signals of local arterial changes [14]. The method of measuring the time difference of the bioimpedance of the blood volume change in the artery is used [15]. Moreover, other sensors have the potential for cuffless BP measurement [16]. Flexible sensors can function through a chemical reaction and physical sense, such as biodegradable ferroelectric skin sensors [17], triboelectric self-powered sensors [18], and microfluidic sensors [19]. Many related studies have shown that various technical means of measuring PTT have been developed. However, in these studies, estimating BP from PTT still involved using the regression method to calibrate the BP curve (i.e., directly converting PTT to generalized PWV and modeling a regression model with PWV-BP) [20]. In recent years, due to breakthroughs in machine learning, some studies of cuffless methods have also tried to use machine learning methods to estimate BP [21]. However, machine learning models need different hyperparameters to predict blood pressure, including demographics (e.g., age and gender). Nevertheless, researchers are unclear how much of the attained BP measurement accuracy, especially of the calibration-free device, is due to the actual hemodynamic measurement [22]. Additionally, the computing loading of deep learning is unsuitable for embedded systems with low computing power.

The calibration curve relating PTT to BP depends on blood density, arterial stiffness, and geometry. Except for blood density, other arterial parameters are patient-specific, with experimental data suggesting that the calibration curves vary among individuals [23]. Therefore, a calibration curve customized to each patient will be optimal. However, the disadvantage of this method is obvious, since the operational complexity of the calibration procedure will increase. In the theory of hemodynamics, the potential variables affecting BP have other contributions from arterial parameters in addition to PWV; thus, the regression model of BP cannot be applied to all patients. There are two reasons why the direct use of PTT and BP to model a regression model for estimating a patient's BP is inaccurate. The first is that arterial parameters affect BP and differences in the arterial characteristics of different patients may cause regression models to fail. The second is that the distance for measuring the PTT is short, and the error generated by the conversion to the PWV difference will increase [24]. Since the regression model is sensitive to PTT error, the result of BP

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estimation can easily produce a larger distribution range. This study proposes a system that uses a combination of piezoelectric sensor arrays for PTT measurement and near-infrared spectroscopy (NIRS) to measure a patient's photoplethysmography (PPG) intensity ratio (PIR) by using NIRS to correlate the PIR with the patient's arterial parameters. We used arterial parameters to calibrate the PTT and BP models based on hemodynamics, which considers the neglected components in previous relevant studies and reduces the error of BP estimation. Finally, we used the ISO 81060-2 standard to evaluate the performance of the hemodynamic method compared to regression models.

Our Contribution

This study developed a small cuffless BP measurement device to verify cuffless BP monitoring (see Figure 1). This device includes the following two parts: a motherboard and a sensor module. The sensor module is connected to the motherboard through a flexible printed circuit (FPC). The motherboard includes a microcontroller unit (a STM32F405, produced by STMicroelectronics Geneva, Switzerland), a wireless communication chip (a NRF52832, produced by Nordic Semiconductor Inc. Trondheim, Norway), and an analog front end (an AD8669, produced by Analog Devices Inc., Wilmington, MA, USA). The sensor module consists of two piezoelectric sensors and a NIRS optical sensor (a MAX30101, produced by Maxim Integrated Inc., San Jose, CA, USA). The analog signal of the piezoelectric sensor is input to the motherboard's analog front end (AFE), while the optical sensor is connected to the inter-integrated circuit (I2C) interface of the microcontroller unit (MCU). When the patient has been measured (Figure 2), the cuffless BP monitor (Figure 2a) will transmit the results to a smartphone, which displays the patient's BP data and records it (see Figure 2b).

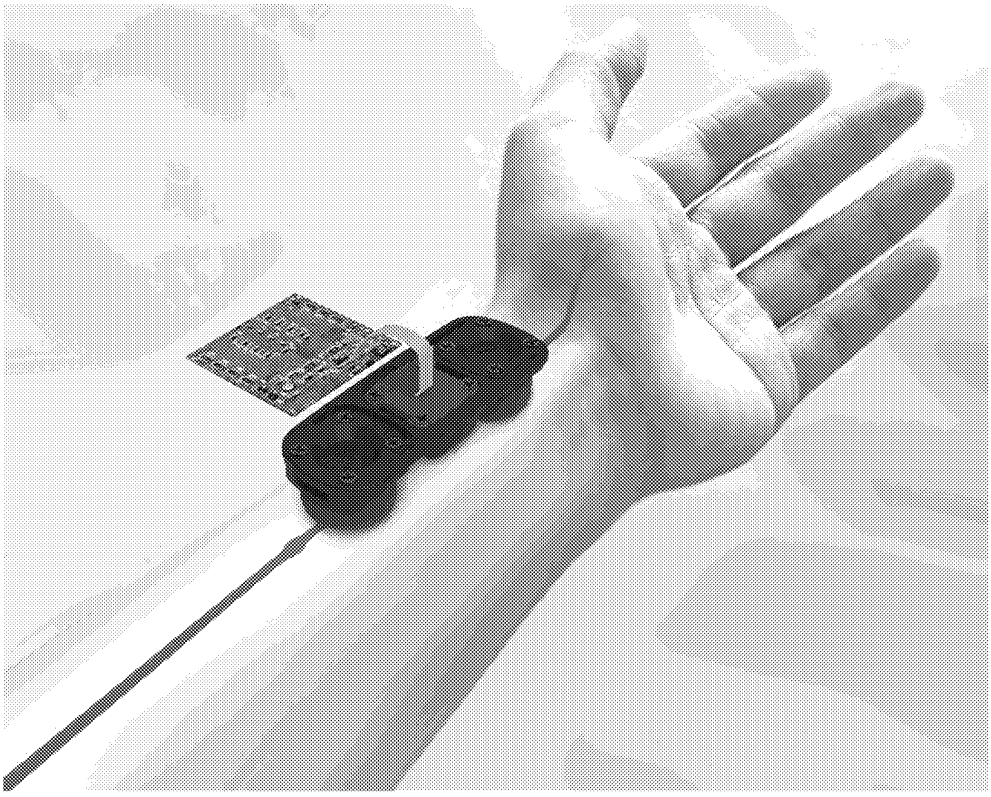


Figure 1. A small cuffless BP measurement device used to verify cuffless BP monitoring.

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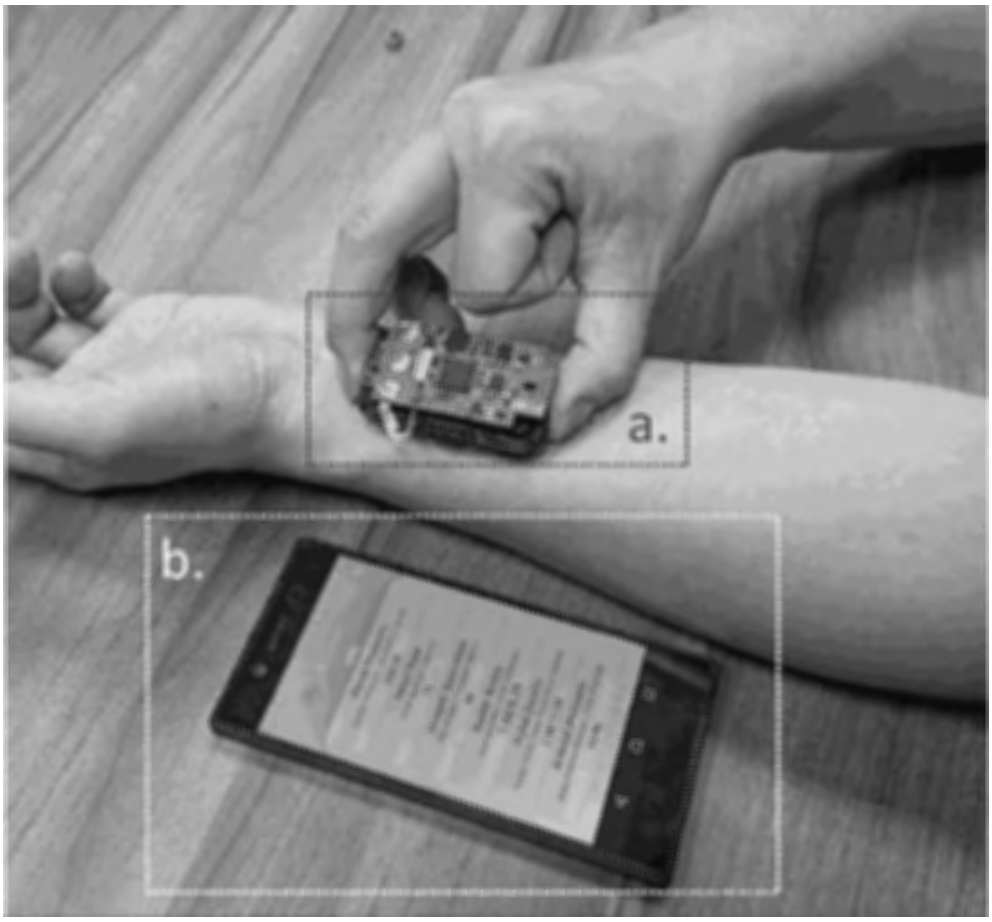


Figure 2. A patient that has been measured. (**a**) the cuffless BP monitor. (**b**) A smartphone displaying the patient's BP data and recording.

We used this cuffless BP monitor to measure 20 adult participants according to the ISO 81060-2 protocol. We estimated BP using the following two methods: a regression model using PTT with BP, and arterial parameters combined with PTT to estimate BP using the P–β model (derived from the MK equation). In the results of this paper, we compare the mean difference and standard deviation of the two methods for the gold standard, assess whether the performance of the P–β model for cuffless BP measurement can be improved, and outline relevant discussions and future work directions based on the results.

2. Materials and Methods

Figure 3 presents the cuffless BP monitor proposed in this study, which uses a multi-sensing module that integrates piezoelectric and optical sensors. Figure 3a–c show the sensor module, which integrates two piezoelectric sensors and one PPG sensor, with the PPG sensor being placed between the two piezoelectric sensors. This is because when two piezoelectric sensors sense the pulse wave of the radial artery, it can ensure that the PPG sensor is placed above the radial artery. If the pulse wave amplitude measured by one of the two piezoelectric sensors does not exceed the threshold, the sensor module may not be placed parallel to the radial artery. Figure 3d shows that the sensor module must be placed parallel above the radial artery. After the two piezoelectric sensors measure the pulse wave in the same cardiac cycle, the pulse wave at two different positions in the radial artery segment can be calculated as the time difference to obtain PTT. Optical sensors can measure optical tissue information, such as changes in blood volume in the radial artery, to estimate arterial parameters.

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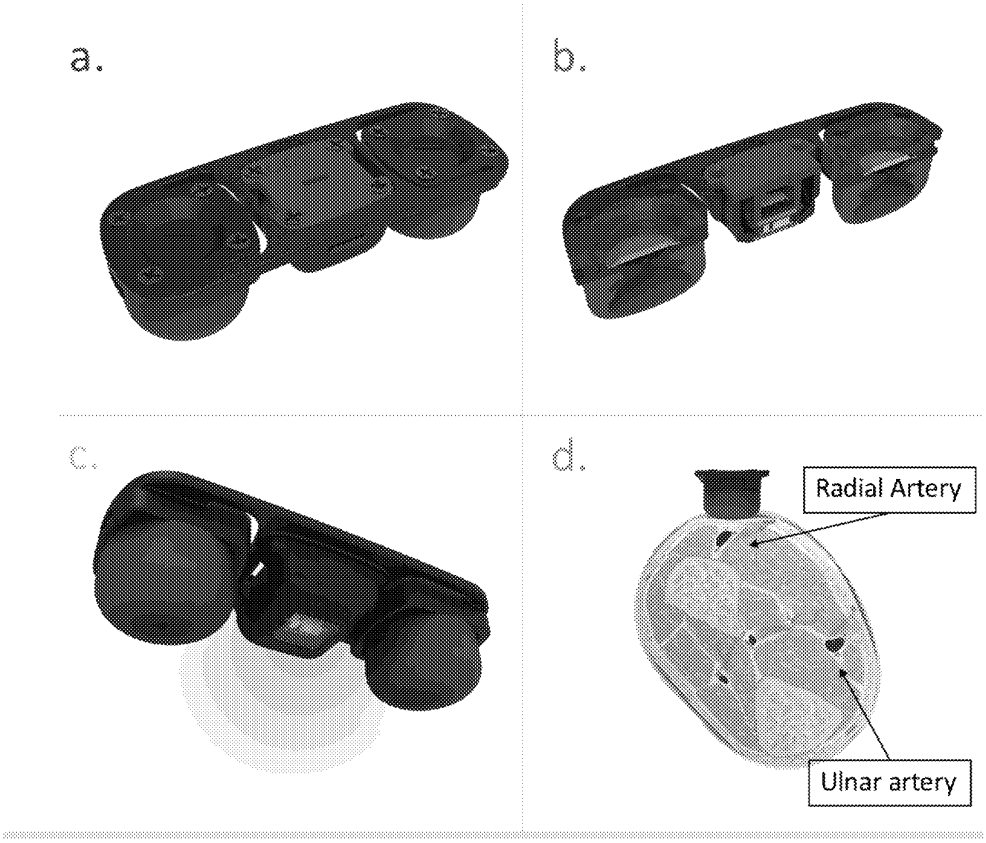


Figure 3. The cuffless BP monitor uses a multi-sensing module that integrates piezoelectric and optical sensors. (**a**) Top view. (**b**) Side view. (**c**) Bottom view. (**d**) the sensor module must be placed parallel above the radial artery.

2.1. Pulse Wave Detection Sensor

Figure 4 is a schematic diagram of the structure of the piezoelectric sensor and the pulse wave transmitted by the radial artery. We used the combination of an O-ring and the assembly of mechanical structures to perform an interference fit on the piezoelectric ceramics so that the inside of the sensor chamber is airtight. Additionally, a hole was opened at the top of the mechanical structure. The signal line of the piezoelectric ceramics was connected to the AFE of the motherboard through this hole. Part of the opening hole was also sealed with airtight glue. The rubber membrane in contact with the skin surface was also assembled with the chamber for an interference fit so that the pressure and volume within the sensor cavity remain stable. When a pulse wave is transmitted to the sensor, the rubber membrane will be moved by the pressure P_a due to the movement of the radial artery and the surrounding tissue so that the internal pressure P_A of the cavity increases and changes, resulting in a pressure difference ΔP, as in Equation (1).

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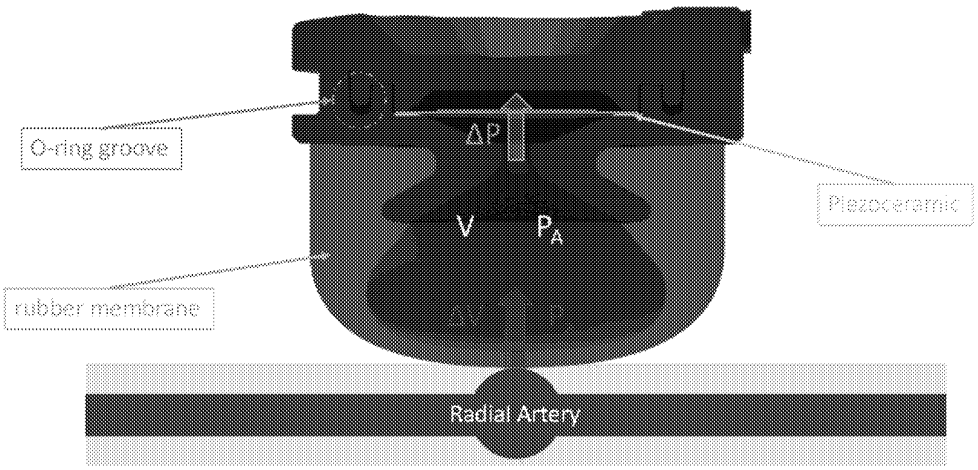


Figure 4. Schematic diagram of the structure of the piezoelectric sensor and the pulse wave transmitted by the radial artery.

$$\Delta P = P_A + P_a \tag{1}$$

The volume V within the chamber is the move distance L into the sensor generated by the rubber membrane and the cross-sectional area A of the rubber membrane itself. The volume value calculated by the product of L and A is the volume [25] inside the compression chamber, which makes the original volume change ΔV, as in the following Equation (2):

$$\Delta V = V - A \cdot L \tag{2}$$

Here, ΔV and P_a can be expressed as the relationship of pressure resulting from a change in volume according to Equation (3), where the resulting equation involves a constant γ, the ratio of specific heats, which is approximately 1.4 for air [26].

$$\frac{P_a}{P_A} = -\gamma \frac{\Delta V}{V} = -\gamma \frac{A \cdot L}{V} \tag{3}$$

Since the mass m of the volume compressed by the rubber membrane into the chamber is $A \cdot L$ multiplied by the air density ρ, as in Equation (4), through Newton's law of acceleration, as in Equation (5), the force F acting on the piezoelectric ceramics and the difference of the acting force can be known. This relationship is expressed in Equation (6).

$$m = AL\rho \tag{4}$$

$$\frac{F}{m} = \frac{d^2x}{dt^2} \tag{5}$$

$$\frac{d^2x}{dt^2} = \frac{P_a S}{SL\rho} = -\frac{\gamma S P_A}{\rho V L} x \tag{6}$$

Piezoelectric ceramics are deformed by pressure. The charge is generated in the piezoelectric ceramics according to the direct piezoelectric effect. We can detect the pulse wave signal through the change in the charge [27]. Piezoelectric ceramics detect that the signal generated by the pulse wave is usually in the order of millivolts. The AFE on the motherboard can pre-process the pulse wave signal to improve the signal-to-noise ratio (SNR) of the pulse wave signal. Figure 5 presents the topology of the AFE on the motherboard, while Figure 5a presents the voltage follower (VF). Since the piezoelectric ceramics' parasitic capacitance C_p is 8000 pF (at 120 Hz) [28], $R1$ is external. When the load resistor forms a high-pass filter, the relationship between the cut-off frequency f and the external load resistor is calculated

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using Equation (7). If $R1$ uses a 20 MΩ resistor, the cut-off frequency is approximately 0.1 Hz. When $R2$ is equal to $R1$, a direct current (DC) offset circuit [29] is formed to increase the voltage level of the pulse wave signal. At this time, the non-inverting input voltage of VF is represented by Equation (8), where V_p is the pulse wave detected by the piezoelectric ceramics' generated voltage. Figure 5b presents a signal amplifier that can amplify the pulse wave signal to improve the SNR. It is possible to use $C1$ to adjust the gain of the amplifier [30]. In this study, an amplification of approximately 18 times is used for gain, calculated as represented in Equation (9), to determine the gain range of the pulse wave signal. Figure 5c is a second-order Sallen–Key low-pass filter (LPF) [31]. Equation (10) is its transform function calculation formula, the cut-off frequency $f_{c(LPF)}$ is determined by Equation (11), and the cut-off frequency of LPF is 10.6 Hz. Here, $R5$ and $R6$ are the same resistance value. Additionally, $C2$ and $C3$ also have the same capacitance value, which can attenuate the high-frequency noise amplified by the amplifier. After the AFE pre-processes the signal, it is sampled and converted into a digital signal by the motherboard's analog-to-digital convert (ADC), as shown in Figure 5d. In our previous study, we developed a series of digital signal processing algorithms to process the piezoelectrically sensed pulse wave signal, which can effectively detect the pulse wave in normal heart rhythm and arrhythmia patients [32]. This study uses the same method to process the pulse wave and calculate the PTT.

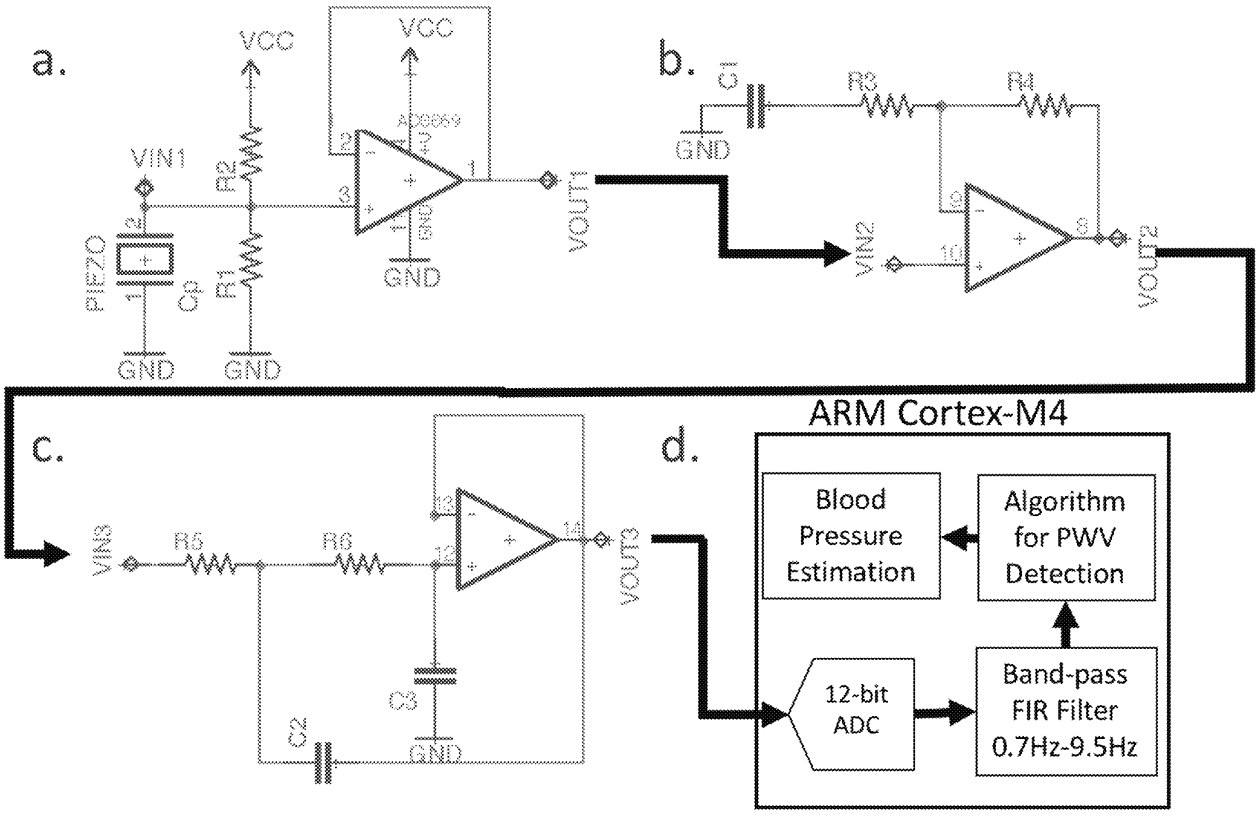


Figure 5. Topology of the AFE on the motherboard. (**a**) the voltage follower (VF). (**b**) the signal amplifier. (**c**) the second-order Sallen–Key low-pass filter (LPF). (**d**) the ARM Cortex-M4.

$$f = \frac{1}{(2 \cdot \pi \cdot R1 \cdot C_p)} \tag{7}$$

$$V_{in} = V_p + \frac{VCC \cdot R1}{(R1 + R2)} \tag{8}$$

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$$V_{out} = V_{in} \cdot \left(\frac{R4}{R3 + \frac{1}{\omega \cdot C1}} + 1 \right) \tag{9}$$

$$\frac{V_{out}(s)}{V_{in}(s)} = \frac{\frac{1}{R5 \cdot C2 \cdot R6 \cdot C3}}{s^2 + s\left(\frac{1}{R6 \cdot C2} + \frac{1}{R5 \cdot C2} \right) + \frac{1}{R5 \cdot C2 \cdot R6 \cdot C3}} \tag{10}$$

$$f_{c(LPF)} = \frac{1}{2\pi \sqrt{R5 \cdot C2 \cdot R6 \cdot C3}} \tag{11}$$

The 12-bit ADC of the motherboard samples the pulse wave signal of the AFE at a sampling rate of 5 kHz and uses the finite impulse response (FIR) to filter the signal [33]. The FIR filter algorithm we use is a band pass filter (BPF), where the cut-off frequency for high-pass filtering is 0.7 Hz and the cut-off frequency for low-pass filtering is 9.5 Hz [34]. After the pulse wave signal is pre-processed by digital filtering, the dynamic threshold algorithm can effectively detect the characteristic points of the pulse wave, as shown in Figure 6. Finally, the PTT (inversely proportional to PWV) can be obtained by calculating the pulse wave time difference between two positions of arterial segments [35].

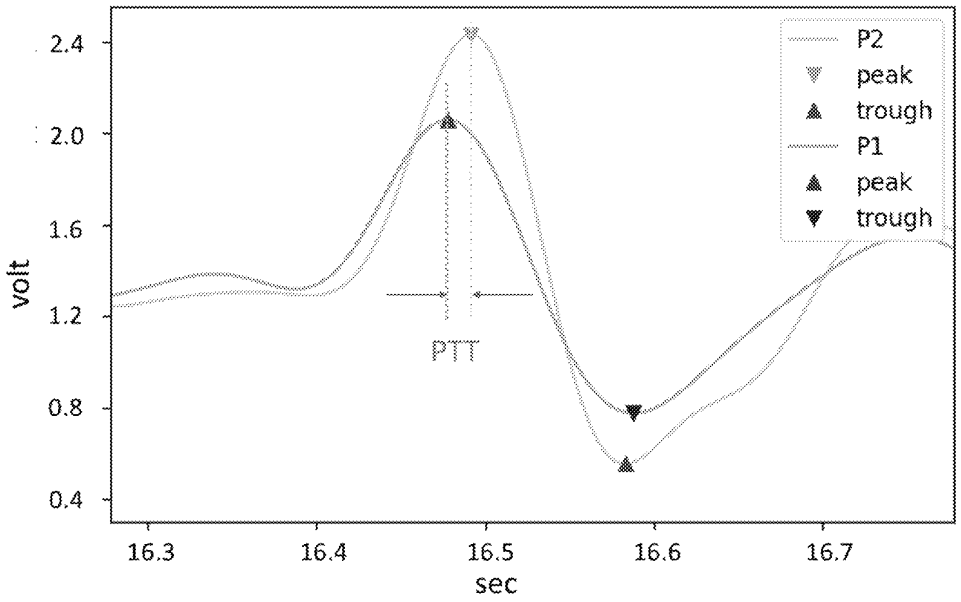


Figure 6. Characteristic points of the pulse wave.

2.2. PPG Signal Process and Arterial Parameter Estimates

To improve the accuracy of the BP estimation model in this study, it was necessary to measure the patient's arterial compliance. We used the PPG sensor to quantify the patient's arterial dimensions and arterial change. The PPG sensor we used is a diffuse reflectance spectroscopy (DRS) sensor that integrates three wavelengths of light-emitting diode (LED) and a photodiode (PD) [36] to ensure that the PPG sensor is placed on the skin surface parallel to the radial artery. When the piezoelectric sensor array of the cuffless BP monitor detects the pulse wave, it will determine that the SNR of the pulse wave qualified the set threshold, indicating that the device is placed on the artery. At this point, the PPG sensor is activated to sense the optical signal of arterial change. When the photons excited by the PPG sensor enter from the epidermal tissue and return to the PD, the optical information of the tissue can be obtained [37]. The depth of the photons entering the tissue depends on the distance of LED to PD and wavelength. To measure the optical characteristics of the tissue as deeply as possible, we chose infrared light with a wavelength of 880 nm as the PPG signal for our estimation of arterial changes. The ADC sampling rate is 100 Hz and the resolution is 18 bits, because infrared light can enter the tissue more than visible

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light. The deeper the depth, the more tissue optical information can be obtained [38,39]. The distance between the LED and PD is 3 mm. Since the light path of the photon in human tissue is banana-shaped [40], the detection depth can be greater than 3 mm, which affects the radial artery depth. The main factor is the body mass index (BMI) [41]. In most cases, the radial artery depth is approximately 2.5 mm in individuals with a BMI of less than 30 [42,43]. After determining that the PPG sensor has known physical parameters and the radial artery's physiological characteristics, we used an ultrasonic imaging device as a reference instrument to model the arterial parameters measured by ultrasonic imaging and the quantized PPG signal [44]. The instruments we used included an ultrasonic imaging device (a uSmart 3300, produced by Terason, Burlington, MA, USA) and an L-type probe (a 16HL7, produced by Terason Inc., Burlington, MA, USA) to sample the radial artery parameters of the participants. The researcher operated the L-type ultrasound probe to collect an ultrasound image of the participant's radial artery and measured the depth, diameter, change, wall thickness, and other information (see Figure 7).

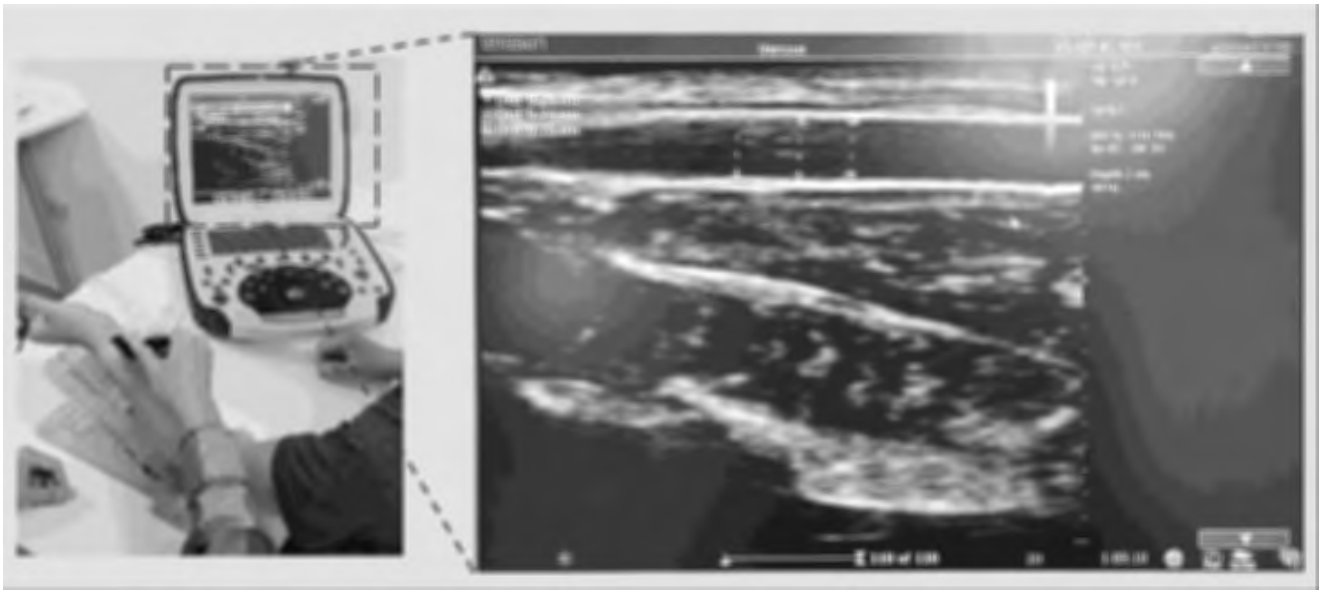


Figure 7. Ultrasound image acquisition of radial artery.

In near-infrared (NIR) tissue spectroscopy, the modified Beer–Lambert law is usually used to detect the mean path lengths of photons in tissue [45]. The optical information included by the tissue can be obtained through the transmission, absorption, and reflection of photons after moving in the tissue. The measurement technology of blood oxygen involves creating a regression model of the blood oxygen curve through the absorption ratio of hemoglobin and oxygenated hemoglobin for different wavelengths [46]. Monte Carlo (MC) simulations and animal experiments (using fresh porcine carotid arteries) have shown that changes in the PPG intensity relative to its mean value can be used to estimate the size of the absorbing medium [47]. The larger the arteries, the higher the absorption rate of the DC component of the PPG signal; thus, the lower the DC value. Additionally, the blood volume changes greatly when the pulse beats, and the amplitude of the AC component of the PPG signal increases. According to this principle, we can use Equation (12) to create a regression model to estimate arterial diameter by using the normalized PPG signal and the arterial dimensions of the ultrasound image. Since the change in end-diastolic diameter D_d is relative to the instantaneous diameter D and differs by less than 10% during a cardiac cycle [48], we use D_d to model the estimation of arterial dimensions. The volume change in the artery due to the pulse will make the intensity of the PPG signal have the highest level I_H and minimal level I_L changes (see Figure 8). The modified Beer–

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Lambert law can express the change in arterial dimensions and the relationship between I_H and I_L in Equations (13) and (14) [49] as $\alpha_{DC} = \varepsilon \cdot c$, where ε is the absorbance coefficient of human tissue and c is the tissue and the material concentration of blood. Here, d_{DC} is the DC component of the light path of photons in human tissue, including the optical properties of the scattering of each tissue layer due to different media. The product of the two contributes to the DC component of PPG. Additionally, I_0 is the initial light intensity. Since D_s and D_d represent changes in arteries with the cardiac cycle, through Equation (15), I_H and I_L can be expressed as a function of PPG signal to arterial change, while I_H and I_L can be expressed as a ratio (i.e., PIR). Therefore, we can express the systolic diameter D_s and end-diastolic diameter D_d of the artery using the formula of Equation (16) [50]. Thus, the normalized PIR signal and the characteristic parameter α create a regression model with the arterial change volume. Using this model, the subject's arterial change volume ΔD can be estimated. Notably, this study used the PPG signal and arterial compliance for regression modeling, with arterial parameters being measured between 2 and 6 cm above the styloid process of the patient's wrist [51].

$$PPG_{norm} = \frac{\ln(AC_\lambda)}{\ln(DC_\lambda)} \tag{12}$$

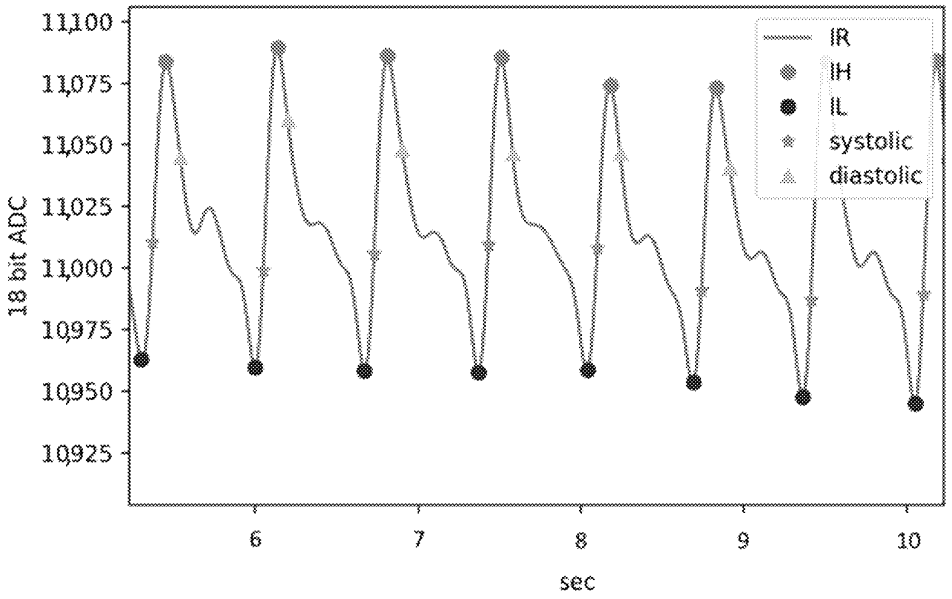


Figure 8. Volume change in the artery.

$$I_L = I_0 \cdot e^{-\alpha_{DC} \cdot d_{DC}} \cdot e^{-\alpha \cdot D_s} \tag{13}$$

$$I_H = I_0 \cdot e^{-\alpha_{DC} \cdot d_{DC}} \cdot e^{-\alpha \cdot D_d} \tag{14}$$

$$\Delta D = D_s - D_d = \frac{\ln(\frac{I_H}{I_L})}{\alpha} \tag{15}$$

$$PIR = \frac{I_H}{I_L} = e^{-\alpha \cdot \pi \cdot D \cdot (D_s - D_d)} \tag{16}$$

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2.3. Cuffless BP Model

According to the principle of hemodynamics, *PTT* can be obtained by measuring the pulse wave time difference between two points on the local artery, which can be expressed as Equation (17), where L is the distance of the sensor's position on the artery.

$$PWV = \frac{L}{PTT} \tag{17}$$

According to the Bramwell–Hill (BH) model [52], the pressure pulse in the artery will generate a local *PWV*, as in the following Equation (18):

$$PWV = \sqrt{\frac{V \cdot dP}{\rho \cdot dV}} \tag{18}$$

The modified BH model can be expressed as a function of the pulse pressure (PP) ΔP relative to the change in the arterial cross-sectional area. Here, V is the initial volume, ΔV and ΔP are the volume changes in the arterial segment for PP, and ρ is the blood density, typically using a whole blood density of 1.06 g/mL [53]. The BH model is derived from the MK equation [54]. The MK equations of Equations (19) and (20) describe the relationship between *PWV* and BP, where D is the diameter, h is the wall thickness or intima-media thickness (IMT), ρ is the whole blood density, E is Young's modulus, P is pressure, and E_0 and γ are coefficients of Young's modulus [55].

$$PWV = \sqrt{\frac{E \cdot h}{D \cdot \rho}} \tag{19}$$

$$E = E_0 \cdot \exp^{\xi \cdot P} \tag{20}$$

Based on Equation (21), we know that the pressure curve of Young's modulus and PWV are related to arterial compliance. We mathematically rewrite Equations (19) and (20) to obtain Equation (22), which can theoretically be directly calculated by the MK equation for B. Notably, P approximates mean arterial pressure (MAP) [56]. Here, ξ is a constant that depends on the particular vessel.

$$E = \frac{\rho \cdot D \cdot PWV^2}{h} \tag{21}$$

$$P = \frac{\ln(\frac{PWV^2 \cdot \rho \cdot D}{h \cdot E_0})}{\xi} \tag{22}$$

Since arterial parameters are not usually easy to measure, recent popular technical studies related to cuffless BP monitors have been based on the MK equation, which creates a regression model for the correlation between *PTT* and blood pressure [57–59]. This type of regression can take many changes in form (e.g., the parameters can be linear or non-linear). This paper uses a popular regression model, namely Equation (23) for performance comparison. Here, K_1, and K_2 is the regression coefficient.

$$P = K_1 \cdot \ln(PTT) + K_2 \tag{23}$$

To evaluate whether introducing arterial compliance into the cuffless BP estimation model can be more accurate than the regression-only approach, we had to use the P–β model based on hemodynamics [60]. The P–β model is derived from the MK equation

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and the BH model. This model relates PWV to ΔP. As in Equation (24), we can estimate the ΔP of the local artery [61] using the PWV, ΔD, D_d, and ρ (using 1.06 g/mL) (PP).

$$\Delta P = \rho \cdot PWV^2 \cdot (2\frac{\Delta D}{D_d} + (\frac{\Delta D}{D_d})^2) \tag{24}$$

The intra-arterial MAP can be estimated by Equation (25), where β is a constant that reflects the local arterial stiffness during a cardiac cycle, independent of changes in arterial pressure during the measurement cycle [62,63]. After obtaining MAP and PP through the P–β model, we can track the systolic BP (SBP) and diastolic BP (DBP) through the calculation method of Equation (26), where the coefficient k needs to be adjusted according to the results of the experiments. In this study, 0.76 was the value for k [64].

$$P = \frac{2 \cdot \rho \cdot PWV^2 \cdot D_d}{\beta D} \tag{25}$$

$$\begin{cases} DBP = MAP \cdot k \\ SBP = MAP + (1-k) \cdot DBP \end{cases} \tag{26}$$

3. Results and Discussion

3.1. Experiment Result

We experimented with 20 adult participants using the cuffless BP monitor proposed in this study. The cuffless BP monitor measured participants' PTT and arterial parameters for 25 s by using regression and P–β models for BP estimation, respectively. This comparative study followed ANSI/AAMI/ISO 81060-2:2018 [65]. We used the Welch Allyn 5098-27 DS66 trigger aneroid sphygmomanometer for reference BP measurement.

Figure 9 presents the two cuffless BP estimation models applied to the distribution of BP statistics of the same participants. The regression model has a more significant measurement dispersion, and the maximum value is also significantly higher than that of the P–β model.

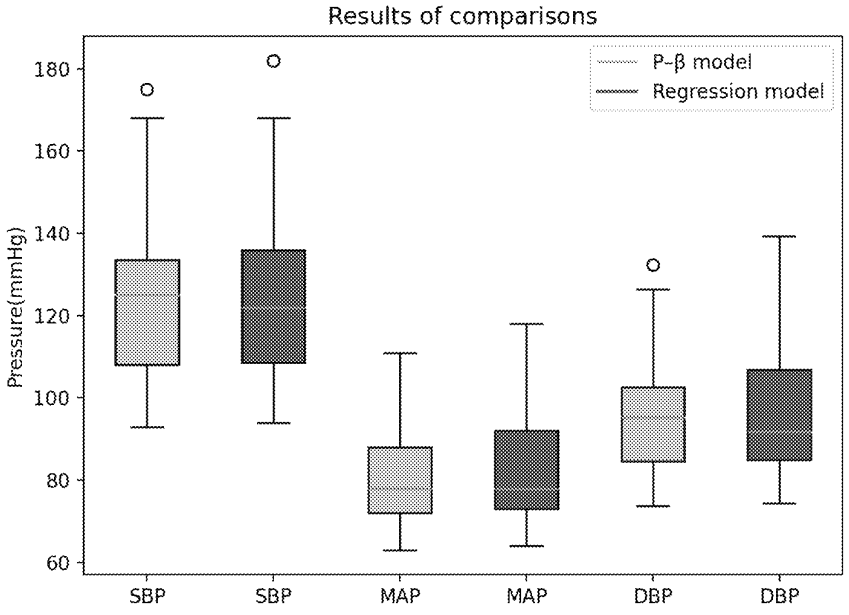


Figure 9. Distribution of BP statistics of the same participants.

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Based on the comparison of the Bland–Altman analysis of SBP (Figure 10), the results of the regression model method indicated a SBP of 0.32 ± 5.94. The results of the P–β model method (Figure 11) indicated an SBP of 0.75 ± 3.9.

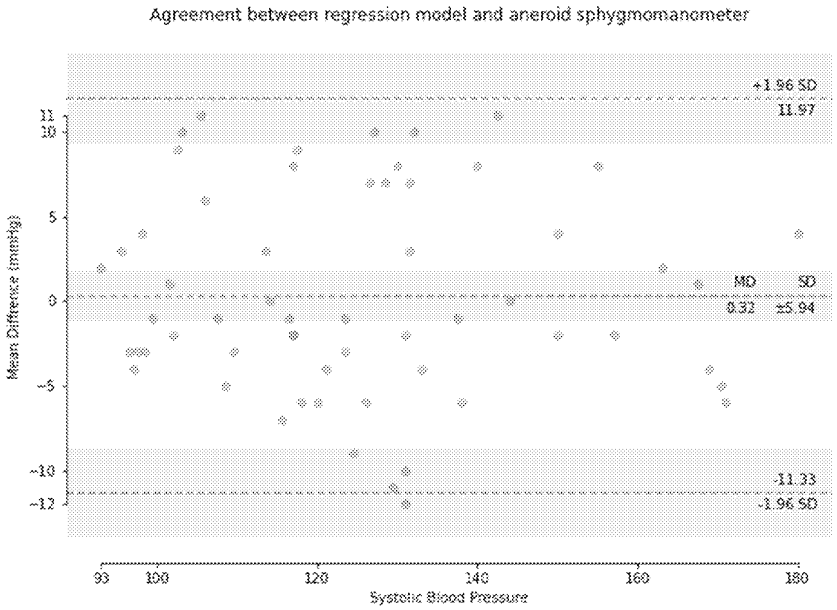


Figure 10. Results of the regression model method for the comparison of the Bland–Altman analysis of SBP.

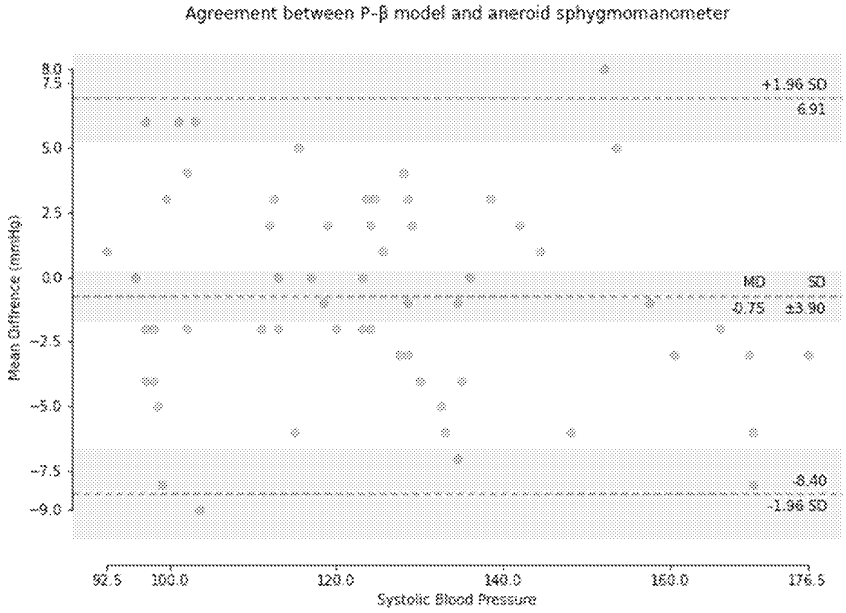


Figure 11. P–β model method for the comparison of the Bland–Altman analysis of SBP.

Based on the comparison of the Bland–Altman analysis of MAP (Figure 12), the results of the regression model method indicated a MAP of 1.55 ± 5.83. The results of the P–β model method (Figure 13) indicated a MAP of 0.49 ± 2.82.

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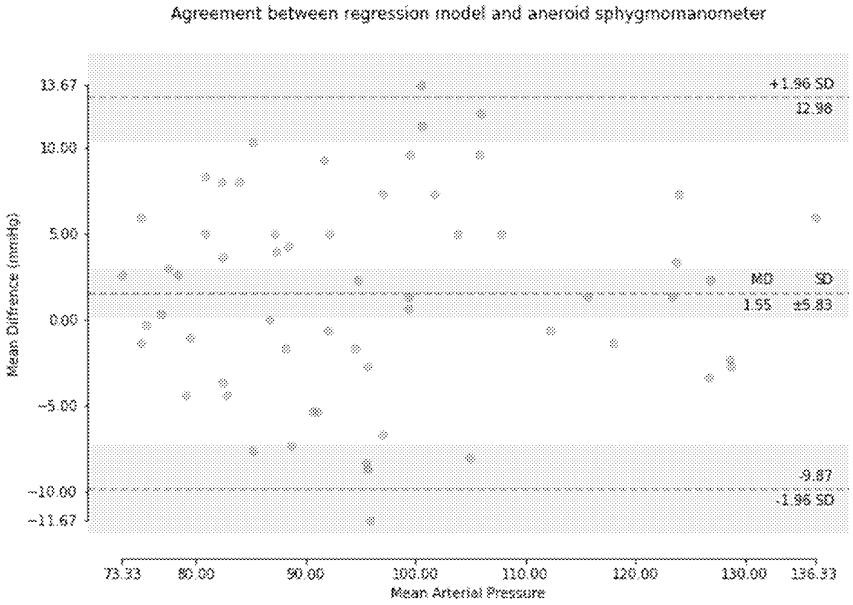


Figure 12. Results of the regression model method for the comparison of the Bland–Altman analysis of MAP.

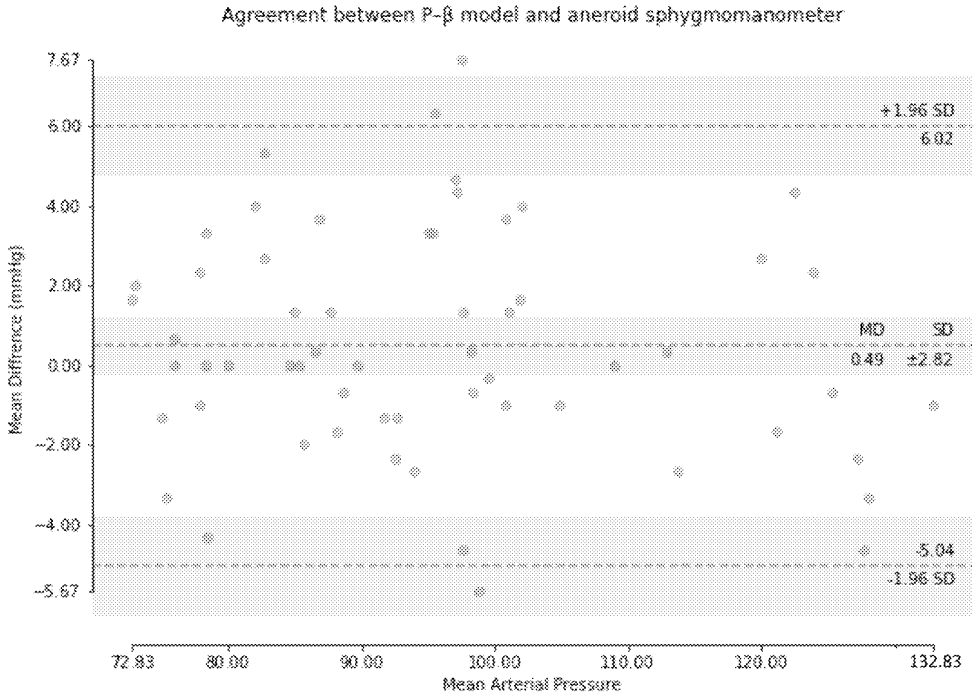


Figure 13. P–β model method for the comparison of the Bland–Altman analysis of MAP.

Based on the comparison of the Bland–Altman analysis of DBP (Figure 14), the results of the regression model method indicate a DBP of 2.17 ± 6.22. The results of the P–β model method (Figure 15) indicate a DBP of 1.1 ± 3.12. According to the results, it was found that the dispersion of BP values estimated by the regression model is greater than that of the P–β model. The SBP value deviation is slightly greater than ±2 SD, while those of the MAP and DBP values are slightly greater than ±3 SD. Additionally, the error mean of the BP estimation for the P–β model is smaller than that of the regression model. As in

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Table 1, the cuffless blood pressure monitor which can pass the measurement performance requirements of criterion 1 and 2 of ANSI/AAMI/ISO 81060-2:2018. Moreover, using the P–β model is better than using the current popular regression model methods since it is more concentrated and accurate. According to the Pearson Correlation analysis, as shown in Figures 16–18, the r value of SBP and MAP is 0.98, and the DBP is 0.97, indicating that the data sets are equal or very close to it.

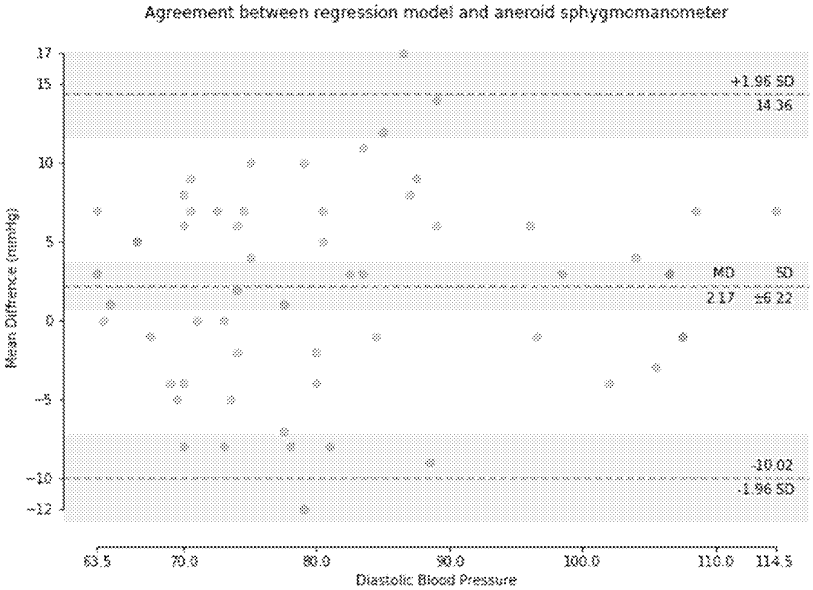


Figure 14. Results of the regression model method for the comparison of the Bland–Altman analysis of DBP.

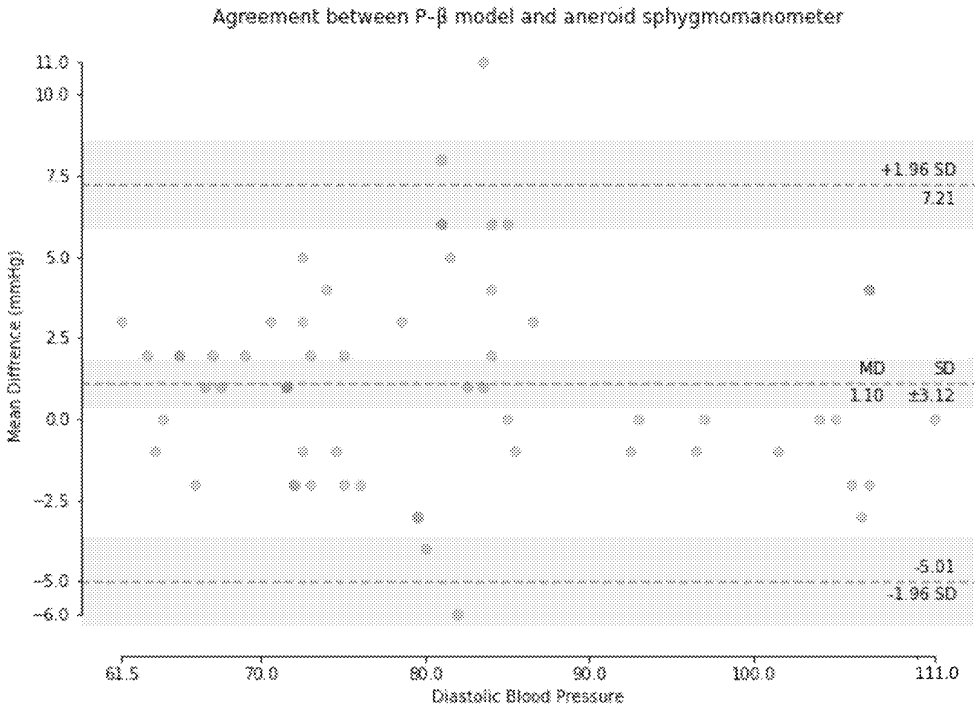


Figure 15. P–β model method for the comparison of the Bland–Altman analysis of DBP.

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Table 1. Validation study results of P–β model method.

	Pass Requirements	Achieved		
		SBP	***DBP***	***MAP***
Criterion 1				
Means (mmHg)	≤5	0.75	0.49	1.10
SD (mmHg)	≤8	3.90	2.82	3.12
Results		**pass**	**pass**	**pass**
Criterion 2				
SD (mmHg)	≤6.89/6.92/6.86	3.71	2.67	2.91
Results		**pass**	**pass**	**pass**
Results			**pass**	

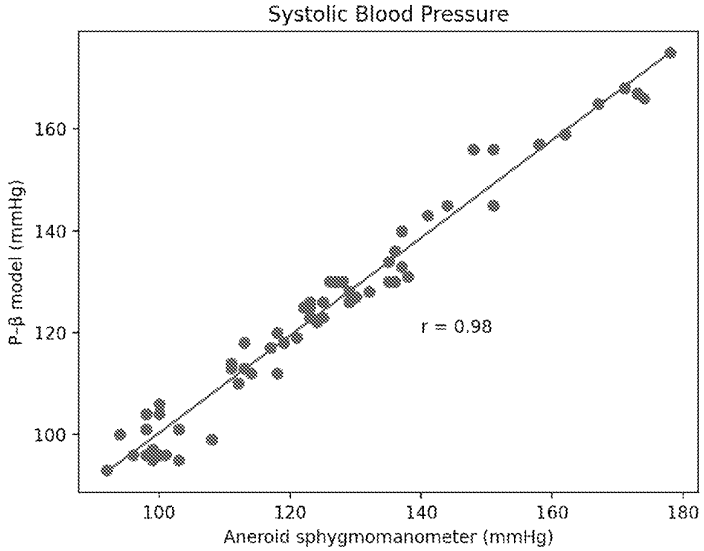


Figure 16. Pearson Correlation of SBP.

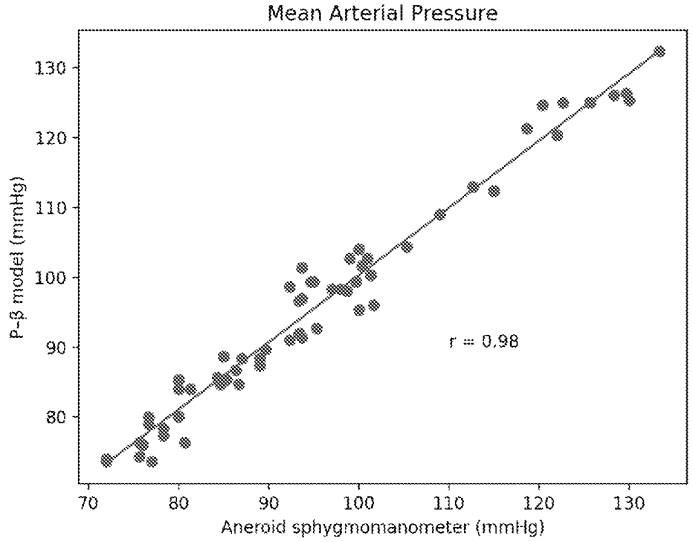


Figure 17. Pearson Correlation of MAP.

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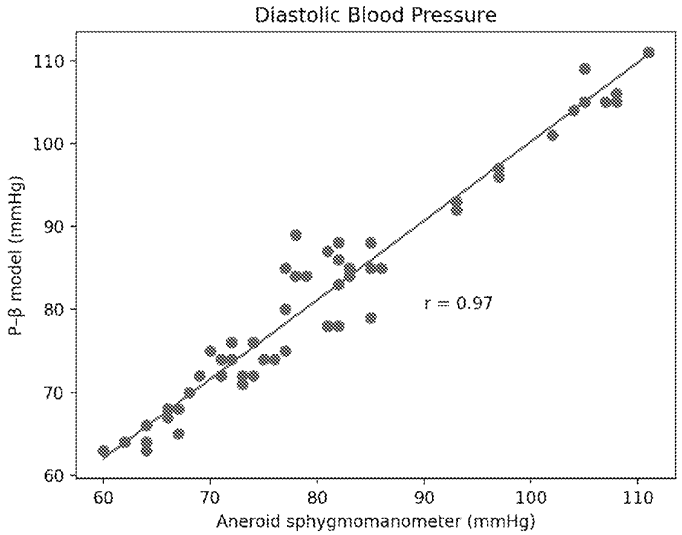


Figure 18. Pearson Correlation of DBP.

3.2. Limitations and Future Works

Although a method of measuring arterial parameters using piezoelectric sensors combined with optical sensors is proposed, we also compared the current popular cuffless BP measurement regression model and the P–β model. Our results indicate that the P–β model introduces arterial compliance for calculation, while the accuracy of BP estimation is greater than that of the regression model. However, there are still some limitations that require further research and improvement. The piezoelectric sensor measures the PTT of the local arteries, and the error is amplified when converted to PWV due to the short distance, which may lead to errors. Therefore, in practice, we must take the median of the PTT in the measurement period as the representative parameter of the BP estimation. In the future, to achieve beat-to-beat BP measurement, the design of the mechanical structure must be improved to reduce the measurement error, which will make the beat-to-beat BP measurement possible. To be able to use the P–β model to estimate BP, we used the PIR technology of the PPG sensor to quantify the arterial parameter. However, at present, we must use an ultrasound imaging device to determine the patient's arterial depth to ensure the depth range that the PPG sensor can measure in the patient's artery. Moreover, future research should include more patients with different tissue characteristics, such as those with a BMI greater than 40 and those who have more adipose tissue (resulting in greater arterial depth).

4. Conclusions

This study involved designing and implementing a cuffless BP monitor combining piezoelectric and optical sensors. Here, we compared the performance of two BP estimation models, namely the popular regression model and the P–β model. According to the results, we verify that the P–β model introduces arterial compliance in BP estimate and is more accurate than the regression model in terms of the accuracy of BP estimation. Notably, it also passes the ANSI/AAMI/ISO 81060-2:2018 performance indicators. In addition to its small size and low cost, our proposed cuffless BP monitor also uses more physiological parameters for BP estimation, thereby improving accuracy. Compared to most studies of cuffless technology, our system design can be integrated into wearable devices or applied in certain BP monitoring scenarios involving small spaces. Additionally, in comparison to traditional BP monitoring approaches, our design is easier and more comfortable to use, which can result in improved patient BP monitoring compliance while making the diagnosis of hypertension more reliable.

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TEST REPORT
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

Report Number. .....:	(b)(4)
Tested by.....:	(b)(4)
Approved by .....:	
Date of issue .....:	
Total number of pages	27
Testing Laboratory.....:	(b)(4)
Address 1 .....:	
Applicant's name.....:	
Address .....:	
Test specification:	
Standard.....:	IEC 60601-1-11:2015 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012 EN 60601-1-11:2015 ANSI/AAMI HA60601-1-11:2015
Test procedure .....:	V.o.C Scheme
Non-standard test method.....:	N/A
Test Report Form No.....:	(b)(4)
Test Report Form Originator .....:	
Master TRF .....:	

(b)(4)

Test item description ..... :	Accurate 24 Non-invasive blood pressure monitor
Trade Mark .....:	Accurate 24
Manufacturer .....:	Accurate Meditech Inc.
Model/Type reference .....:	Accurate 24_BPM
Ratings .....:	(b)(4)

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Report Number: (b)(4)

Skin Sensitization Test of Reusable Blood Pressure Cuff Using ISO 10993-10:2010 Test Methods Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract

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

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Accurate Meditech Inc.

Document name: Accurate 24 BPM EMC Testing for Specific RF Emitters Test Report

Document Number: (b)(4)

Presented by
Falcao Chang

Approved By (b)(6)
Kuan Jen, Wang (General Manager)

Date 2023-04-18

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

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Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

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

[cid:image003.png@01D988AB.566B0660]<http://www.fda.gov/>

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[cid:image005.jpg@01D988AB.566B0660] <https://twitter.com/US_FDA>
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From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Cc: (b)(6) k222658@docs.fda.gov

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was

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sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

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

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Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

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To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

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If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

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Impact of Premature Atrial Contractions in Atrial Fibrillation

THOMAS J. JENSEN,* JENS HAARBO,* STEEN M. PEHRSON,§ and BLOCH THOMSEN*

From the *Department of Cardiology, Gentofte University Hospital, Copenhagen, and the §Department of Cardiology, Rigshospitalet, Copenhagen, Denmark

JENSEN, T.J., ET AL.: Impact of Premature Atrial Contractions in Atrial Fibrillation. *In spite of the increasing knowledge about paroxysmal atrial fibrillation (PAF), details on mode of initiation in unselected patients are scarce. This paper focuses on trigger mechanisms of spontaneous onset of AF in consecutive patients with PAF. One hundred eight consecutive patients with two or more ECG documented AF episodes within the previous year had a 24-hours Holter recording performed. All AF episodes (n = 157) were reviewed and, within the last 10 beats prior to AF initiation. PP intervals were measured on 25 mm/s paper printouts and premature atrial contractions (PACs) were counted. Additionally, randomly selected coupling intervals (PP′) for PACs not triggering AF were measured and compared to AF triggering intervals and to PP′ intervals from healthy controls. PACs preceded all AF episodes. AF initiation displayed a wide variety in terms of PP coupling intervals and number of PACs prior to initiation within and between subjects. In episodes with PACs within the last 10 beats prior to initiation, we observed a long-short PP sequence at the time of initiation. Mean PP′ interval (± SE) for AF triggering PACs was 403 ± 9 ms, significantly shorter, P < 0.0001, than PP′ for nontriggering PACs (584 ± 8 ms) and PACs in healthy controls (589 ± 6 ms). However, a large proportion of nontriggering PACs had short PP′ coupling intervals without triggering AF. These observations highlight the importance of other factors than the trigger per se, such as the arrhythmogenic substrate, and suggest that therapeutic maneuvers aimed at curing PAF should target these as well as the trigger mechanisms. (PACE 2004; 27:447–452)*

atrial fibrillation, PAC, onset

Introduction

Atrial fibrillation (AF) is the most common tachyarrhythmia encountered. Cross-sectional population studies report that the prevalence increases with age, ranging from less than 1% in those under 60 years of age, to higher than 6% in those older than 80 years. It has been estimated that about 2.2 million Americans have AF either in the paroxysmal or persistent form. The arrhythmia is associated with increased morbidity and mortality.[1–10]

The paroxysmal form of AF may be particularly difficult to manage, primarily due to frequent recurrence of episodes despite aggressive therapy with one or more antiarrhythmic agents. Premature atrial contractions, which may lead to AF when occurring in the atrial vulnerable period, are frequent in some patients with paroxysmal AF and are therefore among the principal suspects when causes of attacks are sought. In these patients various new treatment modalities may be justified, such as radiofrequency ablation (RFA) [11,12] or pacing with various algorithms.[13] The basic concept in RFA-based therapy is to eliminate or isolate the foci responsible for spontaneous ectopic activity that may lead to AF. 'Smart' pacemakers rely on the concept that in an appropriately paced atrium, ectopic activity may be suppressed and the atria will be less vulnerable to ectopic activity, should it occur.

In order to eliminate or prevent triggering factors, a thorough knowledge about their nature is mandatory. The present study describes important aspects of the triggering mechanism, such as the coupling intervals of PACs (PP′) eliciting AF compared to innocent PP′ intervals in the same patients as well as in healthy controls.

Methods and Materials

Study Subjects

We prospectively screened all patients admitted to the department or seen in the outpatient clinic from June 1, 2000 to March 12, 2001 (n = 7,447) as described in detail elsewhere.[14] Briefly, all patients with at least two documented spontaneous attacks of AF within the last year, not ascribable to any obvious precipitating event, were asked to have a 24-hour Holter recording performed. One hundred-eight recordings were performed in such patients of which 19 had AF documented during the recording. One recording was excluded

Financial support from Medtronic-Vicare, Denmark and The Kai Houmann Nielsen Foundation is gratefully acknowledged.

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Received April 15, 2003; revised September 22, 2003; accepted October 16, 2003.

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because of incessant ectopic atrial rhythm interrupted by brief periods with sinus rhythm (SR) and AF. Thus, 157 episodes of AF were documented in 18 patients (range 1–57 episodes per recording). In addition, 30 recordings from healthy, sex- and age- matched controls were obtained. This paper reports the findings in the 18 patients with AF on the recording and in 30 healthy, age-matched controls.

Holter Recordings

A commercially available Holter system was used, the Reynolds Pathfinder 700 (Reynolds Medical Ltd., Hertford, UK), version 8.105 analysis station and Tracker III analogue tape recorders. We used a setup with three orthogonal, bipolar leads, corresponding roughly to standard leads I, aVF and V_1, respectively. A premature atrial contraction (PAC) was defined when the RR interval of a supraventricular beat was shorter than 75% of the running mean of the previous 30 beats classified as normal. AF was defined as five or more consecutive beats with irregular RR intervals and fibrillatory wavelets or no discernable P wave. There was no limit of the duration of sinus rhythm prior to an AF episode. Five or more consecutive, conducted atrial ectopics were considered to be an episode of ectopic rhythm and only the first beat contributed to the number of PACs.

Time of onset and duration of each episode were noted. All PP and PP′ intervals were measured from the earliest to earliest identifiable atrial deflection in the same lead, using the lead with the most clearly defined P wave (Fig. 1). The last ten PP intervals prior to AF initiation were measured on 25 mm/s print-outs and the number of PACs within the last ten beats counted. The PP′ intervals initiating AF were measured, and compared to 12 randomly chosen (first PAC in every second hour) PP′ intervals that did not initiate AF in the same patient. Twelve randomly chosen PP′ intervals (first PAC in every second hour) were measured from each recording in the group of healthy controls for comparison. Measurement of ten PP intervals prior to AF initiation was possible for 1,377 intervals. The remainder PP intervals were not measured either due to immediate relapse into AF or artefacts. PP′ intervals initiating AF were analyzable in 136 of 157 episodes; intervals not initiating AF were analyzable in 198 of 216 cases. In the healthy control group, 297 of 360 intervals were analyzable. No AF episodes were observed in the control group.

Additionally, all RR coupling intervals of PACs (RR′) were extracted from the recordings as a surrogate parameter for PP′, and comparison between patients and healthy controls was performed.

A number of PP′ intervals (n = 49) were remeasured to assess precision of measurement (one investigator) and we found a coefficient of variation of the duplicate measurements of 2%.

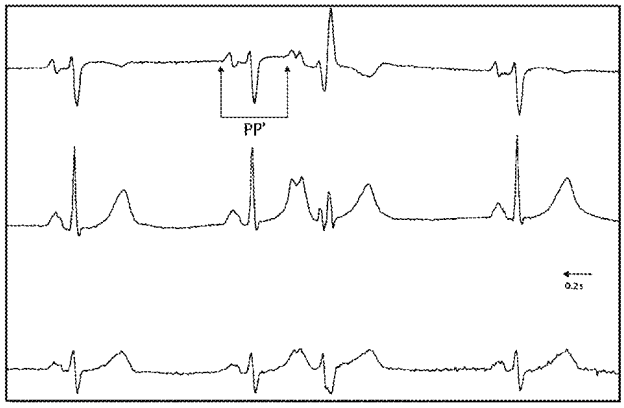


Figure 1. *ECG Holter recording illustrating the PP′ interval from sinus P to P′ of a PAC. Tracings are leads Z, Y, and X from top to bottom.*

Statistics

The Statistical software package JMP version 5 from SAS Institute was used. A significance level of 0.05 was used. Standard parametric statistical methods were used, if necessary after log-transformation of data that exhibited nongaussian distribution.[15] Due to the unbalanced data with different numbers of measurements for each patient, modeling was also performed using a mixed model treating the patients as a random effect. This yielded virtually the same results with regard to PP′ mean values, with slightly higher values for triggering PACs.

Results

There was no significant difference in mean age or sex distribution between patients and controls, but the patients had significantly more PACs than the control subjects (Table I). All analyzable AF episodes started after a PAC. The mean PP′ interval for PACs triggering AF was significantly shorter than for nontriggering PACs in PAF patients (403 ± 9 ms vs 584 ± 8 ms (mean ± SE), $P < 0.0001$, Fig. 2). Approximately 10% of nontriggering intervals were shorter than the median PP′ interval for triggering PACs. Nontriggering PP′ coupling intervals were not different from PP′ in healthy age-matched controls, 584 ± 8 ms vs 589 ± 6 ms (mean ± SE), $P = 0.6$. Patients with lone AF did not differ significantly from those with concomitant disease with regard to PP′ coupling interval (data not shown).

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Table I.

	Patients (N = 18)	Controls (N = 30)	Statistic
Age (years)	65 (60–72)	66 (61–71)	NS
Female	39% (20–51)	33% (19–51)	NS
Lone AF	41% (22–64)		
Hypertension	39% (20–61)		
IHD	17% (5.8–39)		
HF	33% (16–56)		
BMI (kg/m^2)	26.8 (25.2–28.4)	23.9 (22.7–25.2)	P < 0.01
LAD, (mm)	41.9 (39.5–44.3)	37.3 (35.6–39.1)	P < 0.01
LVEF	0.55 (0.52–0.59)	>0.55	NS
Episodes (N = 157)	8.7 (4.4–13.1)	0	
Episode duration (s)	534 (105–2731)	0	
#PACs/24 hr record	300 (135–661)	68 (36–126)	P < 0.01
P duration, lead V_2 (ms)*	99 (90–109)	101 (94–109)	NS
PQ, lead II (ms)*	173 (161–184)	164 (155–174)	NS

Values are means with 95% CI for continuous variable, and percentages with 95% CI for categorical variables. IHD = Ischemic heart disease; HF = Heart failure; BMI = Body mass index; LAD = Left atrial diameter; LVEF = Left ventricular ejection fraction. * = Measured at hook-up time on standard ECG recording, paper speed 50 mm/s.

Figure 3, top panel, visualizes the mean PP intervals for the 10 beats prior to AF initiation. In episodes with several PACs within these last 10 beats (59% of episodes), we found that the mean PP interval was significantly longer for the beat just prior to the initiating beat, (P < 0.001), corresponding to a long-short PP sequence prior to AF initiation. Episodes with only one PAC within the last 10 beats exhibited no significant change in mean PP intervals over the 10 preceding beats. There was no consistent pattern within the same patient with regard to presence of or number of PACs in the preinitiation PP intervals. Figure 3, bottom panel, illustrates the diversity of onset in a single patient.

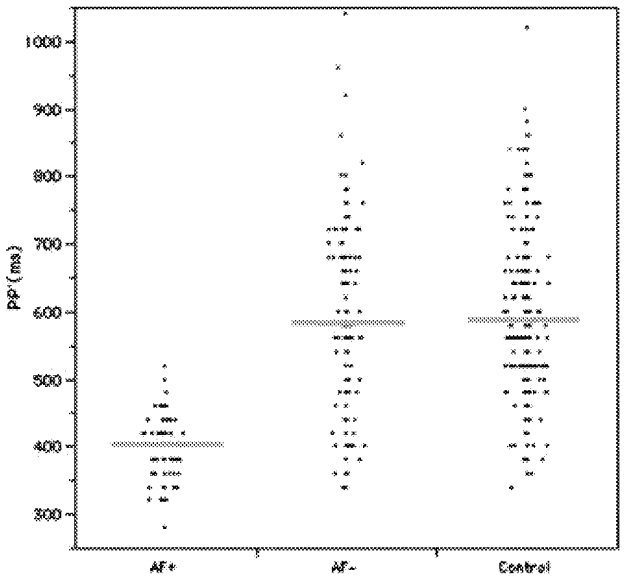


Figure 2. *PP′ coupling intervals for PACs in patients that triggered (AF+), did not (AF–) trigger AF, and for controls. Bars indicate group means.*

The distribution of episodes with regard to duration showed that the 42% of episodes lasted less than 30 seconds, 40% between 30 seconds and 5 minutes, 11% between 5 minutes and 1 hour, and 7% lasted more than 1 hour. The duration of preceding time in SR (for recordings with two or more AF episodes) showed that 26% of episodes occurred within 30 seconds of SR, 51% after more than 30 seconds but less than 5 minutes, 12% after more than 5 minutes but less than 1 hour, and the remainder 12% after more than 1 hour in SR.

There was no significant correlation between RR′ and PP′ for PACs triggering AF (R^2 = 0.01, P = 0.24, n = 136), but for nontriggering PACs the RR′ intervals correlated well with PP′ intervals (R^2 = 0.84, P < 0.0001, n = 495), the PP′ intervals being significantly shorter than the corresponding RR′ intervals, mean 21 ms, P < 0.0001.

When a total of 37,755 RR′ intervals for nontriggering PACs was analyzed, we found no significant difference in the mean RR′ intervals between PAF patients and controls (627 ± 25 ms ± SE ms vs 623 ± 26 ms [mean ± SE], P = 0.9). We computed the positive predictive value of a short PP′ interval predicting AF for different values dichotomizing all intervals into short and long

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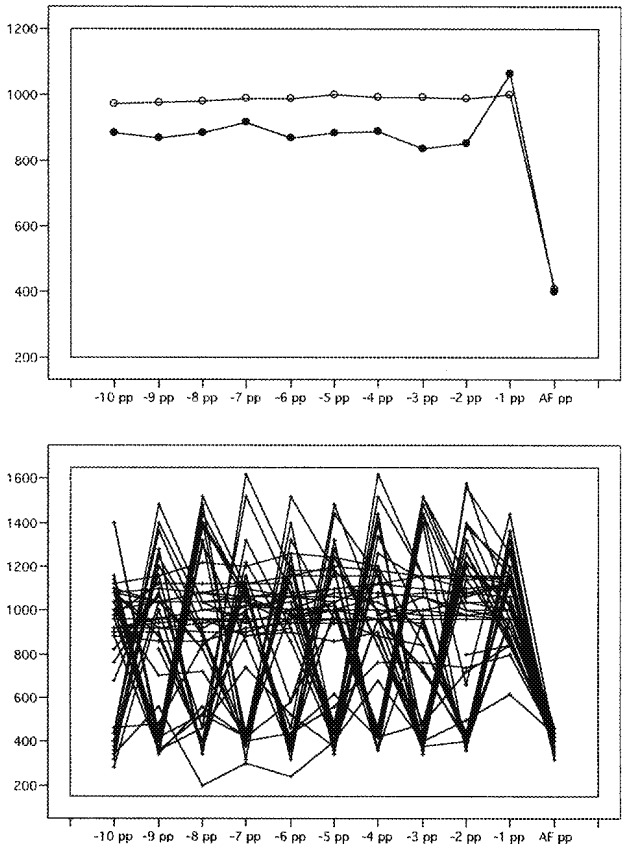


Figure 3. *(Top panel) Mean PP coupling intervals in ms (ordinate) for the beat that triggers AF and the ten previous beats (abscissa). Episodes with (•) (n = 80) and without (○) PACs (n = 56) in the previous ten beats. (Bottom panel) PP coupling intervals in ms for ten beats prior to the ectopic beat eliciting AF for 42 episodes in one patient illustrating the diversity of onset. (See text for further explanation.)*

intervals (using PP′ intervals for PACs triggering AF and corrected (subtracting 21 ms) RR′ intervals for nontriggering PACs). The probabilities thus computed were 2.5%, 2.6%, 1.0%, 0.7%, and 0.6% at values <350 ms, <400 ms, <450 ms, <500 ms, and <550 ms, respectively.

Discussion

In the present study, we describe PP coupling intervals prior to AF initiation and PP′ coupling intervals of premature atrial contractions in PAF patients compared to healthy, age- and sex-matched controls. This is the first time, to our knowledge, that direct measurement of consecutive PP coupling intervals prior to spontaneous AF initiation has been performed in a representative AF population and compared to healthy controls. The AF episodes described in the present study comprise the entire number of episodes obtained in a 24-hours recording in a series of 108 consecutively included AF patients who are representative of the general population suffering from PAF. The 18 patients that had AF episodes on Holter recording did not differ significantly with regard to age, sex, concomitant diseases, number of PACs, or number of previous AF episodes from those without AF on the recording. The conclusions from the present paper are thus likely to be valid for the general PAF patient. The number of individuals in our study is, however, limited and caution is appropriate.

The duration of AF episodes considered for evaluation differs in the literature. In many publications the authors choose to consider only AF episodes longer than 30 seconds, and often restrictions as to the period preceding AF episodes are applied.[16,17] Others have chosen to include episodes of even shorter duration, e.g., three or more ventricular cycles.[18] In the recent joint ACC/AHA/ESC practice guidelines for management of atrial fibrillation,[4] a duration of 30 seconds or more is implied. As our focus was on the initiation of AF we chose to include episodes of very short duration and we did not require more than a single sinus beat prior to the episode. Excluding episodes shorter than 30 seconds did not, however, change our conclusions. Similarly, the duration of sinus rhythm prior to AF initiation did not influence the coupling interval of the triggering beat.

All analyzable AF episodes were triggered by a PAC. This has previously been described in the setting of early reinitiation of AF after external and internal DC cardioversion and in postmyocardial infarction patients.[19–21] Consistent with findings in patients with lone AF,[22] the mean coupling interval of trigger PACs was shorter than in nontriggering PACs. A mean PP′ interval of approximately 400 ms will have the P wave occurring on the T wave; this "P-on-T pattern" has been observed in AF-triggering PACs originating from the pulmonary veins.[23,24] However, the overwhelming majority of PACs do not lead to AF, at least not immediately, even though a substantial number of nontriggering PACs have a short coupling interval. Our study population exhibited a total of 35,114 PACs, yet only 157 episodes of AF were documented. Thus, the probability that any one PAC leads to AF is overall about 0.4%, restricting PACs to only those shorter than 350 ms would increase this probability to 2.5%. On average, patients did have more frequent PACs than healthy controls, but their coupling intervals were not shorter. The occurrence of AF in patients, as opposed to the complete absence of AF in the control group, could be explained by the atria being less resistant to arrhythmia-provoking factors in patients with PAF. Obviously, the presence of a trigger factor is not sufficient for the arrhythmia to occur.

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When the last 10 PP intervals prior to AF were measured, it is interesting to notice that more than one PAC preceded 59% of episodes. Furthermore, AF was elicited by a PAC with short mean coupling interval preceded by a PP mean coupling interval that was significantly longer than the previous nine PP mean intervals. The presence of PACs increases the dispersion of refractoriness and thereby the risk that a critically timed PAC or train of impulses, e.g., from the pulmonary veins or other foci, actually leads to AF. In the remainder, there was no change in mean PP intervals prior to the initiating PAC. The long-short sequence observed in our series is consistent with observations in ventricular tachycardia and fibrillation where a similar (short-long-short) pattern has been reported.[25] Recently, Grönefeld et al.[26] reported the results of applying a dedicated rate stabilizing algorithm in ICD patients. They found no significant decrease in occurrence of ventricular arrhythmias. Of note, they observed a nonuniform pattern of initiation in patients with multiple episodes. Obviously, translation of these observations to patients with AF is not straight forward, given the anatomic and physiological differences between ventricular and atrial myocardium. Hnatkova et al.[17] analyzed the three last intervals prior to AF onset and found a normal-normal-short sequence to be present in 54% of episodes and a short-long-short sequence in about 10%, using RR intervals. Inherently, no information regarding PP coupling intervals was available from their study. In contrast, Lu et al.[27] found that 53% of episodes were preceded by PACs and oscillations in coupling intervals in highly symptomatic patients referred for ablation. These episodes were induced in the laboratory and the coupling intervals obtained from intracardiac recordings were much shorter than those we have obtained from surface recordings. The data illustrate the difficulties faced when applying therapies that try to suppress PACs and thereby prevent AF. It is very difficult to extinguish all PACs, and even a few seem to be enough to initiate an AF episode. Many episodes start with an unheralded PAC, and thus monitoring PP intervals as some "smart" pacemakers do, is also likely to be largely inefficient. Pacemakers may influence PAF by way of rate control, i.e., hindering bradycardia and related dispersion of refractoriness, by suppression of ectopic automatic foci by overdrive pacing using algorithms to ensure high degree of atrial pacing, without inappropriately high pacing rates. The mean PP′ coupling interval for PACs initiating AF was 403 ms regardless of presence of PACs in the previous ten beats; simply increasing the lower limit of pacing rate would be impractical. Furthermore, elimination of post-PAC compensatory pauses that may increase dispersion of refractoriness could reduce AF burden and, finally, multisite pacing may overcome the problem of functional conduction block and decrease the risk of macroreentry occurrence.[28] Wijffels et al.[29] coined the phrase "Atrial fibrillation begets atrial fibrillation" and suggested that the reverse may hold true as well; any therapy that significantly reduces AF burden may contribute to electrical remodeling that renders the atria less susceptible to enter fibrillation. A substantial fraction of the episodes in the present series occurred shortly after the previous episode ended, supporting the concept of increased vulnerability after a period in fibrillation. Comparing PP′ and RR′ intervals for beats that do not trigger AF showed that the RR′ interval is indeed useful as a surrogate parameter for PP′, the former being consistently longer. This could well be explained by delayed conduction in the atria for impulses originating in ectopic foci and by the AV node being still in the relative refractory period. PP′ and RR′ intervals for PAC eliciting AF did not display the same relation. There was no statistically significant correlation between PP′ and RR′ for AF-initiating beats, a finding most likely explained by a variable degree of delay in the AV conduction during fibrillation. The diversity of onset modes across and within patients (Fig. 3, bottom panel), as well as the similarity of PAC coupling intervals between patients and controls, and the huge number of PACs, even with short PP′, that do not trigger AF, call for a strategy that takes into account the arrhythmogenic substrate as well as the possible trigger suppression or elimination.

Conclusion

The present study demonstrates that a PAC preceded all spontaneous AF episodes in patients and that these PACs had a shorter mean PP′ coupling interval than nontriggering PACs or those in healthy controls, however, the overwhelming majority of PACs did not trigger AF. In the presence of several PACs within the last 10 beats prior to AF, a long-short sequence was observed immediately prior to the arrhythmia initiation.

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Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines and Policy Conferences (Committee to Develop Guidelines for the Management of Patients With Atrial Fibrillation): Developed in Collaboration With the North American Society of Pacing and Electrophysiology. J Am Coll Cardiol 2001; 38:1231–1266.
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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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Report Number: (b)(4)

In Vitro Cytotoxicity Test of Reusable Blood Pressure cuff using ISO 10993-5:2009 Test Method MTT Method MEM with 10% FBS extract

(b)(4)

(b)(4)

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

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

June 21, 2023

Accurate Meditech Inc.
Wang Kuan-Jen
General Manager
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.,
New Taipei City, 241406
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 15, 2023
Received: May 15, 2023

Dear Wang Kuan-Jen:

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.

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 2023-10915; Released by CDRH on 07-09-2024

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. 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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

(b)(4)

(b)(4)

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QUALITY TEST REPORT

(b)(4)

(b)(4)

(b)(4)

(b)(4)

TEST ITEM	UNIT	TEST METHOD	SPECIFICATION	RESULTS
(b)(4)				

(b)(4)

APPROVED BY: (b)(4)

(b)(4)

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

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(b)(4)

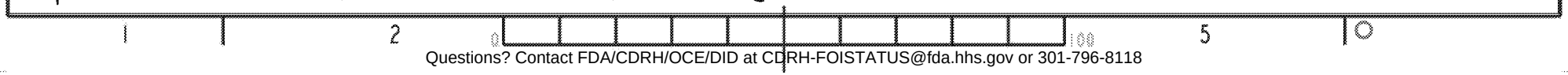
(b)(4)

Product name :

Accurate 24 Non-invasive blood pressure monitor

Accurate Meditech Inc.

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail : info@accurate-meditech.com



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

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Accurate Meditech Inc.-May 2023 Response

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(b)(4)

In Vitro Cytotoxicity Test

(b)(4)

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

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

(b)(4)

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(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6); k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

> On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:
>
> Hi Doug,
>
> We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.
>
> Thanks,
> Meaghan
>
> ---
>
> **From:** (b)(6)
> **Sent:** Wednesday, May 10, 2023 10:06 PM
> **To:** Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> **Cc:** k222658@docs.fda.gov
> **Subject:** RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> 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 Megan,
>
> One last email. I verified that the emails sent include all of the files sent with the original response S002.
>
> Best
> Doug
>
> Herrington Consulting LLC
> Douglas Herrington
> Principal Consultant
>
> ---
>
> **From:** Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> **Sent:** Wednesday, May 10, 2023 8:20 PM
> **To:** (b)(6)
> **Cc:** k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> **Subject:** RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> Hi Doug,
>
> Can you respond to this email with the full response submitted to the DCC for K222658/S002?
>
> Thanks,
> Meaghan
>
> ---
>
> **From:** (b)(6)
> **Sent:** Wednesday, May 10, 2023 1:42 AM

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

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Accurate Meditech Inc.-June 9 2023, Response

(b)(4)

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Description of sensor characteristics

Document Number: (b)(4)
Version: (b)(4)
2022/08/08

Presented by
Falcao/Firmware Manager

Approved By (b)(6) *Date* 2022-08-08

***Kuan Jen, Wang* (General Manager)**

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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Dear Applicant,

Please refer to the attached addendum for details on the correction.

Best regards,

Edwena R. Jones

Program Analyst

Premarket Notification (510(k))

Division of Regulatory Programs |Office of Regulatory Programs

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 1623 |10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-6308

edwena.jones@fda.hhs.gov<mailto:edwena.jones@fda.hhs.gov>

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: IEC 62304 Evaluation Report

Document Number: (b)(4)
Version: (b)(4)
2021/07/26

Presented by
Falcao/Firmware Manager

Approved By (b)(6) *Date* 2021-07-26

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6) k222658@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

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

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ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov> ; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

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

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Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov
<mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov
<mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

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If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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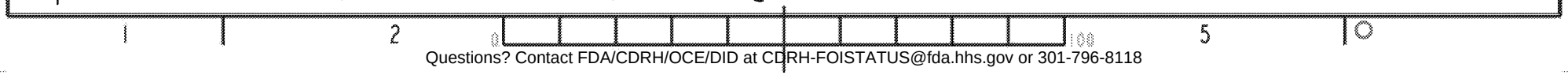
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(b)(4)

(b)(4)	Product name : Accurate 24 Non-invasive blood pressure monitor
	Accurate Meditech Inc.

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail : info@accurate-meditech.com



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SCIENTIFIC REPORTS

OPEN

Pulse Transit Time Based Continuous Cuffless Blood Pressure Estimation: A New Extension and A Comprehensive Evaluation

Received: 9 May 2017
Accepted: 25 August 2017
Published online: 14 September 2017

Xiaorong Ding[1], Bryan P. Yan[2], Yuan-Ting Zhang[1,3], Jing Liu[1], Ni Zhao[1] & Hon Ki Tsang[1]

Cuffless technique enables continuous blood pressure (BP) measurement in an unobtrusive manner, and thus has the potential to revolutionize the conventional cuff-based approaches. This study extends the pulse transit time (PTT) based cuffless BP measurement method by introducing a new indicator – the photoplethysmogram (PPG) intensity ratio (PIR). The performance of the models with PTT and PIR was comprehensively evaluated in comparison with six models that are based on sole PTT. The validation conducted on 33 subjects with and without hypertension, at rest and under various maneuvers with induced BP changes, and over an extended calibration interval, respectively. The results showed that, comparing to the PTT models, the proposed methods achieved better accuracy on each subject group at rest state and over 24 hours calibration interval. Although the BP estimation errors under dynamic maneuvers and over extended calibration interval were significantly increased for all methods, the proposed methods still outperformed the compared methods in the latter situation. These findings suggest that additional BP-related indicator other than PTT has added value for improving the accuracy of cuffless BP measurement. This study also offers insights into future research in cuffless BP measurement for tracking dynamic BP changes and over extended periods of time.

Cardiovascular disease (CVD) is the leading cause of death globally, with stroke being the second biggest contributor. Both types of diseases are associated with poor prognosis, increased mortality and heavy burden on the health care. Hypertension remains the single most important modifiable risk factor for both CVD and stroke, and it is well recognized that the adverse cardiovascular consequences largely depend on high blood pressure (BP) levels[1]. In addition to absolute BP values, evidence from observational studies and post-hoc analysis of data from clinical trials indicates that these outcomes could also depend on increased BP variability (BPV)[2]. Increased short-term and long-term BPV are associated with the development, progression, and severity of cardiac, vascular, and renal damage and with a high risk of cardiovascular events and mortality. It is therefore crucial to minimize the risk by monitoring the changes of BP and maintaining control in the early stage.

The current most common noninvasive method of measuring BP relies either on the auscultatory method or on the oscillometric approach that requires an inflatable cuff, which may cause discomfort and could only provide intermittent BP readings. Though arterial tonometry and volume clamp technique are available for continuous BP monitoring, they are bulky and partly intrusive, which have hampered their widespread application. Noninvasive 24-hour ambulatory BP monitoring allows estimates of BP-related factors for cardiac events. The factors include, for example, the abnormal BP variability or profiles of circadian variability, which can be obtained with ambulatory BP being usually measured at regular intervals, e.g., every 30 min. Nevertheless, such ambulatory device cannot avoid using the cuff, and to some extent has been too bulky for wearables. There is therefore a very high demand for the development of novel technologies to monitor BP continuously and unobtrusively without a cuff. For decades, researchers have attempted to develop cuffless technique for BP measurement. Methods are mainly based on pulse wave velocity (PWV)/pulse transit time (PTT) and pulse wave analysis (PWA), where the pulse,

[1]Department of Electronic Engineering, The Chinese University of Hong Kong, Hong Kong, China. [2]Department of Medicine and Therapeutics, The Chinese University of Hong Kong, Hong Kong, China. [3]Yuan-Ting Zhang is with Key Laboratory for Health Informatics of the Chinese Academy of Sciences (HICAS), Shenzhen Institutes of advanced technology, Shenzhen, China. Correspondence and requests for materials should be addressed to H.K.T. (email: hktsang@ee.cuhk.edu.hk)

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

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e.g. electrocardiogram (ECG), photoplethysmogram (PPG) and ballistocardiogram (BCG), originates from the cardiovascular system and can be obtained noninvasively and even unobtrusively.

The technology of cuffless BP has been attractive in recent years, and there are a wide variety of studies in terms of sensing[3,4], signal processing[5], calibration or modeling[6], and performance validation[7,8]. Among the different methods being developed for cuff-free BP measurement, PTT method has shown great potential and attracted much attention over the years[6]. There are a few commercially available devices that are based on this method, including the FDA cleared Sotera ViSi Mobile continuous noninvasive BP (cNIBP) monitoring and the SOMNOtouch NIBP systems[9]. Although it is promising, there are still many challenges ahead for the extensive clinical application[6,10]. The accuracy is one of the key issues to address. Previous studies have proposed and developed various calibration models to translate the PTT or BP-related indicators to BP. These approaches mainly include application of the Moens-Korteweg (M-K) formula, heuristic modeling with regression technique, or predictive modeling with data-driven methods such as machine learning. For example, early studies by Chen *et al.*[11] and Poon *et al.*[12] have developed PTT-BP models based on the M-K equation, and their results demonstrated that PTT is able to track BP with quite promising accuracy. Most of the studies on heuristic modeling used linear or nonlinear regression, to adapt indirect indicators to BP, where the indicators include PTT or extra parameters, such as heart rate (HR)[13]. The modeling can be derived by simple regression technique or advanced machine learning method. Muehlsteff *et al.*[14] investigated various calibration models to estimate BP, such as linear logarithmic function and inverse (square) function, and found that inverse square function achieved the lowest error with intra root mean square error of 3.6 mmHg. Further to explore more comprehensive indicators that are available in ECG or PPG signals, researchers have analyzed pulse wave morphology and employed machine learning method to obtain model for better describing the relationship between BP-indicators and BP[15–17]. One study by Monte-Moreno *et al.* estimated BP with sole PPG waveform with random forest technique, and achieved the correlation coefficients between reference and prediction value of 0.91 and 0.89 for systolic BP (SBP) and diastolic BP (DBP), respectively[15]. However, most of these studies focus on using only PTT to indicate BP, and the translation from PTT to BP has been implemented through regression method. Moreover, the majority of studies were validated only with subject at rest state within a short period of time, e.g., minutes to hours. There is a need for a more comprehensive study to evaluate the performances of various models, the performances in monitoring dynamic BP variations induced by exercise, and the performances over longer calibration intervals.

In this study, we assess the accuracy of a new model with an extra indicator – PPG intensity ratio (PIR), which has been demonstrated to reflect the arterial vasomotion and thereby slow variations of BP in our previous studies[18,19]. The model combines PIR and PTT to estimate beat-by-beat BP from the physiological perspective. We experimentally compare our methods that used PTT and PIR, with other six commonly used PTT models. We then analyze the BP estimations of those methods for different subject group, while at rest and performing different maneuvers, and over an extended period of time.

Results

The performances of cuffless BP estimations using the methods with PTT and PIR and methods with sole PTT are firstly compared for all subjects (19 normotensive and 14 hypertensive) at rest. Then, the performances of these methods are evaluated for normotensive and hypertensive subjects, respectively. The comparisons are also analyzed with BP changes elicited by various maneuvers, i.e., active standing (AS), deep breathing (DB), Valsalva maneuver (VM), and sustained handgrip (HG). Finally, their performance with a calibration interval of 24 hours will be presented.

Overall Comparison. The overall performance of the proposed methods as well as the compared methods were validated over 5024 beats from 33 subjects (19 normotensive and 14 hypertensive) with subject supine and seated at rest. The values of SBP and DBP during the monitoring period for all the samples were 132.99 ± 17.94 mmHg and 75.12 ± 12.04 mmHg, respectively.

The performance of the proposed method PTT&PIR#2 for SBP and DBP estimations against the reference BP that were measured with Finometer are shown in Fig. 1. The estimation errors for SBP and DBP were 1.17 ± 5.72 mmHg and 0.40 ± 7.11 mmHg, respectively. We may observe from the Bland-Altman plots that the estimations agreed well with the reference, with 95% of the differences lie within the agreement area. Further, the differences of BP estimation for the normotensive group agreed better with the reference BP than with that of the hypertensive group. One specific sample, as shown in Fig. 1c and d, further demonstrates that the estimation is able to track BP, with the estimation error of 1.62 ± 4.84 (3.52) mmHg and -1.29 ± 7.22 (5.62) mmHg for SBP and DBP, respectively. For this proposed method, the SBP estimation was more accurate than DBP estimation.

The estimation errors of the proposed methods with PTT and PIR were compared with those with sole PTT for SBP and DBP, and the results are illustrated in Fig. 2. For SBP (Fig. 2a), the mean of the estimation errors by all methods were comparable, $F(7, 40184) = 1.72$, $p = 0.098$, being around 1 mmHg and within 5 mmHg, while their SD of the errors were significant, $F(7, 40184) = 89.41$, $p = 0.000$. Among the proposed methods and the compared methods, PTT&PIR#2 worked the best, with its estimation precision about 0.3 mmHg higher than that of PTT&PIR#1, and around 0.5–3 mmHg higher than all the other comparison methods. The methods using PTT and PIR, as well as PTT#1 and PTT#2, performed better than PTT#3-PTT#6, with the SD of the error bias within 8 mmHg and MAD within 5 mmHg. It is noted that there was no significant difference among the estimations within methods PTT#3-PTT#6, and the SD of the estimation biases exceeded 8 mmHg.

Similarly, for DBP as shown in Fig. 2b, the means of the estimation error by all the methods were not significantly different, $F(7, 40184) = 0.60$, $p = 0.757$, whereas the SD of the estimation errors were significantly different at the 0.05 level, $F(7, 40184) = 50.84$, $p = 0.000$. However, the values of the error means and SD were within 5 mmHg and 8 mmHg for all those methods. The MAD of the estimation errors were also significantly different among these methods, $F(7, 40184) = 48.37$, $p = 0.000$, among which PTT&PIR#1 had a significant lowest MAD

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

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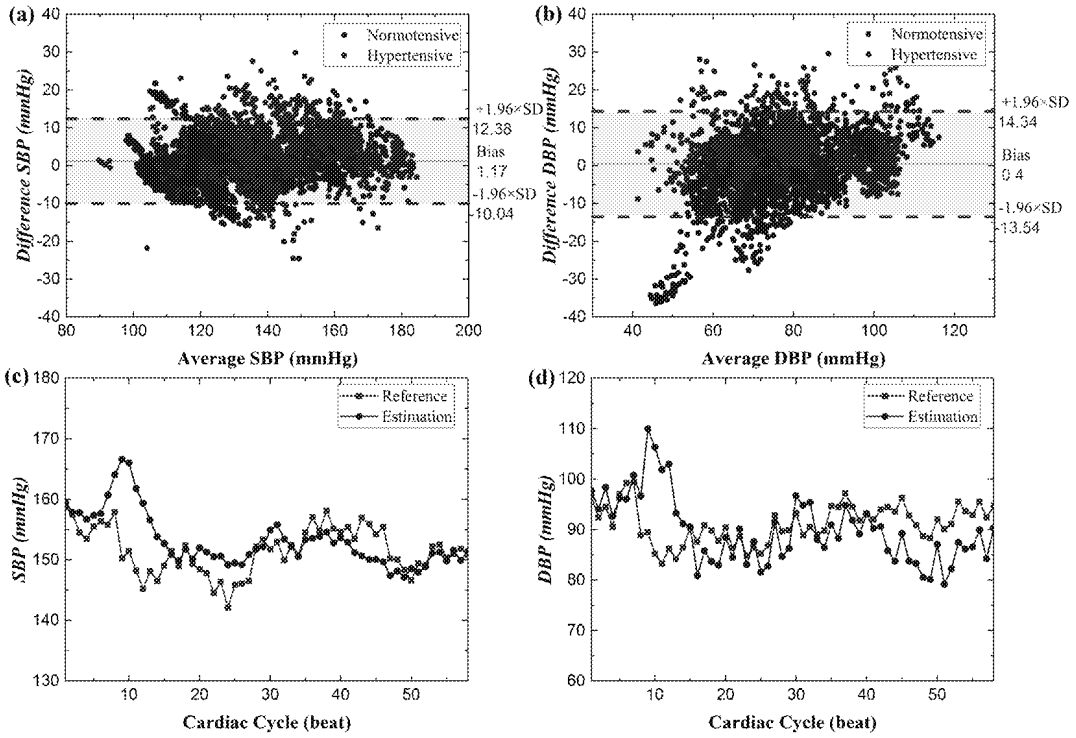


Figure 1. The Bland-Altman plots of the overall BP estimation with the proposed method against the reference method for (**a**) SBP and (**b**) DBP. And one representative (**c**) SBP and (**d**) DBP estimation (blue) versus reference (red) of one hypertensive subject seated at rest state.

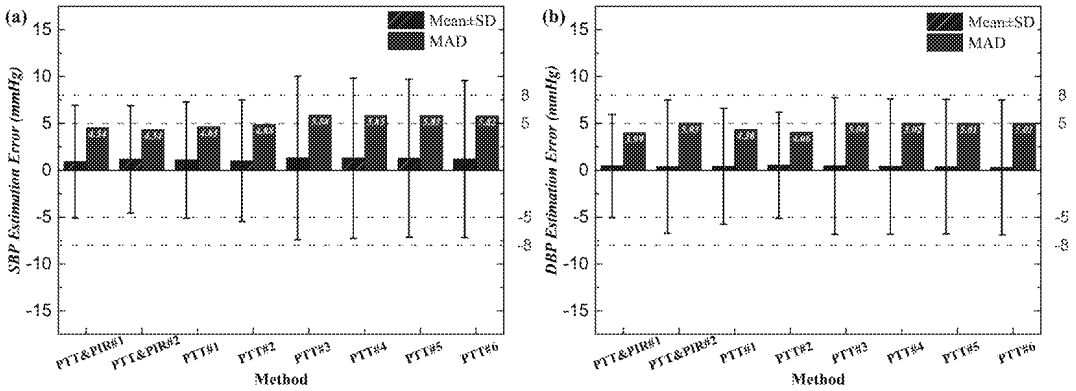


Figure 2. The overall comparison of different methods for (**a**) SBP and (**b**) DBP measurement.

than all other methods. Likewise, there were no significant differences among those regression methods, i.e., PTT#3-PTT#6, and they were not as good as the methods with PTT and PIR as well as PTT#1 and PTT#2.

Comparison between Normotensive and Hypertensive Group. The performance of these methods was evaluated separately for the normotensive group and the hypertensive group, and the results are illustrated in Fig. 3. There were 3160 beats of estimation for normotensive group, with the reference average SBP and DBP of 128.75 ± 16.39 mmHg and 68.73 ± 11.09 mmHg, respectively. And there are 1864 beats of estimations for the hypertensive group, with the reference average SBP and DBP of 136.67 ± 17.40 mmHg and 74.80 ± 12.82 mmHg, respectively. The estimation errors of the hypertensive group were significantly higher than those of the normotensive group, for both SBP and DBP, and for all the methods, except for PTT&PIR#1 when estimating DBP. The error bias of hypertensive group was larger than that of the normotensive group for all the methods, so was the SD of the bias, indicating that the estimations for hypertensive subjects might be overestimated and the variations in individuals were higher. The discrepancies were particularly obvious in SBP estimation.

Comparison of Different Maneuvers. The performance of these methods with subjects at different positions and undergoing different maneuvers was analyzed. The BP estimation errors evaluated by MAD are

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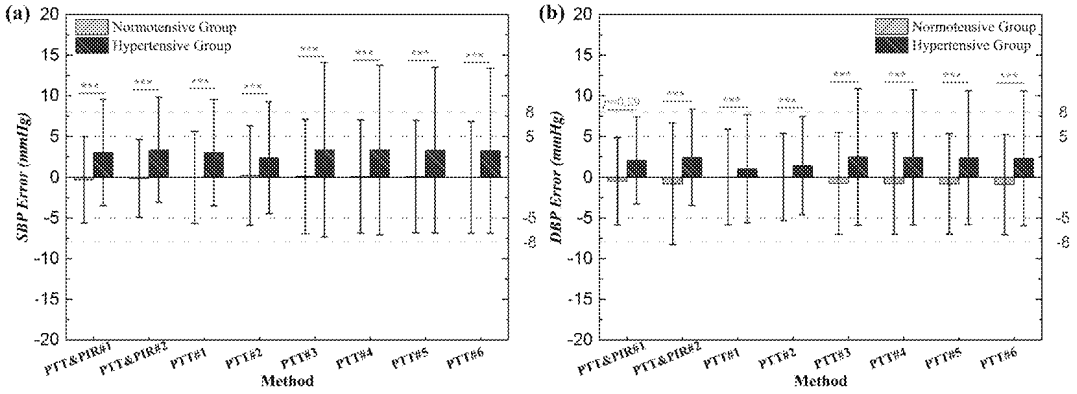


Figure 3. Performance comparison in normotensive group and hypertensive group for (**a**) SBP and (**b**) DBP measurement.

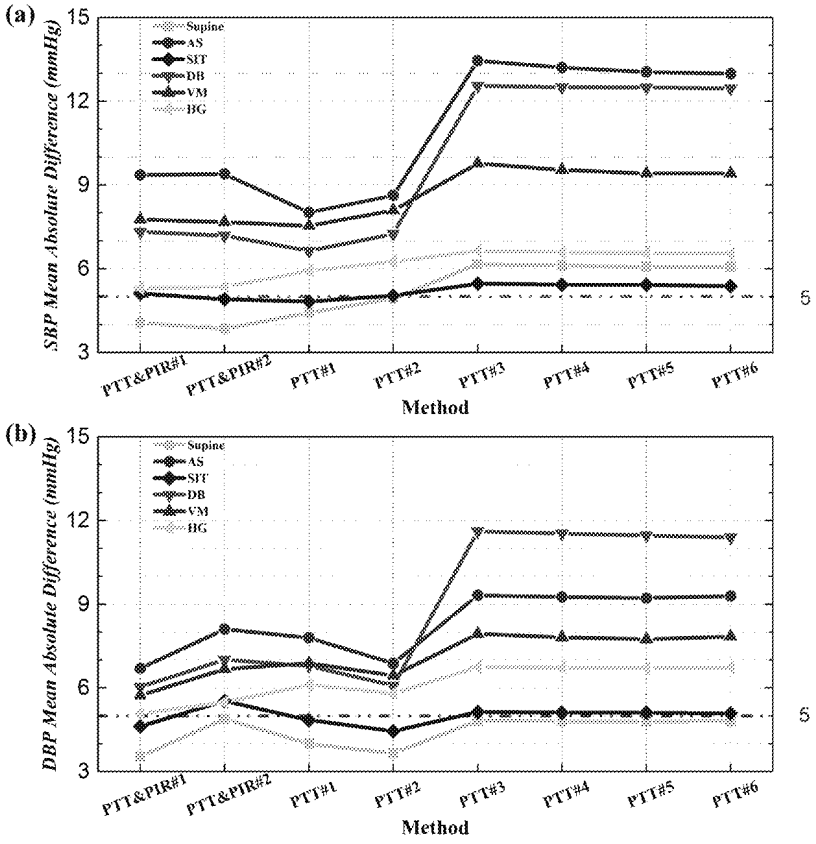


Figure 4. Performance comparison for different maneuvers for (**a**) SBP and (**b**) DBP measurement.

presented in Fig. 4. We can see that the performance of those methods varied at different statuses. While supine at rest, PTT&PIR#2 was the most accurate for SBP estimation, meanwhile PTT&PIR#1 the best for DBP estimations. While sitting at rest, PTT#1 worked the best for estimating SBP, but there was no significant difference between PTT#1 and PTT&PIR#2. For DBP estimation, PTT#2 as well as PTT&PIR#1 were superior to the others. For AS, DB, and VM, when there were dynamic BP changes, PTT&PIR#1 and PTT&PIR#2 performed comparably with PTT#1 and PTT#2 ($p = 0.17$, $p = 0.85$, $p = 0.15$, $p = 0.83$), and they significantly outperformed the four regression methods, though the estimation errors were beyond 5 mmHg for all those methods. And for HG, the performance of PTT&PIR#1, PTT&PIR#2, and PTT#1 were comparable, and superior to the remaining methods.

Figure 5 shows one representative beat-to-beat SBP estimations for these methods under different states. The cuffless methods tracked SBP well at rest state either with supine or seated positions. However, large deviations existed between the estimations and the reference when BP changes were elicited by AS (Fig. 5b), DB (Fig. 5d), VM (Fig. 5e) and HG (Fig. 5f).

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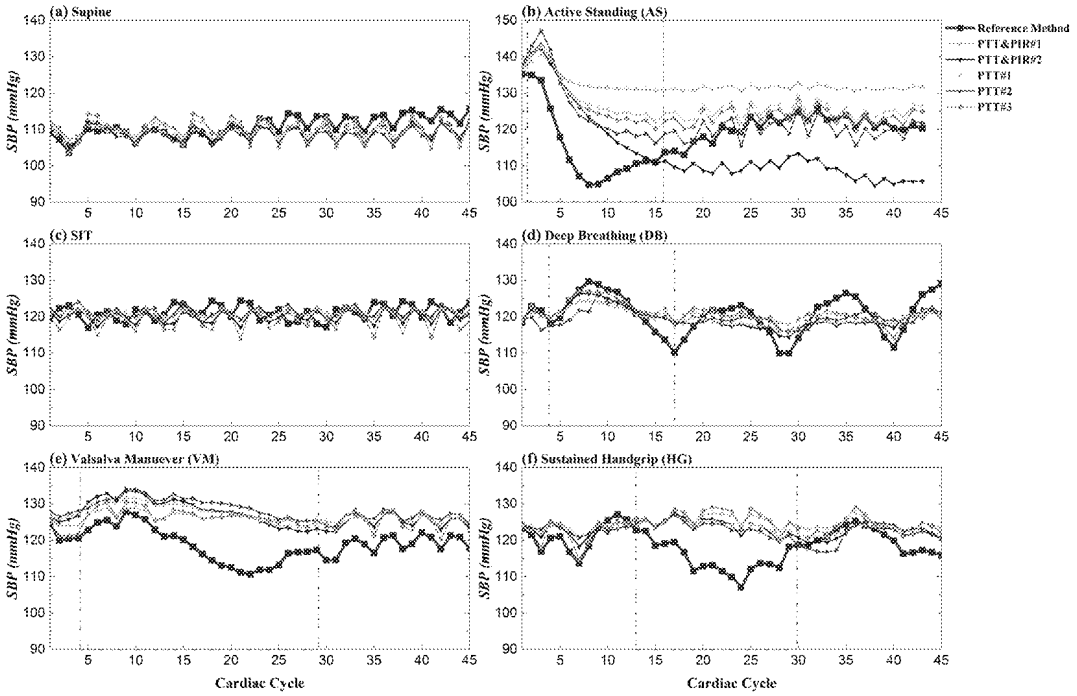


Figure 5. A representative beat-to-beat SBP estimation by different methods against reference SBP measured by Finapres at different maneuvers: (**a**) supine, (**b**) active standing, (**c**) sit, (**d**) Valsalva maneuver, (**e**) deep breathing, and (**f**) sustained handgrip.

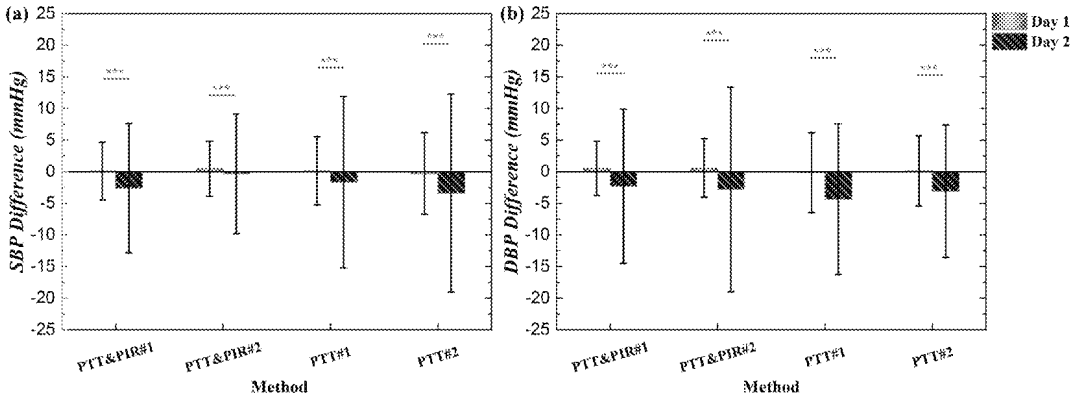


Figure 6. Performance comparison at different days for (**a**) SBP and (**b**) DBP measurement with the proposed methods, i.e., PTT&PIR#1 and PTT&PIR#2, and the compared methods, PTT#1 and PTT#2.

Comparison of Different Calibration Intervals. To validate and compare the performance of the proposed and compared methods over an extended calibration interval, e.g., 24 hours, the initial calibrations of these models were conducted at the beginning of the first day measurement. The errors of SBP and DBP estimations using the methods with PTT and PIR as well as the two best of the methods that used sole PTT, on the first day (Day 1) and second day (Day 2) after the calibration are shown in Fig. 6. Noticeably, the estimation errors of SBP and DBP by either the methods with PTT and PIR or the methods with sole PTT were significantly increased at Day 2 after the initial calibration, with both the bias and the SD of the bias increased. For SBP, the estimation accuracy of PTT&PIR#2 remained better in the Day 2, with the SD of the discrepancy increased by around 5 mmHg. PTT&PIR#1 was as good as PTT&PIR#2. However, the SD of the estimation bias for PTT#1 and PTT#2 approximately raised, from 5 mmHg to 13 mmHg. For DBP, estimations by PTT#1 performed better than all the others the current day of the calibration, however the SD surged from 4 mmHg to 12 mmHg at Day 2. And PTT#2 worked the best at Day 2, with the increment of the SD of the estimation error at around 5 mmHg.

For SBP in Day 2, the means of the estimation errors were comparable, except that the error mean of PTT#2 was significantly higher than the PTT&PIR#2. In addition, the SD of the estimation errors were significantly different, $F(3, 1336) = 39.53$, $p = 0.000$. For DBP in Day 1 and Day 2, there is no significant differences between the estimation biases, but their SD was significantly different, Day 1: $F(3, 1256) = 19.76$, $p < 0.001$; Day 2: $F(3, 1336) = 28.03$, $p = 0.000$.

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Discussion

PTT method has been the most commonly employed technique for cuffless BP measurement. However, previous studies have demonstrated that sole PTT is unreliable to offer full insights into BP variations in different situations. The introduction of extra parameter that is indicative of BP changes is expected to improve the methods using single PTT. We used PIR and PTT to establish models for BP estimation, and compared them with approaches using single PTT. Experimental results show that the proposed methods overall achieved better estimation accuracy than methods with sole PTT with subjects at rest. Furthermore, they were more accurate for measurements on either normotensive or hypertensive group, for estimations under dynamic cardiovascular changes, and for long-term monitoring over 24 hours.

For the overall performance, the proposed methods with both PTT and PIR had the lowest errors of 1.17 ± 5.72 (4.34) mmHg and 0.46 ± 5.49 (3.99) mmHg for estimation of SBP and DBP, respectively. This indicates that it would beneficial to introduce extra BP indicators for improving the estimation accuracy. Among the methods that use sole PTT, PTT#1 and PTT#2 were superior to PTT#3-PTT#6, revealing that the models that were derived based on M-K equation were more efficient than those based on regression methods. Further, methods PTT#3-PTT#6 provided very similar estimation accuracy with SD of the errors beyond 8 mmHg for SBP. This demonstrate that it is inadequate to map PTT to BP with regression technique. One major limitation of the regression model is that it cannot adequately reflect the variability of BP if the regression function does not involve the variable that is indicative of BP changes. This is the reason why the estimation accuracy would be improved when extra parameter except for PTT are introduced, e.g., HR. For example, Kim *et al.* has added HR and another indicator of arterial stiffness that was calculated from PPG as the duration from the maximum derivative point to the dicrotic peak of PPG signal. With the combination of these indicators and PTT via multiple regression analysis, the performance of BP estimation was significantly enhanced[20]. The regression method also bears other shortcomings. For instance, it is too simple to reflect the complicated regulation of the cardiovascular system.

The proposed methods worked better than the compared methods on either normotensive or hypertensive group. The estimation errors were significantly higher in hypertensive subjects for all those methods. This is in agreement with our earlier study[21], which showed that the overall accuracy of SBP estimation was significantly lower in subjects with hypertension and heart diseases than in healthy subjects. However, except for the evidence that the SD of the estimation errors of PTT#3-PTT#6 went beyond 8 mmHg in hypertensive group, all the other estimations error biases and SD were within 5 ± 8 mmHg. These reveal the potential of those PTT methods for monitoring continuous BP for normotensive users. It is also noteworthy that DBP estimation achieved comparable accuracy on those two groups using the method PTT&PIR#1, indicating this method is applicable for either hypertensive or normotensive individuals. For hypertensive group, the mean error bias for both SBP and DBP estimations were negative, indicating the BP of this group was overestimated. Since the arterial stiffness is higher on average in the hypertensive group than in the normotensive group, one possible reason for the overestimation is the improper mapping from PTT to BP in this group. This suggests that it may be valuable to explore the calibration model on diverse groups to obtain a more precise estimate of a wide range of population.

Performance validation with dynamic BP change induced by various cardiac maneuvers (i.e., AS, DB, VM and HG) showed that the cuffless estimations of BP were deviated more from the reference BP compared to that at rest condition, with the MAD exceeded 5 mmHg for all methods. For SBP estimation, PTT#1 and PTT#2 were on the whole better than other methods, with the estimation difference at those dynamic situations were less, and this occurred in PTT&PIR#1 for DBP estimation. These findings reveal the inadequacy of those methods to follow the dynamic changes in BP elicited by the cardiovascular autonomic nervous activities. When there is stimulus to the cardiovascular system, there is a series of reactions which causes complex response that ultimately changes the cardiac output, peripheral resistance and BP. As can be observed from Fig. 5a and c, while at rest with different positions, BP fluctuated mainly due to the spontaneous respiration, and the estimations could track well the fluctuations. By contrast during cardiac maneuvers, other than the respiratory-induced oscillations, there were dynamic changes of the slow variations in BP. During AS (Fig. 5b), a transit but large drop of SBP was caused at the initial phase due to a reduction total peripheral resistance. This change can be explained by the integrated effects of changes in intro-abdominal pressure and hence volume of venous return, cardiopulmonary baroreflex sensitivity and other possible influences[22]. Cuffless estimations can, to some extent, track the drop but fail to recover, indicating the parameters – PTT and PIR, or the established models is unable to reflect the changes in the overall peripheral resistance or stroke volume. For DB (Fig. 5d), these methods were able to trace the trend during inhalation and exhalation, but the changes in level cannot be followed. As the pressure change during DB involves cardiopulmonary activity that cannot be well reflected by the BP indicators in this study, the estimations thus cannot be accurately obtained. And the responses of BP to VM were characterized by a pronounced reduction of BP, which elicited the sympathetic-mediated vasoconstrictor response resulting in BP recovery via baroreflex[23]. Compared with other maneuvers, estimations of BP changes in HG were more accurate. Usually during HG, there is a small decrease in BP that is possibly due to a reduction in peripheral vascular resistance as well as a decline in cardiac output. Since PIR is potential to evaluate the peripheral resistance, the DBP estimation with PIR was significantly better than other methods. Usually, the transit changes in BP are related the baroreflex regulation, and HR is an efficient variable to evaluate this activity. Thus, it would be better to involve HR in this kind of dynamic situation.

The extension of the calibration interval to 24 hours indicate that the estimation accuracy substantially decreased the second day after the initial calibration, for all those methods. However, the proposed methods still performed better for SBP estimation than those of the other methods at the second day. The proposed methods, particularly PTT&PIR#1, were not as good as PTT#2 for DBP estimation on Day 2. This can be explained by the fact that the variability of DBP is low while PIR and PTT track mainly the LF and HF variations of BP respectively, and the combination of PIR and PTT for DBP was not able to work well for a long period of time.

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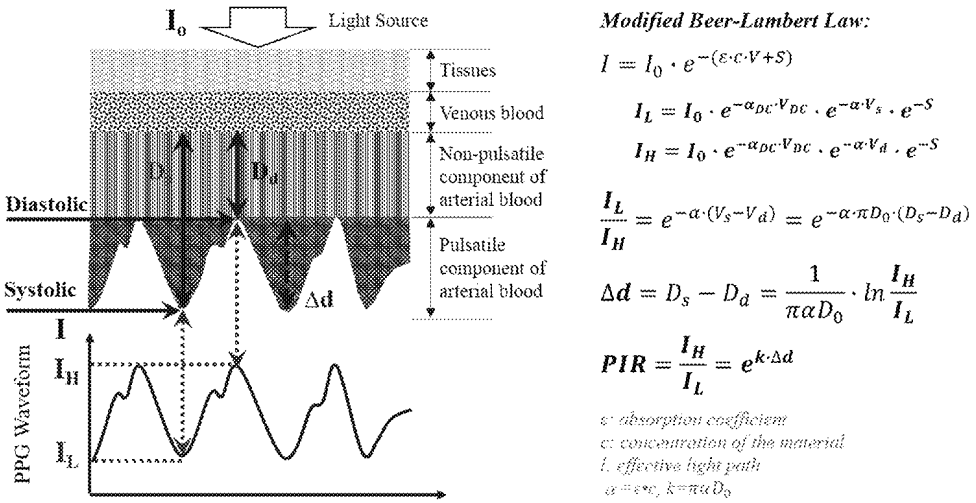


Figure 7. Diagram for derivation of PPG intensity ratio (PIR).

There are several limitations of this investigation. First, the reference BP was measured with Finapres system. Though it is reported to be able to track dynamic change, its accuracy for measuring absolute BP amplitude remains controversial. There has been a study using advance volume-compensation method to improve the accuracy of such method, which may be used in further study to reduce the error for reference measurement[24]. Second, performance of extended calibration interval was only validated on a small sample size, and it has not been conducted in the hypertensive groups. Although there is much to be done, our work generates important findings in the field of cuffless BP measurement. To move forward the goal to measure continuous BP with acceptable accuracy over a longer period of time and at various dynamic conditions, future efforts should, on the one hand, focus upon the exploration of new features that can characterize the BP changes. On the other hand, dynamic adaptive model rather than static model should be considered to reflect the regulation mechanism of BP.

Conclusion

In this work, we have investigated the accuracy of PIR with PTT for cuffless continuous BP monitoring. The methods using PIR and PTT were compared with other commonly used PTT algorithms in normotensive and hypotensive subjects, with subjects at different positions, undergoing various maneuvers, and over an extended period beyond 24 hours after calibration. In general, the PIR with PTT approach outperformed the other comparison methods, though the ability of tracking abrupt changes in BP that are regulated by the autonomic nervous activities should be further addressed. The accuracy of extended calibration interval remains to be resolved. The potential of PIR with PTT technique for unobtrusive monitoring of BP for ambulatory or home healthcare is significant. Although cuffless technique holds great promise, the true potential of this approach will be realized only when efficacy and effectiveness studies show that its application can reduce the incidence of hypertension and improve the cardiovascular health of populations.

Methods

PTT Measurement and Preprocessing. We calculated PTT as the time difference between the R wave peak of the ECG signal and the peak of the first derivative of the PPG signal (dPPG). High and low frequency noise in ECG and PPG signals were removed with zero-phase filter and wavelet denoising method. For the latter method, we used wavelet Daubechies 3 (db3) to decompose the signal at level 16 and then reconstructed without the noise component.

PIR Derivation and Cuffless BP models. With PPG signal collected from a peripheral artery as shown in Fig. 7, the incident light intensity I_0 of the light emitter will become I detected by the light detector after the transmission through the tissue, venous blood, and arterial blood. It should be noted that the arterial blood contains non-pulsatile component as well as pulsatile component. During diastole, the arterial diameter is at its minimal level D_d, and consequently the transmitted light intensity will be at the highest level I_H. On the contrary, the transmitted light intensity will decrease to the minimal level I_L during systole as a result of the increase of arterial diameter from the minimal D_d to maximal D_s. During one cardiac cycle, the change of the optical path is corresponding to the diameter change Δd. Therefore, the diameter change can be derived from the peak and valley intensity of the PPG signal. The detected PPG signal consists of DC component mainly due to the light absorption of the tissue, the venous blood and non-pulsatile blood, while the alternating component is generated because of the blood pulsation. According to the modified Beer-Lambert law[25,26], PIR – ratio of PPG peak intensity I_H to valley intensity I_L can be derived in terms of the arterial diameter change under the assumption that the characteristic parameter α keeps constant and there is seldom change of the baseline arterial diameter, as explained in Fig. 7.

Our preliminary study indicates that MBP can be correlated with PIR, as PIR can potentially reflect the peripheral resistance[27,28]. Further based on the Bramwell and Hill (B-H) equation[29]:

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	PTT-BP Model	
	SBP	DBP
PTT&PIR#1[19]	$DBP + PP_0 \cdot \left(\frac{PTT_0}{PTT}\right)^2$	$DBP_0 \cdot \frac{PIR_0}{PIR}$
PTT&PIR#2	Eq. (7)	Eq. (8)
PTT#1[11]	$SBP_0 - \frac{2}{\gamma PTT_0}(PTT - PTT_0)$	$DBP_0 - \frac{2}{\gamma PTT_0}(PTT - PTT_0)$
PTT#2[12]	$DBP + PP_0 \cdot \left(\frac{PTT_0}{PTT}\right)^2$	$MBP_0 + \frac{2}{\gamma}\ln\frac{PTT_0}{PTT} - \frac{1}{3}PP_0 \cdot \left(\frac{PTT_0}{PTT}\right)^2$
PTT#3[30]	$a_3 \cdot PTT + b_3$	$a_3' \cdot PTT + b_3'$
PTT#4[31]	$a_4 \cdot \ln PTT + b_4$	$a_4' \cdot \ln PTT + b_4'$
PTT#5[32]	$\frac{a_5}{PTT} + b_5$	$\frac{a_5'}{PTT} + b_5'$
PTT#6[14]	$\frac{a_6}{PTT^2} + b_6$	$\frac{a_6'}{PTT^2} + b_6'$

Table 1. Comparison methods.

$$PWV = \sqrt{\frac{V}{\rho dV/dP}} \tag{1}$$

which relates PWV to arterial compliance dV/dP, blood density ρ and volume V, and the consideration that the arterial pressure change in one cardiac cycle is pulse pressure (PP), and the volume change is approximately the sectional area change ΔA which can be further expressed in terms of arterial diameter change Δd, (2) can be obtained accordingly.

$$\frac{\Delta V}{V \cdot \Delta P} = \frac{\Delta A}{A \cdot PP} = \frac{D_s^2 - D_d^2}{D_d^2 \cdot PP} = \frac{D_s + D_d}{D_d^2} \cdot \frac{\Delta d}{PP} \tag{2}$$

Substituting PWV = L/PTT and (2) into (1), we have:

$$\frac{L}{PTT} = \sqrt{\frac{1}{\rho \cdot (D_s + D_d)/D_d^2} \cdot \frac{PP}{\Delta d}} \tag{3}$$

As a result, PP can be derived in terms of Δd and PTT:

$$PP = \frac{\rho L^2 (D_s + D_d)}{D_d^2} \cdot \Delta d \cdot \frac{1}{PTT^2} \tag{4}$$

Under the assumption that the parameters such as ρ, L, D_s, D_d, and α keep constant, Δd is approximately linear with PIR, i.e., $\Delta d \propto PIR$. Therefore, (5) can be obtained.

$$PP \propto \frac{PIR}{PTT^2} \tag{5}$$

And ultimately PP can be derived with the calibrated PP, PIR and PTT, i.e., PP0, PIR_0, and PTT_0.

$$PP = PP_0 \cdot \frac{PIR}{PIR_0} \cdot \left(\frac{PTT_0}{PTT}\right)^2 \tag{6}$$

Finally, SBP and DBP can be derived with PIR and PTT accordingly.

$$SBP_i = MBP_0 \cdot \frac{PIR_0}{PIR_i} + \frac{2}{3} \cdot \frac{PIR_i}{PIR_0} \cdot \left(\frac{PTT_0}{PTT_i}\right)^2 \tag{7}$$

$$DBP_i = MBP_0 \cdot \frac{PIR_0}{PIR_i} - \frac{1}{3} \cdot \frac{PIR_i}{PIR_0} \cdot \left(\frac{PTT_0}{PTT_i}\right)^2 \tag{8}$$

where the subscript of *i* and zero indicate the *i*th heart beat and the initial calibration value, respectively.

The proposed method is compared with our previously established PIR model – PTT&PIR#1[19], and other six commonly used PTT methods, including the two most cited previous works that are based on PTT and four commonly studied regression methods. They are listed in Table 1.

It should be noted that some models estimated only SBP in the original works, e.g., PTT#1, PTT#3, and their corresponding DBP was estimated in this study in a similar way to that for SBP estimation. Those models were calibrated using Finapres BP and the simultaneously obtained parameters at the beginning of the test. For the

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	Subjects (n = 33)	Normotensive Group (n = 19)	Hypertensive Group (n = 14)
Mean age (range)	43 (21–77)	26 (21–47)	67 (43–77)
Gender (M/F, n)	20/13	10/9	10/4
Height (cm)	165.9 ± 8.9	167.3 ± 8.2	164.1 ± 9.8
Weight (kg)	64.1 ± 14.6	55.6 ± 10.7	75.7 ± 10.7
Hypertension (n)	14	0	14
Prehypertension	7	0	7
Stage I hypertension	6	0	6
Stage II hypertension	1	0	1
SBP (mmHg)	121.12 ± 19.52	107.74 ± 10.04	139.30 ± 13.50
DBP (mmHg)	68.92 ± 8.16	65.21 ± 6.96	74.00 ± 7.00

Table 2. Subject characteristics.

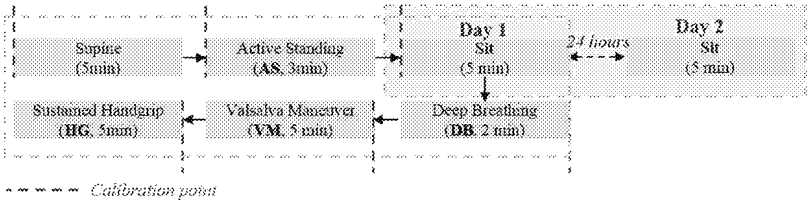


Figure 8. Diagram of the experiment protocol.

proposed models with PTT and PIR, PTT#1 and PTT#2, only one beat of BP, PTT and PIR were used. For the regression models PTT#3 – PTT#6, two beats of BP and PTT were used to derive the coefficients. Thereafter, beat-by-beat BP can be obtained with PTT and PIR. The calibration was conducted individually for each maneuver. For the 24 hours measurement, it was only calibrated at the beginning of the first day measurement. The performance was evaluated against the reference BP measured in the same way in the calibration method.

Subjects and Experiment. Nineteen healthy normotensive subjects and 14 subjects with hypertension were recruited in this study. All the subjects volunteered to participate and gave their informed consent before taking part in this study. The study was approved by the Institutional Review Board of the Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee, Hong Kong, China, and conducted according to Declaration of Helsinki ethical principles for medical research on human subjects. Subject aged between 18–80 years old with a specified range of BP among less than 120 to over 160 mmHg was included. Subject with implantable cardiac devices including permanent pacemakers, cardiac-resynchronization therapy or defibrillator, pregnancy and unable to sign informed consent was excluded. The subject characteristics are illustrated in Table 2.

The performance of BP estimation was validated with subjects at rest state and with subjects undergoing various maneuvers which are assumed to induce dynamic BP changes. The experimental protocol involves acquiring ECG, PPG, continuous BP simultaneously with subjects at rest while supine, from supine to active standing (AS), as well as during various maneuvers while sitting (Fig. 8). The maneuvers, including deep breathing (DB), Valsalva maneuver (VM), and sustained handgrip (HG) test, have been commonly used in clinical to assess cardiovascular autonomic function[33]. AS was performed 5 min after rest at supine, when the subject was asked to stand up from the supine position and to remain in the standing posture for 3 min. The cyclic DB was performed with the breathing rate of six breaths/min and lasted for two minutes. VM is a sensitive, noninvasive, and widely available clinical test and it provides an indirect index of sympathetic vasoconstrictor functions based on characteristic BP responses. It was performed with moderately forceful attempted exhalation against a closed airway for 20 s, followed by a rest period of one minute. VM was conducted twice continuously; and HG was conducted with continual handgrip at 1/3 of the subject's maximal strength for 150 s.

ECG was acquired with one-lead ECG electrodes placed on left and right arms, and PPG was recorded with a reflectance type of probe that consists of infrared LED (SFH 4250, 850 nm) and phototransistor (SFH 320) in the left index finger, respectively; and the reference BP was measured by Finometer® (Finapres Medical System, Amsterdam, Netherlands) with the finger cuff on the left thumb and the brachial cuff on the left upper arm. ECG, PPG, and the continuous BP were collected with a sampling rate of 1000 Hz through DATAQ and imported to computer for ad-hoc processing.

To investigate the extended calibration interval of those algorithms, the follow-up experiment was carried out on eight subjects from the healthy group, with data collected from these subjects while seated at rest the same time of the first day and the next day. Those models were calibrated at the beginning of the first day measurement.

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Data Analysis. The estimate error was calculated as the difference between the reference and the BP estimation, i.e., error = estimated BP − reference BP, and evaluated as the error mean ± standard deviations (SD), as well as mean absolute difference (MAD). They are defined as below:

$$\text{mean} = \frac{1}{n}\sum_{i=1}^{n}\left(BP_{EST_i} - BP_{REF_i}\right) \tag{9}$$

$$\text{SD} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}\left(BP_{EST_i} - BP_{REF_i}\right)^2} \tag{10}$$

$$\text{MAD} = \frac{1}{n}\sum_{i=1}^{n}\left|\left(BP_{EST_i} - BP_{REF_i}\right)\right|. \tag{11}$$

BP_{REFi} and BP_{ESTi} represent the ith beat BP measured by the reference method and estimated by the cuffless methods, respectively, and n is the number of cardiac cycle that used for evaluation. For normotensive and hypertensive group comparison, the student's t-test was used to test the significance between the two groups. One-way analysis of variance (ANOVA) was conducted to test the significance of various methods for BP estimation. The differences between the estimations and the references were tested to be normal distribution. Thus the Tukey's honestly significant difference was used for comparing group means, and Levene's test (absolute deviations) was applied for homogeneity of variance test. $p < 0.05$ is taken as statistically significant.

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Author Contributions

Xiaorong Ding proposed the method, designed the experiments, analyzed the results and drafted the article. Bryan P Yan advised and carried out the clinical experiment. Yuan-Ting Zhang guided the study. Jing Liu collected part of the data. Ni Zhao advised on the methods. Hon Ki Tsang provided supervision and helped in writing the manuscript. All authors reviewed the manuscript.

Additional Information

Competing Interests: The authors declare that they have no competing interests.

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Report Number: (b)(4)

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In Vitro Cytotoxicity Test of
Reusable Blood Pressure Cuff
using ISO 10993-5: 2009 Test Method
MTT Method
MEM with 10%FBS extract

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Accurate Meditech Inc.
Wang Jen
General Manager
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.,
New Taipei City, 241406
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 15, 2023
Received: May 15, 2023

Dear Wang Jen:

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. You must comply with all the Act's

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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,

Robert Kazmierski
Acting Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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Clinical Study Summary Table

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Assessment of a calibration-free method of cuffless blood pressure measurement: a pilot study

Cheng-Yan Guo, Chia-Chi Chang, Kuan-Jen Wang and Tung-Li Hsieh[#,*] (*Member, IEEE*)

Abstract This study proposes a low-cost, high-sensitivity sensor of beat-to-beat local pulse wave velocity (PWV), to be used in a cuffless blood pressure monitor (BPM). **Objective:** We design an adaptive algorithm to detect the feature of the pulse wave, making it possible for two sensors to measure the local PWV in the radial artery at a short distance. Unlike the cuffless BPM that needs to use a regression model for calibration. **Method:** We encapsulate the piezoelectric sensor material in a cavity and design an analog front-end circuit. This study used color ultrasound imaging equipment to measure radial arterial parameters, including the diameter and wall thickness, to aid the estimation of blood pressure (BP) using the Moens-Korteweg (MK) equation of hemodynamics. **Results:** We compared the blood pressure estimated by the MK equation with the reference BP measured using an aneroid sphygmomanometer in a test group of 32 people, resulting in a mean difference of systolic BP of -0.63 mmHg, and a standard deviation of ±5.14 mmHg, a mean difference of mean arterial pressure (MAP) of 0.97 mmHg, with a standard deviation of ±3.54 mmHg, and a mean difference of diastolic BP of -1.14 mmHg, with a standard deviation of ±4.08 mmHg. This study has verified its compliance with ISO 81060-2. **Conclusions:** A new type of wearable continuous calibration-free BPM can replace the situation that requires the use of traditional ambulatory BPM and reduce patient discomfort. **Clinical impact:** In this study can provide long-term continuous blood pressure monitoring in the hospital.

***Index Terms*—Moens-Korteweg equation, blood pressure, mean artery pressure, pulse wave velocity, blood pressure monitor.**

Clinical and Translational Impact Statement— The correction-free cuffless BPM, which can pass ISO 81060-2 criteria in the pilot study, can replace the traditional BPM using inflating cuffs and reduce the interference of ambulatory BP monitoring in patients' daily life.

I. Introduction

In recent years, wearable devices have begun to integrate a large number of functions into a system [1], and now they have begun to have health care and vital sign monitoring, such as pulse rate, blood pressure, oxygen situation, and arrhythmia detection [2]. Blood pressure is one of the vital signs of the human body [3], and it is also one of the research focuses of wearable devices with vital sign monitoring. The electronic blood pressure monitor (BPM) uses a cuff with the oscillometric method to measure blood pressure [4]. A cuff that can be inflated and pressurized to connect to the Wheatstone bridge sensor [5], and use the motor to increase the internal pressure of the cuff dynamically, make the cuff press the radial artery or brachial artery of the arm. When the internal cuff pressure and the arterial pressure are equal, the amplitude of the air oscillating inside the cuff will be the maximum. At this time, the cuff's pressure is the mean arterial pressure (MAP) [6]. When the MAP position of the envelope of an oscillating signal of the cuff is determined, the systolic blood pressure (SBP) and diastolic blood pressure (DBP) can be estimated from the peak relative to the MAP position [7].

However, the oscillometric method must use components such as a cuff, motor, and valve to make the size of the BPM larger than wearable devices. On the other hand, in the traditional hypertension clinic monitoring scenario, non-invasive ambulatory blood pressure monitoring (ABPM) is a valuable tool for monitoring BP abnormality in the

C.-Y. Guo, C.-C. Chang, T.-L. Hsieh, and K.-J. Wang conceived the presented idea. C.-C. Chang and C.-Y. Guo developed the theory and performed the computations. C.-C. Chang, T.-L. Hsieh and C.-Y. Guo verified the analytical methods. K.-J. Wang encouraged the investigation [a specific aspect] and supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

We declare that we have no significant competing financial, professional, or personal interests that might have influenced the performance or presentation of the work described in this manuscript.

All data generated or analyzed during this study are included in this published article (and its supplementary information files).

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clinical setting. Monitoring a patient's 24-hour blood pressure changes allows patients to manage their treatment better [8]. However, ABPM requires intermittent inflation of the cuff, which interferes with the patient's daily life, causes discomfort, and reduces treatment compliance with blood pressure monitoring [9]. Cuffless BP monitoring technology can overcome patient discomfort when measuring for a long time. In order to enable wearable devices to achieve cuffless BP measurement, the current primary research is based on hemodynamics and measuring pulse wave velocity (PWV) to estimate artery pressure. According to the definition of a cuffless BPM in the Institute of Electrical and Electronics Engineers (IEEE) standard, BPM without an occluding cuff is defined as cuffless BPM [10]. An advantage of cuffless BPM compared to traditional BPM is that it enables a more comfortable and long-term BP monitoring to be realized [11]. The techniques used in this field include ECG combined with PPG, phonocardiographic sensors, elastic modulus, dimensions and stiffness of the intervening vessels, and other methods to measure physiological parameters. The selected technique builds a mathematical model to estimate BP. Commercial products such as Maisense's Freescan use Electrocardiography (ECG) and Photoplethysmography (PPG) to measure pulse arrival time (PAT) and convert it to PWV to estimate blood pressure [12]. BPro uses tonometry to measure the time difference between the primary peak of the pulse wave and the second peak of the reflection [13]. Physiologically, the time difference between the second peak and the primary peak of pulse wave reflection will reflect the arterial stiffness, which can be used to estimate blood pressure [14]. Other studies also measure two points in a short distance of the artery and measure the local pulse transit time (PTT) difference to estimate blood pressure [15].

Although these methods can reduce the device's size so that the sensor can integrate into the wearable device, they all use the measured values of BPM and PWV to build regression models or use some non-linear methods to map the PWV and blood pressure. The user must first input the blood pressure value of the BPM into the system and map the PWV and blood pressure by algorithms for calibration [16]. This calibration process is necessary for the current popular cuffless technology and needs to be performed periodically. In addition, the current cuffless wearable blood pressure measurement devices [17-19] use ECG and PPG sensors to measure PAT, which uses PAT and blood pressure for the regression model. However, studies have pointed out that PAT will be affected by the pre-ejection period (PEP) [20-21] As a result, PAT cannot accurately estimate PWV and then estimate blood pressure. Although human blood pressure does not change drastically in a short time, using a PAT and BP regression model will cause many potential parameters to be ignored and lose accuracy. The MK equation [22] in hemodynamics describes the relationship between PWV and blood pressure. The characteristics of arterial parameters must be considered. Different individual arteries have different characteristics of hemodynamics. Therefore, only the mapping between PWV and blood pressure may be inaccurate. Many studies have used machine learning models in recent years, using various physiological signal characteristics and demographics (e.g., age, sex, weight) as parameters and matching different hyperparameters to predict BP. Although it is claimed that the cuffless system can obtain acceptable accuracy under calibration-free, it is unclear how much of the attained BP measurement accuracy is due to the actual hemodynamic measurement [23]. The current machine learning model has insufficient interpretability for BP estimation, so regulatory agencies in various countries cannot approve this type of cuffless BPM. Based on hemodynamic cuffless BPM, calibration-free can also accurately estimate BP. The feasible way in the current research is to measure the artery parameters of different individuals, combine the measured PWV, and modify the BP estimation method based on the MK equation. For example, use two PPG probes to detect individual PWV [24] and set up an ultrasonic probe between the two PPG probes to measure the participant's arterial pressure waveforms, simultaneously acquired arterial dimensions, and local PWV. Perform calibration-free cuffless BP estimation based on the measured data [25]. This technology has been able to realize calibration-free cuffless BP estimation based on hemodynamics. However, it needs to be measured by professionals in operation, and it is not easy to apply to long-term BP monitoring scenarios. Therefore, we propose a low-cost and small-sized PWV measurement device, which is used with color ultrasound imaging equipment to obtain the arterial parameters of the participant and combines the two to estimate BP with a hemodynamic mathematical model. As a pilot study, we studied the participants who need to perform long-term BP monitoring records in the future. Before collecting long-term BP, use color ultrasound imaging equipment to determine the participant's arterial parameters, then combine the small wearable device proposed in this study with the hemodynamic mathematical model to estimate BP. Finally, we discussed the accuracy and future works that this method needs to be improved.

II. Our Contribution

The contribution of this research is to propose a small, low-cost local PWV sensor and design algorithm to analyze pulse waves to estimate BP. We use color ultrasound imaging equipment to measure the arterial parameters required by the MK equation. These arterial parameters, along with the PWV measured by the sensor, are used to estimate BP using the MK equation. Also, we follow the ISO 81060-2 standard and the Bland–Altman plot statistical method to analyze data from 32 participants. We compare some cuffless technical characteristics in Table 1, including the currently popular cuffless methods [26] and potentially feasible calibration-free cuffless methods [27]. The advantages of our

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method are that it does not use intermittent inflation BPM for calibration and has the potential for beat-to-beat BP monitoring. Finally, according to the results of our experiments, this pilot study verifies that the measurement method of the cuffless BPM we proposed can estimate BP calibration-free. It provides a more convenient method for future calibration-free cuffless BPM research work.

Table 1. Compare the current popular cuffless technology and electronic BP monitor.

	Our proposed method	Oscillometric finger pressing method	Popular cuffless BP monitor	Electronic BP monitor
Sensing technology	Pulse wave sensor (Ultrasound image aid)	Pressure and PPG sensor	ECG and PPG sensor	Arterial pressure sensor
Measurement parameter	Pulse transit time	Pressure curve and optical envelope of heart beats	Pulse arrival time	The heart beats envelope curve
Principle	MK equation (with artery parameter)	Oscillometry method	Regression model	Oscillometry method
Calibration*a	No	No	Necessary	No
Beat-to-beat	Yes*b	No	Yes*b	No
Cuffless	Yes	Yes	Yes	No
Intermittent inflation	No	No	No	Necessary
Reliability	Good	Depends on the operation of the user	Influenced by pre-ejection period	Good
Measurement time	Beat-to-beat	Depends on the operation of the user	Beat-to-beat	30 to 40 seconds

*a. According to the IEEE 1708 standard, an additional BP measuring device is required to reference the calibration point, usually an electronic BP monitor compliant with the ISO 81060-2 standard.
*b. It is technically feasible, but it is still necessary to average several data to reduce errors.

I. Local PWV Sensor and Analog Front End(AFE) Design

Piezoelectrics are able to convert mechanical waves into electrical signals. Piezoelectric ceramic is a highly efficient electromechanical transducer that can sense weak vibrations through the direct piezoelectric effect [28]. We developed a low-cost glued and airtight packaging method to use piezoelectric ceramics to sense arterial pulse waves. The piezoelectric is sealed in an airtight cavity, and the sensor surface is placed in contact with the radial artery. When the aortic valve opens, blood is ejected into the aorta, and the pulse wave generates tension around the artery wall [29]; the pressure generated by this tension is detected by the deformation of the compression sensor surface. The airtight cavity in the sensor pressurizes in response to this deformation, in turn deforming the piezoelectric sensor and generating an AC signal that can be measured. The PWV can then be determined by measuring the difference in pulse arrival time between two such sensors. We use a mechanical model to analyze the mechanical structure of the sensor proposed in this study.

A. Sensor Design

A schematic of the sensor package is shown in Fig. 1. The piezoelectric ceramic is encapsulated in a cavity, and the surface in contact with the radial artery has a layer of the compressible rubber film. The volume of rubber film can be expressed according to Eq. 1, where m is the mass of rubber, ρ is the density of air, L is the effective length and S is the cross-sectional area. The volume of the cavity is V, and the atmospheric pressure is P_A. When the radial artery pulse wave reaches the contact surface of the sensor, the rubber film will be compressed by the distance x. As described in Eq. 2, the volume will decrease by the product of the cross-sectional area S and the compression distance x. This compression will increase the pressure in the cavity by an amount of P_a (Eq. 3).

When the pressure in the cavity increases, the pressure of the gas on the piezoelectric increases. The piezoelectric sensor packaged inside the cavity will then be deformed by the pressure generated during compression. The pressure increase will determine the deformation of the piezoelectric (Fig. 2), which is mathematically equivalent to the mass-on-a-spring system shown in Fig. 2. The force F pushes the rubber film m, and the compressed gas k in the cavity causes the piezoelectric to be deformed; the piezoelectric effect then generates an electrical signal. The electrical signal generated is equivalent to a direct conversion of the mechanical wave propagating along the artery [30].

The proportional relationship between the volume and pressure changes is described by Eq. 4, because the rubber film is squeezed by the pulse of the radial artery so that the internal pressure increases by P_a. The pressure change P_a is produced by a small volume change ΔV, and the resulting equation involves a constant, γ, the ratio of specific heats, which is approximately 1.4 for air [31]. Newton's law of

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acceleration is Eq. 5. We can find the relationship between the force F and the action force of the piezoelectric ceramic with Eq. 6.

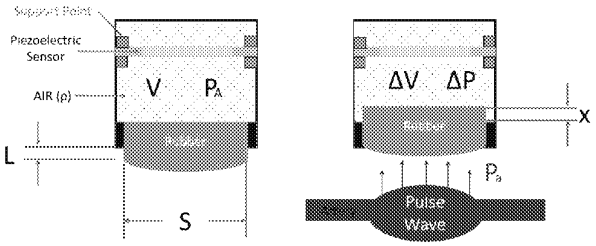


Fig. 1. The sensor package

$$m = \rho SL \tag{1}$$

$$\Delta V = V - Sx \tag{2}$$

$$\Delta P = P_A + P_a \tag{3}$$

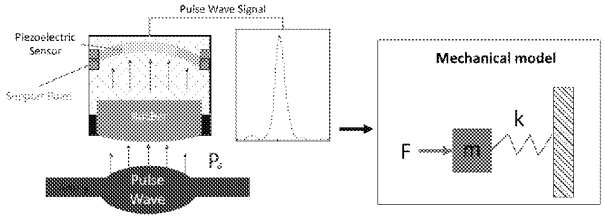


Fig. 2. The pressure increase will determine the deformation of the piezoelectric.

$$\frac{P_a}{P_A} = -\gamma\frac{\Delta V}{V} = -\gamma\frac{Sx}{V} \tag{4}$$

$$\frac{F}{m} = \frac{d^2x}{dt^2} \tag{5}$$

$$\frac{d^2x}{dt^2} = \frac{P_a S}{SL\rho} = -\frac{\gamma S P_A}{\rho V L}x \tag{6}$$

B. Analog Front End Design

The flowchart in Fig. 4 shows the relationship between the piezoelectric sensor and AFE. The signal output of the AFE is sampled by the 12-bit analog-to-digital converter (ADC). The ADC is integrated in the STM32F4 microcontroller, and the microprocessor runs the digital signal processing algorithm in real-time. Samples the pulse wave signal at a rate of 10 kHz, which can achieve a PTT measurement accuracy of 0.1 milliseconds.

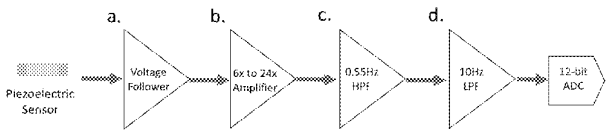


Fig. 4. The piezoelectric sensor. a) The piezoelectric is connected to the input of the voltage follower. b) The output of the VF connects to the amplifier circuit. c) The output signal of the amplifier is passed through a high-pass filter. d) High-frequency AC signals above 10 Hz are attenuated by a low-pass filter.

Fig.5a shows the voltage follower (VF), providing the complete input of the piezoelectric sensor signal. If we connect the piezoelectric sensor to the external load, we get a high-pass filter (HPF). The cut-off frequency of the HPF is the point in the circuit with a 3dB drop in magnitude. Therefore, we need to add an external load resistor to ensure the quality of the signal. To determine the corresponding load resistor R1 in Eq.7, we need to measure the parasitic capacitance Cp of the piezoelectric sensor [32], and f is the cut-off frequency of 1 Hz of heartbeats with rates around 60 beats per second of an average. The Cp of the piezoelectric ceramic we chose is 8000 pF ±30%. Therefore, the load resistance range can be calculated to be about 15M ohms to 28M ohms. Fig.5b is the signal amplifier. Eq.8 selects R2 and R3 to adjust the gain. The signal passes through the signal amplifier, and the pulse wave signal is amplified to hundreds of millivolts. When the signal of the pulse wave is amplified, the noise will also be amplified. Fig.5c is the second-order Sallen-Key HPF; Eq.9 is its transformation function, and the cut-off frequency is determined by Eq.10. This study's HPF cut-off frequency set is 0.55 Hz; R4 and R5 are equal, and C1 and C2 are also designed to be the same value. After the signal passes through the HPF, the DC component can be filtered out. Fig.5d is the second-order Sallen-Key low-pass filter (LPF) [33,34]; Eq.11 is its transform function, and the cut-off frequency is determined by Eq.12. In this study, the cut-off frequency of LPF is 10 Hz; R6 and R7 are equal, and C3 and C4 are also equal. They can attenuate the interference caused by the supply mains frequency and other disturbances.

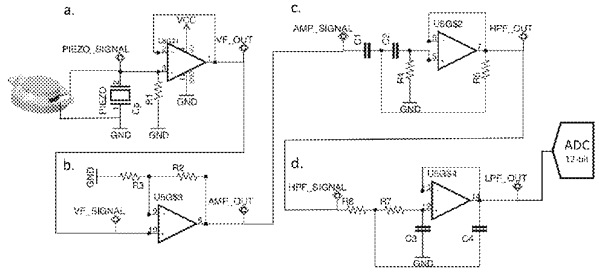


Fig. 5. (a) VF and (b) signal amplifier and gain adjust. (c) Second-order Sallen–Key HPF and (d) second-order Sallen–Key LPF.

$$R1 = \frac{1}{(2\cdot\pi\cdot f\cdot C_p)} \tag{7}$$

$$Vout = Vin\cdot\frac{R2}{R3} \tag{8}$$

$$\frac{Vout(s)}{Vin(s)} = \frac{s^2}{s^2 + s\left(\frac{1}{R4\cdot C1} + \frac{1}{R4\cdot C2}\right) + \frac{1}{R4\cdot C1\cdot R5\cdot C2}} \tag{9}$$

$$fc_{HPF} = \frac{1}{2\pi\sqrt{R4\cdot C1\cdot R5\cdot C2}} \tag{10}$$

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$$\frac{Vout(s)}{Vin(s)}=\frac{\frac{1}{R6\cdot C3\cdot R7\cdot C4}}{s^2+s\left(\frac{1}{R7\cdot C3}+\frac{1}{R6\cdot C3}\right)+\frac{1}{R6\cdot C3\cdot R7\cdot C4}} \tag{11}$$

$$fc_{LPF}=\frac{1}{2\pi\sqrt{R6\cdot C3\cdot R7\cdot C4}} \tag{12}$$

C. Local PWV Measurement

The local PWV is the pulse wave time difference generated by two sensors on the same arterial segment, separated by a small distance. In this study, the local PWV was measured on the radial artery. Two sensors were connected to two AFEs and placed on the radial artery at a fixed separation distance. A schematic of the device is shown in Fig. 6. When the pulse wave is transmitted from **P1** to **P2**, the time difference between the peaks of the AFE output at **P1** and **P2** can be measured to obtain the pulse transit time (PTT) [35]. The distance L between **P1** and **P2** is fixed, and L divided by the PTT gives the PWV. The shorter the PTT, the higher the blood pressure.

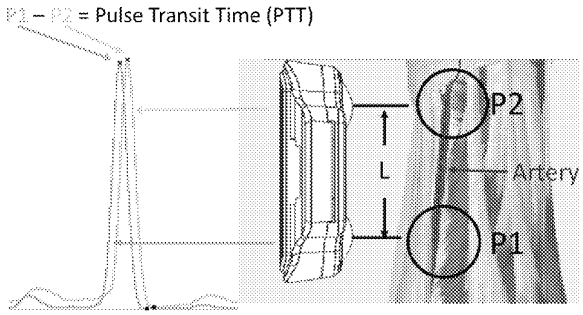


Fig. 6. In this study, the local PWV was measured on the radial artery.

D. Pulse Wave Signal Processing

The AFE output signal was sampled using a 12-bit ADC and then pre-processed using a finite impulse response (FIR) digital filter [36]. As shown in Eq.13, the pulse wave signal x sampled by the ADC is convolved with the filter coefficient bk to obtain the filtered pulse wave signal y [37]. As in Eq.14, the filter coefficients need to calculate the frequency response and window function coefficients according to different FIR filter types and the size of the convolution kernel. The related research on pulse wave analysis shows that the pulse wave frequency ranges from 0.8Hz to 30Hz [38-41]. Therefore, we use a bandpass filter (Eq.15) and set the cutoff frequencies fc1 and fc2 to 0.6 Hz and 5 Hz, respectively. Since the pulse wave represents the heartbeat signal generated by the human body, periodic or quasi-periodic, the range of 0.6Hz to 5Hz represents 36 to 300 beats per minute, this frequency range includes the normal heartbeat range [42-43], so this study selected this range as the cutoff frequency. Where ωc1 and ωc2 are the cutoff frequencies of the bandpass filter, and fc1 and fc2 are the transition frequencies, which need to be divided by the ADC sampling rate of 10kHz (Eq.16). The term w is the window function of the Kaiser window [44], as defined in Eq.17, and N is the window size chosen to be 128 in this study. The variable I0 is the second kind of modified Bessel function, as defined in Eq.18, where β can adjust the frequency domain's main lobe and sidelobe levels.

$$y[n]=\sum_{k=0}^{N-1}b_k\cdot x[n-k] \tag{13}$$

$$b[n]=w[n]\cdot h_d[n],0\le n\le N-1 \tag{14}$$

$$h_d[n]=\begin{cases}\frac{\sin(\omega_{c2}(n-N))}{\pi(n-N)}-\frac{\sin(\omega_{c1}(n-N))}{\pi(n-N)}, n\neq N\\ \frac{\omega_{c2}-\omega_{c1}}{\pi}, n=\frac{N}{2}\end{cases} \tag{15}$$

$$\omega_{c1}=f_{c1}\frac{1}{f_s},\omega_{c2}=f_{c2}\frac{1}{f_s},f_s=10{,}000Hz \tag{16}$$

$$w[n]=w_0\left(\frac{L}{N}(n-\frac{N}{2})\right)=\frac{I_0[\beta\sqrt{1-(\frac{2n}{N}-1)^2}]}{I_0[\beta]},0\le n\le N \tag{17}$$

$$I_0=\sum_{i=1}^{n}\left(\frac{(\beta/2)^i}{i!}\right)^2 \tag{18}$$

Different participants may have different pulse wave amplitudes. Therefore, it is necessary to design a method that can dynamically adjust the threshold of the pulse wave detection algorithm. Eq.19 is the calculation method of dynamic threshold, and Eq.20 is the formula of covariance (CV) used to calculate the rate of change of the signal strength in the past. Before calculating CV, determine the mean value of the signal amplitude according to Eq.21. The root mean square (RMS) is the signal amplitude level according to Eq.22. It should be noted that the window size M for the dynamic threshold calculation is different from the FIR filter's window size. This window's size will affect the dynamic threshold's response speed. In this research, the window size of the dynamic threshold calculation is set to be the same as the sampling rate, which can have an excellent dynamic adaptation to detect regular or irregular pulse waves. In our previous study [45], the window size could be set to half the sampling rate for patients with arrhythmia. The gain can adjust the dynamic threshold level, and we set it 1.1 times in this study. When the signal-to-noise ratio (SNR) is low, the waveform of the pulse wave has a smaller CV for the entire signal. Increasing the gain can reduce the false positive of peak detection.

$$\text{gradient}=\text{RMS}\cdot\frac{CV}{100}\cdot gain \tag{19}$$

$$CV=\frac{\left(\sum_{k=0}^{N-1}x_k-mean\right)^2}{M} \tag{20}$$

$$mean=\frac{\sum_{k=0}^{N-1}x_k}{M} \tag{21}$$

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$$RMS = \sqrt{\frac{\sum_{k=0}^{N-1} x_k^2}{M}} \tag{22}$$

Algorithm (1) is the pseudocode [46] of the feature detection algorithm based on a dynamic gradient. When the signal amplitude starts to rise, the pulse wave is transmitted to the sensor. When the current signal amplitude is greater than the previous value, the local maximum is updated; the signal amplitude is less than the local maximum minus the gradient, and the previous local maximum is the peak of the pulse wave. The local minimum is updated when the signal amplitude decreases and the current amplitude is smaller than the previous value. The local minimum is the pulse wave trough when the signal amplitude is greater than the local minimum plus the gradient. The algorithm only needs to update the gradient and record the local maximum, local minimum, current state, and the previous state of Eq.19 to Eq.22, which can be used for real-time pulse wave detection. Moreover, this algorithm does not need to record part of the signal segment or signal data of a specific window size in the internal memory space. The current popular peak detection algorithm needs to store the signal. Need to calculate the mean and standard deviation and store the signal that the candidate features to further search for local peaks [47-48], and an automatic multiscale-based peak detection (AMPD) algorithm [49], which requires a scaling window to detect signals stored in memory. The memory used by these algorithms varies with the signal's sampling rate. In our proposed method, which only needs to store the state of the dynamic gradient calculation, the memory used is a fixed size, which is more suitable for running on wearable devices with limited memory and performance.

Algorithm 1 Local Maximum and Minimum Detection Based on Dynamic Gradient

Inputs: sensor signal{index, value}, and gradient
is_peak, is_trough := **FALSE**
if value > local_maxima **then**
local_maxima := signal{index, value}
end if
if value < local_minimal **then**
local_ minimal := signal{index, value}
end if
if is_emission == **TRUE** and x < local_maxima – gradient **then**
is_emission := **FALSE** , is_peak := **TRUE**
falling := signal{index, value}
local_minimal := local_maxima
result := {is_peak, local_maxima}
end if
if is_emission == **FALSE** and x > local_minimal + gradient **then**
is_emission := **TRUE** , is_trough := **TRUE**
rising := signal{index, value}
local_maxima := local_minimal
result := {is_trough, local_minimal}
end if
if is_ peak != **TRUE** and is_ trough != **TRUE then**
result := { -1, the current signal is not a peak or trough }
end if
Outputs: result

The filtered pulse wave signal can be obtained, and apply the feature detection algorithm based on the dynamic gradient proposed in this research to label features, as shown in Fig. 7. The PTT was calculated from the relative time difference between the peak-to-peak (p-p) or foot-to-foot (f-f) [50] of the two pulse wave signals from **P1** and **P2**, as shown in Fig. 8.

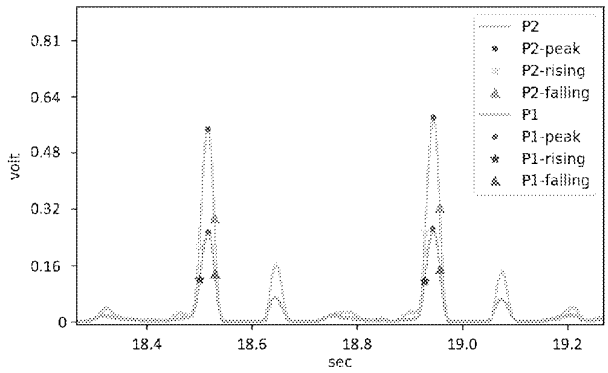


Fig. 7. The digital filter and feature detection algorithm proposed in this research is applied to the measured pulse wave results.

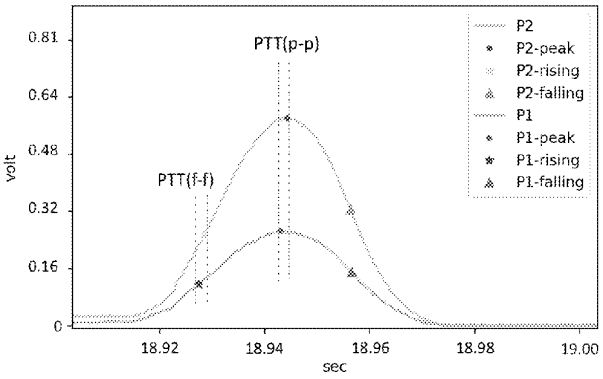


Fig. 8. Peak-to-peak and foot-to-foot PTT detection.

II. Cuffless Blood Pressure Measurement

A. Use PWV Blood Pressure Algorithm

The Bramwell-Hill (Eq. 23) and MK (Eq. 24,25) equations [51], based on hemodynamics, describe the basic principles widely used in cuffless BPM technology. The MK equation describes the relationship between PWV and BP, where D is the diameter of the radial artery, h is the wall thickness of the radial artery, ρ is the average density of human blood (1.06 g/mL [52]), E is Young's modulus, P is the pressure, and E_0 and γ are coefficients with values of 1428.7 and 0.031 respectively [53]. E_0 and γ depend on the stiffness of the radial artery and may be different in different individuals [54]. This study does not account for these differences, and uses con-

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stant E_0, γ, and ρ values from previous studies to verify the BP measurement using local PWV. Ultrasound imaging was used to measure the radial artery diameter and artery wall thickness [55] of each participant, in order to verify the estimation of BP using the MK equation. PWV can be calculated from the measured PTT and the sensor separation distance, L, as described above (Eq. 26), and, according to Eq. 27, there is a non-linear function conversion between PWV and P. The pressure in this study is the radial artery pressure. Arterial pressure changes throughout the cardiac cycle. For the relationship between PWV and P, previous studies took P as the mean arterial pressure (MAP). Since the systolic and diastolic phases take up approximately one third and two thirds of the cardiac cycle respectively [56], MAP is approximately equal to 1/3 multiplied by the systolic BP plus 2/3 multiplied by the diastolic BP (Eq. 28).

$$PWV = \sqrt{\frac{V \cdot dP}{\rho \cdot dV}} \tag{23}$$

$$PWV = \sqrt{\frac{E_{inc} \cdot h}{D \cdot \rho}} \tag{24}$$

$$E_{inc} = E_0 \cdot \exp^{\xi \cdot P} \tag{25}$$

$$PWV = \frac{L}{PTT} \tag{26}$$

$$P = \frac{\ln(\frac{PWV^2 \cdot \rho \cdot D}{h \cdot E_0})}{\xi} \tag{27}$$

$$MAP \approx \frac{SBP}{3} + \frac{DBP \cdot 2}{3} \tag{28}$$

B. Artery Parameter and Blood Pressure Measurement

In previous studies, the arterial diameter and arterial wall thickness of the Moens-Korteweg equation were assumed to be constant [57], and regression models were used to simplify the equation to estimate the MAP, SBP, and DBP [58]. The problem with this method is that individual differences in arterial parameters may reduce the accuracy of the regression model, such that the blood pressure measurements fail to meet the ISO 81060-2 criteria of a mean difference of less than 5 mmHg and a standard deviation of less than 8 mmHg when compared to an aneroid sphygmomanometer.

In this study, the participant's wrist was fixed to a holder, and the researcher operated the ultrasound imaging equipment to measure the radial artery. We used the measured diameter and wall thickness of each participant as the D and h parameters of the MK equation, and used the local PWV sensor proposed above to calculate the MAP.

III. Experiment Results and Analysis

Before executing the ISO 81060-2 protocol, this study used ultrasound imaging equipment to measure the participant's radial artery parameters. Then use our calibration-free cuffless BPM (Accurate24), combined with radial artery parameters and a mathematical model to estimate BP. As shown in the flowchart in Fig. 9, participants need to perform reference BPM (aneroid sphygmomanometer) four times to measure BP and average two adjacent reference BP to get a total of three averaged reference BP. Accurate24 performs three BP measurements. Finally, we will perform a Bland-Altman analysis to evaluate the performance of the calibration-free cuffless BPM.

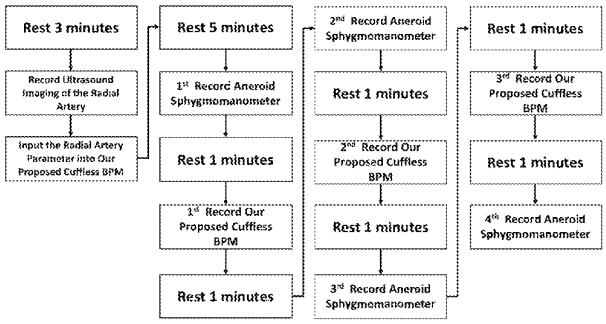


Fig. 9. The flowchart of acquiring color ultrasound images of the participant's radial artery and ISO 81060-2 protocol for non-invasive sphygmomanometers.

A. Ultrasound Imaging of the Radial Artery

Radial artery parameters can be measured using ultrasound imaging equipment [59]. We used the uSmart-3300 portable ultrasound scanner (Fig. 10a) and the L-type probe (Terason-16HL7), both produced by Terason, to measure the radial artery parameters of each participant. The participant's left arm was placed on a 30° inclined platform, the position of the wrist was fixed, and the researcher operated the ultrasound probe to collect an image of the participant's radial artery (Fig. 10b). The researcher who collected these data has good clinical practice (GCP) certification for the portable ultrasound scanner, and is qualified to make ultrasound readings for clinical trials.

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Fig. 10. a) The portable ultrasound scanner uSmart-3300 produced by Terason. b) The L-Type ultrasound probe used to collect the ultrasound image of the participant's radial artery.

The MK equation of the hemodynamics model assumes an ideal circular and straight cylinder. So we choose different measurement points on the radial artery segment. The average diameter and wall thickness measured at each point is the artery parameters for the entire artery segment.

As shown in Fig. 11, we used the L-Type ultrasound probe to measure the participant's radial artery [60]. We placed the ultrasound probe against the contact surface without pressure between 2 cm above the styloid process and 6 cm above the styloid process [61]. We reference the method of assessing radial artery in systemic disease to measure the arterial diameter and intimal thickness [62].

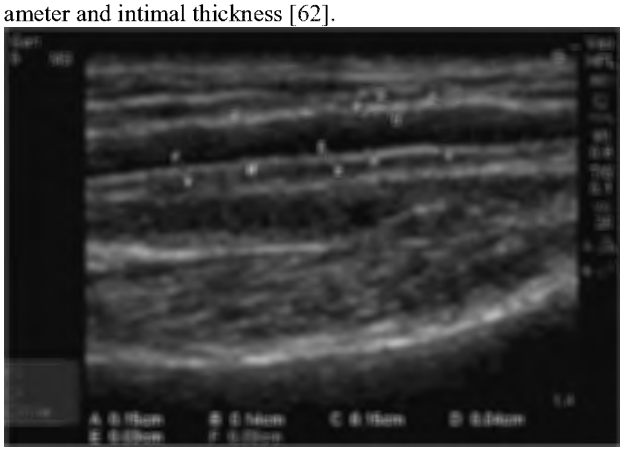


Fig. 11. Labels A, B, C are artery diameters; Labels D, E, F are intima-media thickness.

B. *Local Pulse Wave Velocity Measurement*

The measurement of local PWV uses the PTT [63] between two measurement points on an artery. Since the distance between the two measurement points in our sensor was fixed at 3 cm (Fig. 12), the PTT could be used to directly calculate the local PWV. We used Accurate24 (Fig. 13a), a novel device developed as part of this study, to measure the participants' PWV in each cardiac cycle, as described above. The two sensors of the Accurate24 measure the local PWV of the participant, as shown in Fig. 13b. It only needs to be fixed on the contact surface, and the pulse wave signal can be sensed without pressure. The dynamic threshold algorithm can track the pulse wave and detect the feature points after the participant stands still for one second. For each cuffless measurement in this study, we collected the 30-second cardiac cycle of the participants. A participant with a heartbeat of 60 beats per second can obtain 30 PWV data sets. We calculate the median of the PWV data set as the participant's PWV. The participant placed their left arm on a 30° inclined platform, and the position of the wrist was fixed at the level of the heart. The researcher used the PC-host software to connect to the Accurate24 and collect the participant's radial artery PTT, divide PTT by the distance L between the two sensors, convert it to the local PWV, and record it. Accurate24 will estimate the BP value based on the participant's arterial parameters and PWV.

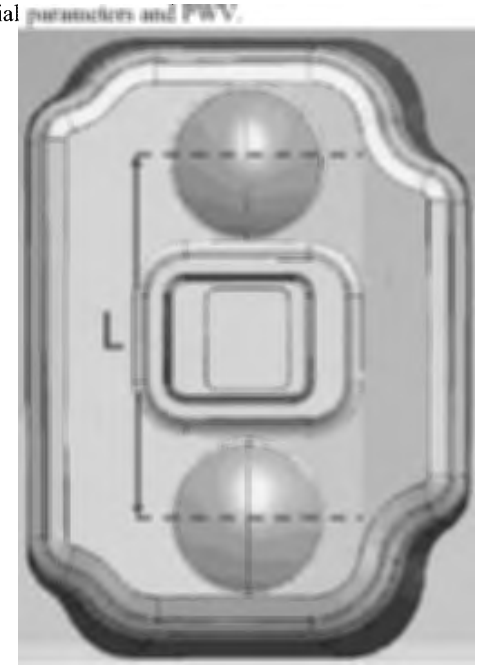


Fig. 12. The measurement of local PWV uses the PTT between two measurement points on the artery.

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Fig. 13. a) A device developed as part of this study, capable of measuring the user's PWV in each cardiac cycle. b) Each pulse wave signal between the two sensors generates a local PWV.

C. Blood Pressure Measurement

The Korotkoff sounds method is the gold standard [64] for non-invasive BP measurement. The participant's left arm is cuffed, and a stethoscope is placed inside the cuff (Fig. 14a). The cuff is pressurized until the arterial pulse cannot be heard. The vent valve releases gas at a rate of 3 to 5 mmHg per second. When the first sound of the pulse beating is heard, the reading on the pressure gauge (Fig. 14b) is the participant's systolic BP. When the sound of pulse beating is no longer audible, the reading on the pressure gauge is the diastolic BP of the participant. The experiment setup is shown in Fig. 14. We used a Welch Allyn 5098-27 DS66 trigger aneroid sphygmomanometer.



Fig. 14. Welch Allyn 5098-27 DS66 trigger aneroid sphygmomanometer. a) The participant's left arm is cuffed, and a stethoscope is placed inside the cuff. b) A pressure gauge is used to read the participant's systolic BP.

We sampled the participant's arterial parameters, used Accurate24 to sample the participant's local PWV, used the MK equation to calculate BP, and compared the BP calculated from the MK equation to that measured using the aneroid sphygmomanometer. Since the aneroid sphygmomanometer can only measure SBP and DBP, we used Eq. 29 to calculate MAP [65]. Conversely, the pressure calculated by the MK equation approximates MAP, so we used Eq. 30 to estimate the SBP and DBP from the calculated MAP [66]. In this study, we used a k factor of 0.76. We then compared the BP measured by the aneroid sphygmomanometer with the BP calculated using the MK equation.

$$MAP = \frac{SBP + (2 \cdot DBP)}{3} \tag{29}$$

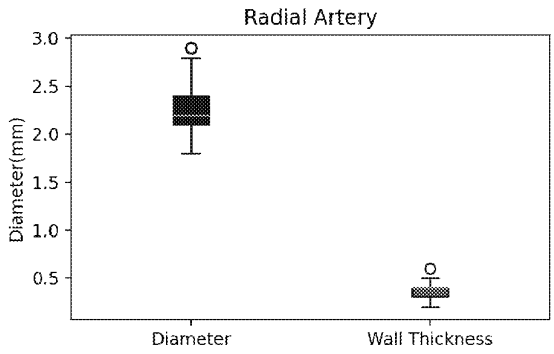
$$\begin{cases} DBP = MAP \cdot k \\ SBP = MAP + (1-k) \cdot DBP \end{cases} \tag{30}$$

D. Result

Table 2 is the statistical data of the physiological characteristics of the 32 participants, including basic information, arterial parameters, and BP measured by both local PWV (Accurate24), and an aneroid sphygmomanometer. Fig. 15 and Fig. 16 are boxplots of the radial artery diameter, the wall thickness, and the PWV of the participants, respectively. Fig. 17 shows a box plot of BP calculated using the MK equation, and the BP measured by an aneroid sphygmomanometer.

Table.2 Subject characteristics.

	Subjects (n = 32)
Gender (M/F, n)	19/13
Mean age (range)	43 (23-74)
Artery diameter (mm)	2.35±0.55
Artery wall thickness (mm)	0.4±0.2
PWV (m/s)	4.25±1.33
ReferenceSBP (mmHg)	129±25
ReferenceMAP (mmHg)	97±22
ReferenceDBP (mmHg)	81±21
Accurate24SBP (mmHg)	124±24
Accurate24MAP (mmHg)	96±19
Accurate24DBP (mmHg)	82±18



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Fig. 15. Box plot of the radial artery diameter and wall thickness.

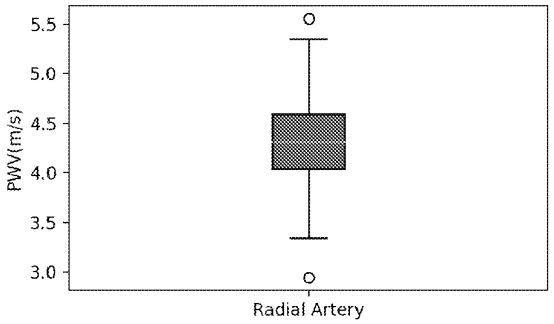


Fig. 16. Box plot of the PWV of the participants measured by the sensor.

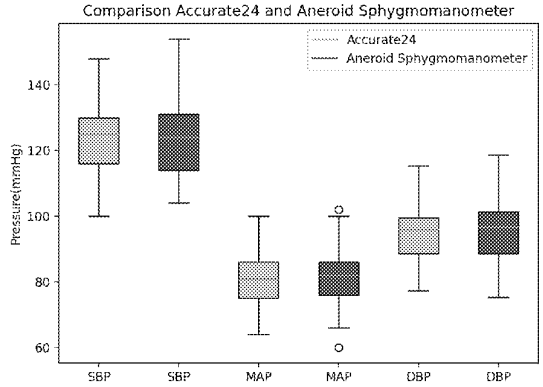


Fig. 17. Box plot of BP of 32 participants, using MK equation to estimate BP, compared with reference BP. SBP – systolic blood pressure, MAP – mean arterial pressure, DBP – diastolic blood pressure.

ISO 81060-2 is a non-invasive electronic sphygmomanometer clinical standard. The standard requires that the mean difference between the BP measured by the tested sphygmomanometer and the reference BP measured by the aneroid sphygmomanometer should be less than 5 mmHg. In addition, the standard deviation should be less than 8 mmHg. The aneroid sphygmomanometer and the tested sphygmomanometer need to be used alternately 4 and 3 time respectively. The i^{th} measurement from the tested sphygmomanometer needs to be compared with the average value of the i^{th} and $i+1^{th}$ measurements of the aneroid sphygmomanometer. The mean difference and standard deviation are calculated according to Eq. 31 and Eq. 32:

$$md = \frac{1}{n} \cdot \sum_{i=1}^{n} (BP_{SUT_i} - BP_{REF_i}) \tag{31}$$

$$std = \sqrt{\frac{1}{n} \cdot \sum_{i=1}^{n} (BP_{SUT_i} - BP_{REF_i})^2} \tag{32}$$

where BP_{SUT_i} is the BP measured by the tested sphygmomanometer and BP_{REF_i} is the reference BP measured by the aneroid sphygmomanometer.

We used the Bland-Altman plot statistical method [67] to compare the BP measured using Accurate24 and the aneroid sphygmomanometer. Fig. 18 shows the Bland-Altman plot of SBP, with a mean difference of -0.63 mmHg and a standard deviation of ±5.14 mmHg. Fig. 19 shows the Bland-Altman plot of MAP, with a mean difference of -0.97 mmHg, and a standard deviation of ±3.54 mmHg. Fig. 20 shows the Bland-Altman plot of DBP, with a mean difference of -1.14 mmHg, and a standard deviation of ±4.08 mmHg. These results demonstrate that the BP calculated using our method conforms to the ISO 81060-2 criteria of a mean difference ≤ 5 mmHg and a standard deviation ≤ 8 mmHg. Therefore, the calibration-free cuffless BPM proposed in this study complies with ISO 81060-2. This result indicates that this device could be used in a hospital intensive care unit (ICU) or in a remote health care setting, along with prior measurements of the patient's arterial parameters, to perform beat-to-beat BP monitoring.

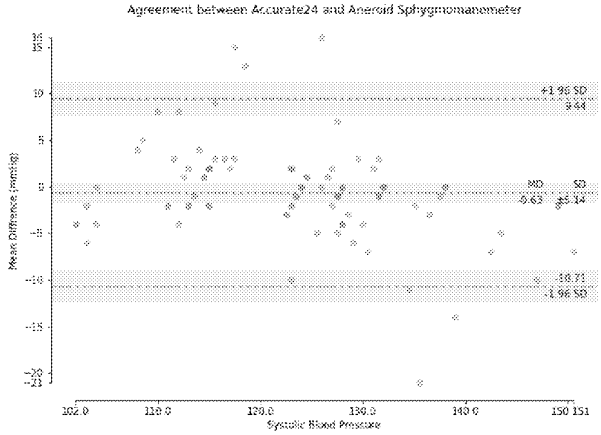


Fig. 18. Bland-Altman plot of systolic blood pressure.

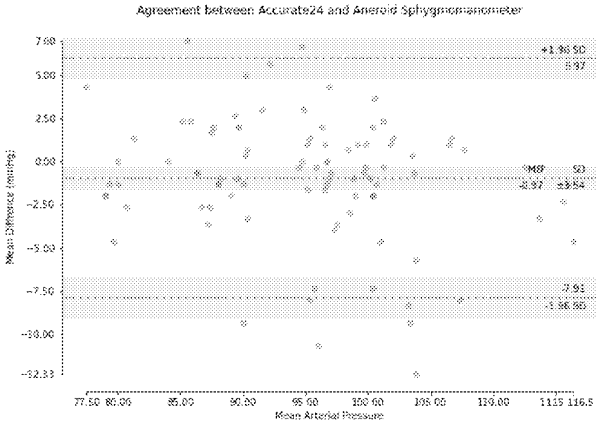


Fig. 19. Bland-Altman plot of mean arterial pressure.

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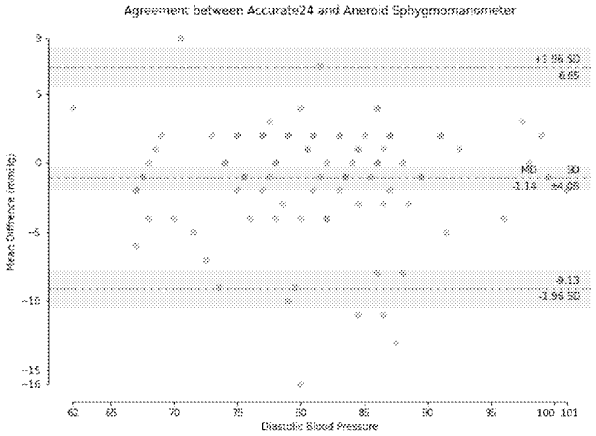


Fig. 20. Bland-Altman plot of diastolic blood pressure.

E. Limitations and Future Works

Although the calibration-free cuffless BPM proposed in this study has verified its compliance with ISO 81060-2 through Bland-Altman analysis based on the experimental results of 32 participants, some limitations need further improvement for feasibility in long-term BP monitoring scenarios. First, for short-distance PWV measurement in the arterial segment, it is necessary to record a set of PWV and calculate the median as the PWV of the participant. It is because small changes in PTT will cause the error to be amplified when converting to PWV, which will cause a greater error when using hemodynamics to do BP estimation. The measurement techniques and algorithms must be optimized to reduce the error of beat-to-beat PTT measurement [68]. Secondly, the BP estimate of the MK equation is proximate to MAP. This study used the proportional coefficient to estimate SBP and DBP using MAP to get a larger standard deviation. It is because the pulse pressure (PP) of each individual is different. The PP of an individual with arteriosclerosis will be higher than that of a healthy person [69]. In addition to the BP estimation of the MK equation, it is still necessary to develop the technique of PP estimation. Combine the values of MAP and PP to make the estimation of SBP and DBP of calibration-free cuffless BPM more accurate. Finally, we still need to do more research on Young's modulus of the MK equation. This coefficient makes the relationship between BP and PWV nonlinear. Although we use the coefficients obtained from previous animal experiments for calculations, different individuals have different arterial stiffness in practical applications. In the future, non-invasive equipment is needed to detect the participant's arterial stiffness and improve the BP measurement accuracy of calibration-free cuffless BPM. Furthermore, after improving this research, the effective number of participants will be increased to 85 or more.

IV. Conclusion

This study discusses the principles of current wearable cuffless BP measurement technology and describes the shortcomings that need to be addressed. We used a novel local PWV measurement sensor and ultrasound imaging equipment to collect participants' arterial parameters and estimate their BP based on the Moens-Korteweg equation. In contrast to other cuffless BPM approaches, we explicitly account for individual differences in arterial parameters. We also verified that local PWV and ultrasound arterial parameter measurements can be used to directly calculate BP using the Moens-Korteweg equation. Furthermore, our proposed method does not require calibration against a standard BP measurement. Thus, this study demonstrates proof-of-principle for a novel non-invasive calibration-free cuffless BP estimate technology. Our piezoelectric sensor uses passive sensing without external power consumption. The size of the device can be small, which is suitable for long-term BP monitoring. The low-cost and highly sensitive sensor, which is conducive to integration into consumer electronic products such as wearable devices and remote health care monitors, could be used as a primary ambulatory BP monitoring tool in the future.

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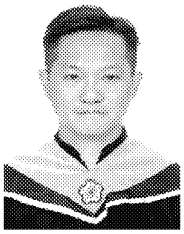


Cheng-Yan Guo received his M.S. from National Taiwan University College of Medicine in 2017, and B.S. from the National Taichung University of Education in 2014. He is currently Director of R&D at Accurate Meditech Inc. His research inter-ests include software testing, robotics, computer vision, bio-signal processing, and embedded systems.



Chia-Chi Chang graduated from National Taiwan University of Science and Technology with a Master's of Computer Science in 2019 and a Bachelor's of Science in 2015. Her research ranges from machine learning and automation technology to digital learning and user experience design.

She has been working as the packaging engineer at AMD since November 2019. The job requires her to investigate and implement innovative technologies and evaluate ball grid array distribution rules when designing IC chips. Her specialty is in the development of machine learning algorithms for packaging design and simulation automation.



Kuan-Jen Wang Received his M.S. in 2021 from Department of Business Management at Tatung University and B.S. in 2006 from Moorpark College in California, U.S.A.

His research interests researching raw components and product integration and production, also bio-signal sensor development. His experience has the product integration, production, biomedical signal sensor development of healthcare, medical devices, and technology surveys.



Tung-Li Hsieh (M'19) received a M.S. degree in mechanical engineering from National Cheng Kung University, Tainan, Taiwan and a Ph.D. in Department of Photonics, National Sun Yat-sen University: Kaohsiung, Taiwan

Since 2016, he has been an assistant professor at the General Education Center, Wenzao Ursuline University of Languages. His research interests include automatic control, signal processing, and opto-Electromechanical Integration.

Mr. Tung-Li Hsieh's patents include a bone conduction audio transmission device, a sound transmission device, a sound laser control lock device, a tooth vibration mode sound transmission device, and a protein battery.

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
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)*
K222658

Device Name
Accurate 24 Non-invasive blood pressure monitor

Indications for Use *(Describe)*
The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

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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12. Substantial Equivalence Discussion

12.1 Summary Statement

The Accurate 24 Non-invasive blood pressure monitor is as safe and effective as the predicate device BB-613WP. The Accurate 24 Non-invasive blood pressure monitor has the same intended uses and similar indications, technological characteristics, and principles of operation.
In addition, the minor technical differences between the Accurate 24 Non-invasive blood pressure monitor and its predicate devices raise no new issues of safety or effectiveness.
The non-clinical data support the safety of the device, and the hardware and software verification, and validation demonstrate that the Accurate 24 BPM device should perform as intended in the specified use conditions. The clinical testing demonstrated that the Accurate 24 BPM device is accurate according to the applicable ISO 81060-2-2018 and IEEE Std 1708a:2019 standard. Thus, the Accurate 24 BPM is substantially equivalent to the predicate.

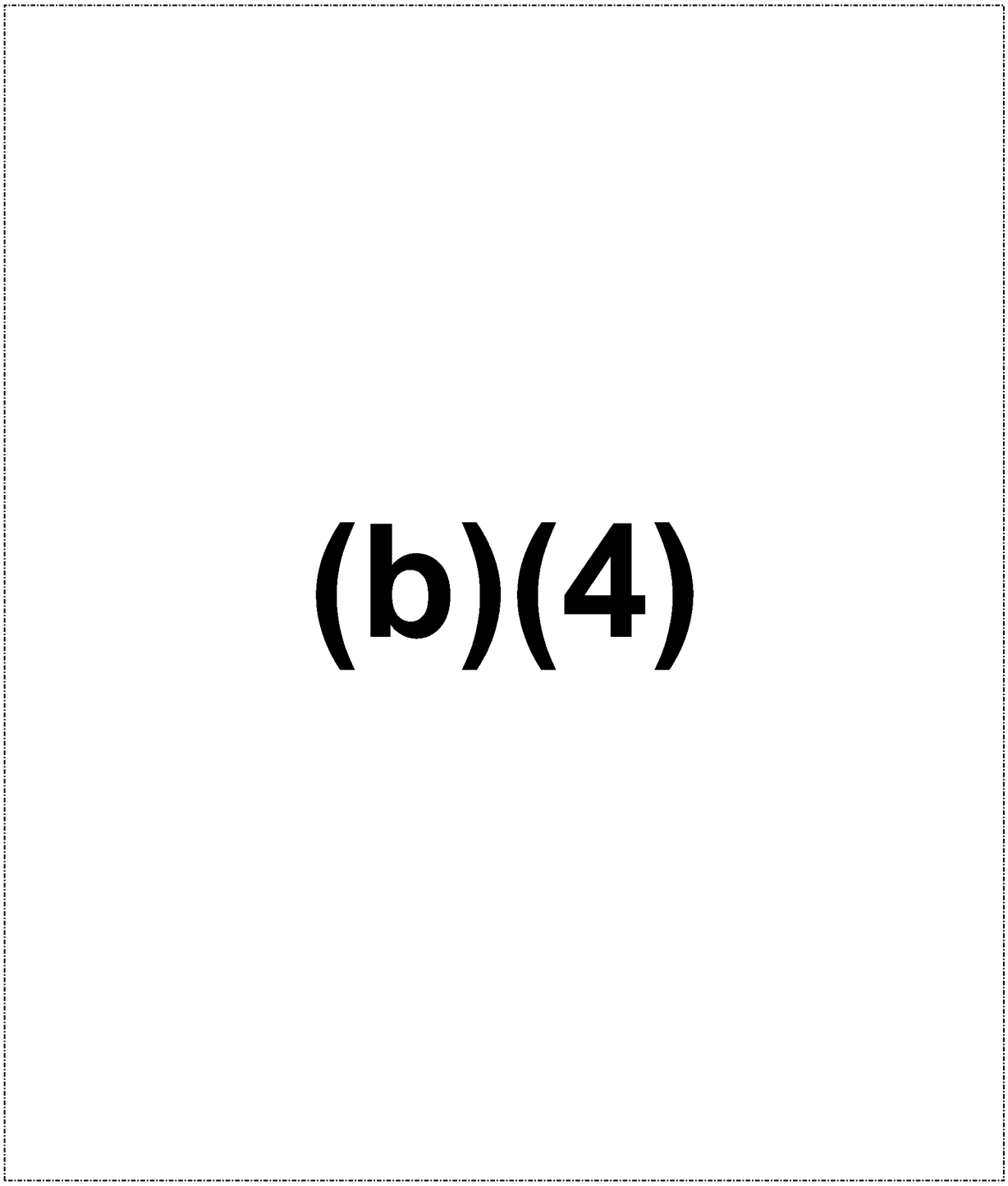
12.2 Comparison Data

Table 12-1 provide comparison data for the purpose of demonstrating substantial equivalence between the Model Accurate 24 BPM (new device), and the Model BB-613 WP (predicate device)

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12.3 Substantial Equivalence Tree

The 510(k) "Substantial Equivalence" Decision-Making Flowchart, as outlined in FDA's Guidance Document" The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)'s] dated July 28, 2014, was used to confirm the substantial equivalence of the proposed device to the predicate devices described. The completed Decision-Making Flowchart from FDA's Guidance Document is presented in Figure #1, and was utilized to

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determine that the proposed Accurate 24 BPM is substantially equivalent to the predicate device. The answers to the Decision Questions are provided in Table#12-2, bellows:

Table #12-2 Answer to Decision-Making Flowchart Questions	
Decision-Making Flowchart Question	**Summary Response**
1. Is the predicate device legally marketed?	(b)(4)
2. Do the devices have the same intended use?	
3. Do the devices have the same technological characteristics?	
4. Do the different technological characteristics of the devices raise different questions of safety and effectiveness?	
5a. Are the testing methods acceptable?	
5b. Does the data demonstrate equivalence and support the indications?	

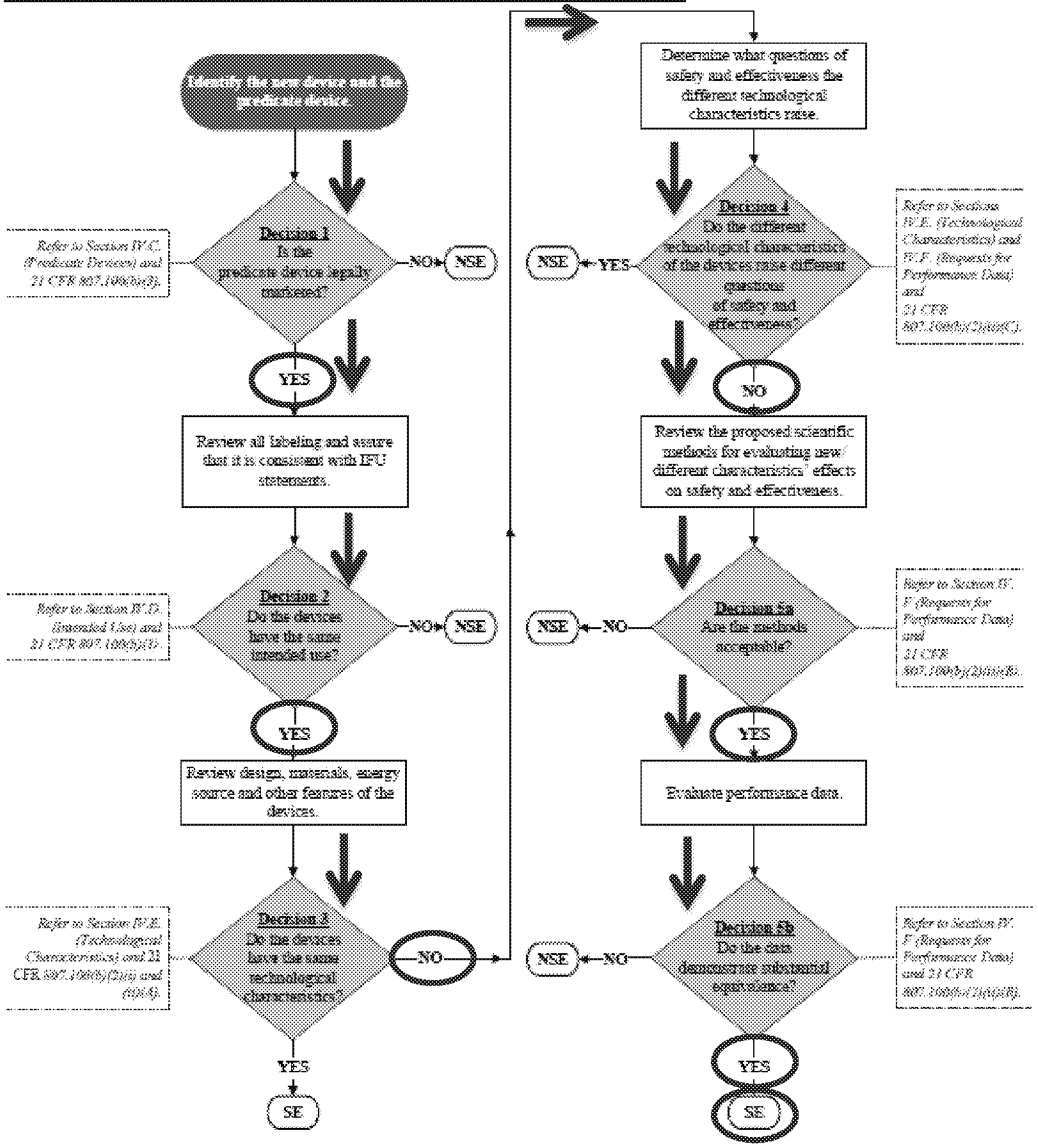
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Figure #1 Decision-Making Flowchart

Contains Nonbinding Recommendations

Appendix A. 510(k) Decision-Making Flowchart



SE = "Substantially Equivalent"
NSE = "Not Substantially Equivalent"
IFU = "Indications For Use"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.

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Produkte
Products

Prüfbericht - Nr.: *Test Report No.:*	(b)(4)
Auftraggeber: *Client:*	
Gegenstand der Prüfung: *Test Item:*	
Bezeichnung: *Identification:*	
Anlieferungszustand: *Delivery condition:*	
Prüfort: *Testing location:*	
Prüfgrundlage: *Test specification:*	
Prüfergebnis: *Test result:*	

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 5/9/2023 4:58:30 PM
To: stanley@accurate-meditech.com
CC: DCCLetters@fda.hhs.gov
Subject: K222658/S002 Acknowledgement Letter
Attachments: K222658-S002-Acknowledgement Letter.pdf

May 9, 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.

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

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Acknowledgement Letter

05/09/2023

Wang Kuan Jen, General Manager
Accurate Meditech Inc.
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.,
New Taipei City,
241406 TAIWAN

Dear Wang Kuan Jen:

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: K222658/S002
Received: 05/02/2023
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

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

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10. Executive Summary

This Traditional 510(k) Premarket Notification is being submitted to obtain FDA clearance to introduce a non-invasive blood pressure monitor, namely the Accurate 24 Non-invasive blood pressure monitor, into US commercial distribution.

The Accurate 24 Non-invasive blood pressure monitor has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device and display, data storage and sensor application are different, but it has been validated. In addition, the minor technical differences between the Accurate 24 Non-invasive blood pressure monitor and its predicate devices raise no new risk issues and decrease effectiveness.

10.1 Indications for Use

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

10.2 Subject Device Information

Trade/Device Name	**Accurate 24 Non-invasive blood pressure monitor**
Model	Accurate 24 BPM
Common Name	Non-invasive blood pressure monitor
Regulatory Classification	Class II 870.1130 Noninvasive blood pressure measurement system
Submission type	Traditional 510(k)
Product Code	DXN

10.3 Predicate Device Information

Predicate Device	**Sponsor: Biobeat Technologies Ltd.** Device: BB-613 WP 510(K) Number: K190792

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

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10.4 Comparison to the Predicate Device

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A more detailed description of the device including drawings, photographs/computer renderings, FDA product code, and other information can be found in Section 11, Device Description. A summary of Substantial Equivalence and a completed Decision Tree can be found in Section 12, Substantial Equivalence Discussion. Lastly, results of bench testing that support conformance to FDA recognized standards can be found in Section 18, Performance Testing (Bench).

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

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Accurate Meditech Inc.-June 9 2023, Response

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FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGIC HEALTH
Office of Product Evaluation and Quality

Memo:	Pre-submission Clinical Review/510(k) Clinical Consult
Date:	December 1, 2022
From:	Bindi K. Shah, MD
To:	Meaghan Erlewein, Lead Reviewer
	Stephen Browning, AD Blood Pressure and Hemodynamic Team
Subject:	K222658/S001
	Accurate Meditech Inc
	Accurate 24 Noninvasive Blood Pressure Monitor

(b)(5)

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510(k) Cover Letter

May 08, 2023

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

Re: This refuse-to-accept (RTA) for K222658 response is being submitted for the Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

(b)(4)

We have contacted Douglas Herrington, the principal consultant of Herrington Consulting LLC, to act as our official correspondent. He should be contacted directly for any questions, comments or issues arising from review of this submission.

Sponsor & Manufacturing Address:

Accurate Meditech Inc
8F-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.
Sanchong District
New Taipei City 241406
Taiwan (R.O.C.)
Phone: +886.937.987.729
Fax: +886.2.2999.1196

Official Contact Name

Douglas Herrington
No 64, Haijing 3rd St
Sanzhi District
New Taipei City 252, Taiwan (R.O.C.)
Telephone: 1.248.369.5564
Fax: 1.877.881.4412
E-mail: **(b)(6)**

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

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Sincerely,

(b)(6)

Kuan-Jen, Wang
CEO, Accurate Meditech Inc.

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

January 4, 2022

Accurate Meditech Inc.
Kuan Wang
General Manager
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.
New Taipei City, 241406
Taiwan

(b)(4)

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

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Journal of Biomedical Optics

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Intraoperative blood vessel detection and quantification: a Monte Carlo study

Amal Chaturvedi
Shetha A. Shukair
Mayank Vijayvergia
Paul Le Rolland
Jonathan W. Gunn
Hariharan Subramanian

SPIE.

Amal Chaturvedi, Shetha A. Shukair, Mayank Vijayvergia, Paul Le Rolland, Jonathan W. Gunn, Hariharan Subramanian, "Intraoperative blood vessel detection and quantification: a Monte Carlo study," *J. Biomed. Opt.* 23(6), 067002 (2018), doi: 10.1117/1.JBO.23.6.067002.

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Journal of Biomedical Optics 23(6), 067002 (June 2018)

Intraoperative blood vessel detection and quantification: a Monte Carlo study

Amal Chaturvedi,* Shetha A. Shukair, Mayank Vijayvergia, Paul Le Rolland, Jonathan W. Gunn, and Hariharan Subramanian
Briteseed LLC, Chicago, Illinois, United States

Abstract. With better surgical outcomes, quicker recovery times, decreased postoperative pain, and reduced scarring at the surgical site, the application of minimally invasive surgery (MIS) has gained a lot of prominence in the last 30 years. This change in surgical practice has taken away the ability of a surgeon to palpate for the presence of a blood vessel as would occur in an open procedure. They instead must rely on a laparoscopic video camera feed that unfortunately cannot detect the presence of a blood vessel hidden beneath tissue. In certain scenarios, a surgeon can accidentally cut a blood vessel, which can lead to severe, even fatal, complications. Here, we show that by adding a near-infrared LED and a photodiode onto the opposing jaws of laparoscopic graspers, blood vessels buried under tissue can be detected. We show the results of Monte Carlo simulations to support our theory that the blood vessels ranging from 3 to 6 mm buried under up to 1 cm of tissue can be detected and quantified. This technology could be added to already existing laparoscopic tools that have limited surface areas on the jaws to assist surgeons during MIS procedures. *© 2018 Society of Photo-Optical Instrumentation Engineers (SPIE)* [DOI: 10.1117/1.JBO.23.6.067002]

Keywords: smart surgery; intelligent grasper; minimally invasive surgery; laparoscopic tools.

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1 Introduction

The application of minimally invasive surgery (MIS) techniques has gained a lot of prominence in the last few decades. MIS techniques offer better surgical outcomes, quicker recovery times, decreased postoperative pain, and reduced scarring at the surgical site.[1–4] However, with the increased adoption of MIS procedures, some challenges have emerged. Surgeons are unable to feel for the natural pulsation of blood flow within blood vessels making the identification of tissue-embedded blood vessels highly dependent on the experience of the surgeon.[5] The challenges not only include the detection of hidden blood vessels but also the perioperative management of bleeding complications that arise. Inadvertent cuts into vasculature cause billions of dollars as nonreimbursable amount in hospital costs in the United States every year [assuming a 1% incidence rate (see Opitz et al.) and $210,000 cost per incidence]. Studies also indicate that the most common cause for conversion during laparoscopic surgeries is excessive hemorrhage.[6] Patients who suffer vascular injury during surgery may face an increased risk of developing an infection; decreased quality of life following discharge; or, in up to 32% of cases, death.[7] Moreover, those who do survive have an average added cost of care of hundreds of thousands of dollars due to corrective procedures and a hospital stay of multiple additional days.[8,9] To assist surgeons in preventing these major complications, there is a need for advanced tools that can identify the presence of blood vessels that must be avoided or strategically divided in real time.

There are already existing modalities, such as ultrasound and fluorescence angiography, for intraoperative blood vessel visualization, but they either lack the desired speed and resolution or are too bulky to be easily integrated into the surgical workflow.[10–12] Near-infrared (NIR) imaging has been pursued in breast reconstruction and colon surgery to offer information about the microvasculature, but offers low sensitivity and requires expensive contrast agents.[13] The main limitations of existing vascular detection systems include the inability to quantitate vessel metrics, added complexity during surgery, and cost. Importantly, advanced MIS tools are increasingly being miniaturized to increase maneuverability and allow access into tighter spaces during laparoscopic procedures.[14,15] In addition, manufacturers have been advised by surgeons to increase multifunctional product offerings to further streamline costs and simplify procedures.[16,17]

Briteseed has developed a technology that addresses these problems by exploiting the pulsatile light absorption characteristics of hemoglobin in blood; the technological basis of pulse oximetry, which is the standard of care for monitoring a patients' blood oxygen saturation. However, pulsatile light absorption has never been applied to intraoperative use for the real-time detection and analysis of vasculature. We have developed a light absorption-based technology that provides identification and characterization of vasculature during MIS procedures. Whereas pulse oximetry uses pulsatile light absorption properties of hemoglobin to provide blood oxygen saturation, our device uses pulsatile blood flow to identify and characterize blood vessels without the need of a contrast agent. We also created a prototype of the grasping device and added an LED and a photodetector on its opposing jaws. Importantly, the technology is simplified to contain a single LED and a photodetector on the opposing jaws in order to easily integrate them into MIS tools

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with limited surface area such as a Maryland dissector (the jaws are about 22.4 mm long and have an average width of about 3 mm), right angle dissector (jaws are 32 mm long and have an average width of about 3.75 mm) or a laparoscopic stapler. These tools are typically used to dissect different tissues in various procedures, where it is critical to characterize the blood vessels.

We present the results of extensive Monte Carlo simulations to validate the theoretical foundation of this technology. We also present *ex vivo* experiment results to demonstrate feasibility of this technology using a prototype of the laparoscopic grasper. The prototype was first tested on blood vessel phantoms with and without porcine tissues and then on *ex vivo* porcine blood vessels. The results from these studies indicate that the system is able to quantify blood vessels between 3 and 6 mm in diameter buried under tissues as thick as 1 cm. This quantification can be accomplished with minimal hardware components, allowing for the design of sensing-capable tools of nearly any size.

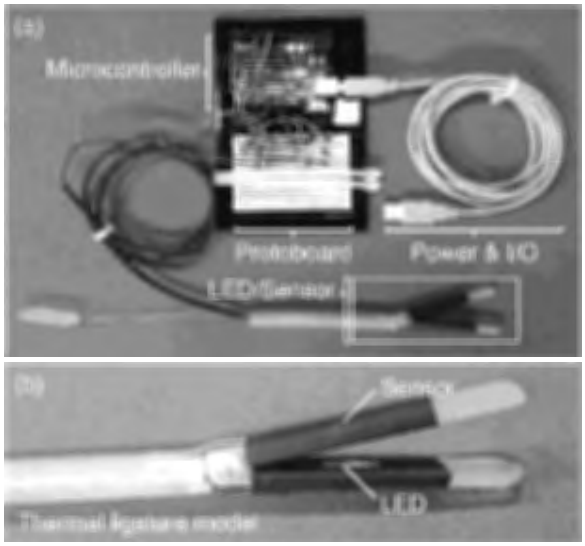


Fig. 1 The prototype of the smart grasper laparoscopic tool. One jaw of the prototype has an LED and the other has a photodetector on it.

2 Theory

2.1 *Pulse Oximetry*

Pulse oximetry is a technique used to estimate the heart rate and the oxygen saturation of the blood noninvasively. In traditional settings, a pulse oximeter has an LED with two wavelengths, where one is in the visible range (660 nm) and the other is in NIR range (910 nm) on the one side and a photodetector on the other side. These wavelengths have different absorption properties based on the oxygenated and deoxygenated fractions of blood. The device is clipped onto the finger or ear of the person, where it shines light on that body part. The light is attenuated by the skin, underlying tissue and blood present in the capillaries. The attenuated light received by the photodetector is mainly related to the amount of tissue and the oxygen saturation of the blood. In time, the signal received by the sensor is sinusoidal because of the periodic expansion and contraction of the arterioles. The frequency of this signal gives the heart rate and the ratio of the normalized standard deviation of the absorption values of the two wavelengths gives the oxygen saturation of the blood. Pulse oximeters are widely used in different clinical settings and have validated the underlying principle of light absorption by periodic blood flow. The underlying technology behind our device is based on the pulsatile light absorption of arterial blood, similar to the technology behind pulse oximeters.[18]

2.2 *Prototype Design*

To test the technology in the *ex vivo* setup, we created a prototype of the smart grasper laparoscopic tool to. We added an LED (OSRAM SFH4441) with wavelength 940 nm and a photodetector (APMKorea DDN2090M) on the opposing jaws of the prototype (Fig. 1) to use the tool in the transmission mode. The prototype, which provides the initial proof of concept, utilizes infrared light to measure the presence and size of blood vessels. The LED and sensor are controlled by an Arduino Uno 8-bit AVR microcontroller board. The conditioning circuitry of the photodetector is made of a transimpedance amplifier and a noninverting amplifier of gain $K = 6$ (both Texas Instruments OPA333). The anode of the photodetector was biased to 0.3 V. The LED was driven with a pulse width modulation coming from the Arduino Uno at a frequency of 244 Hz through an Infineon IRLML0040 MOSFET transistor. It was then filtered through a passive RC low-pass filter (cut-off frequency $F_c = 72$ Hz, $R = 100\ \Omega$, $C = 22\ \mu$F) to prevent the pulsation of the LED to interfere with the readings of the photodetector. The light from the LED undergoes attenuation (absorption and scattering) that is dependent on the optical characteristics of the tissue and the blood it encounters. The sensor on the opposing jaw then receives this attenuated light. The received light is clearly a function of the size of the blood vessel it goes through. The output of the detector is fed to a computer through the USB cable. A custom GUI was developed in MATLAB® to collect, display, and analyze the signals.

2.3 *Principle of Operation*

As mentioned earlier, the underlying technology is based on the pulsatile absorption of transmitted light by the arterial blood. While pulse oximeters are used to measure blood oxygenation by quantifying light absorption at two different wavelengths (e.g., 660 and 910 nm) in capillary beds, the same light absorption technology has not yet been applied to determine blood vessel presence or measure vessel diameter. In a general optics-based setup, the amount of light attenuation is used as a marker to understand the optical properties of the media. Beer–Lambert law states that the light gets attenuated exponentially with a linear increment in the distance it travels through an absorptive medium. More specifically, it states that if a light of a given intensity (I_0) passes through a medium of a given length (L), the intensity of the light received at the other end (I) will be $I = I_0 e^{-\alpha L}$ with attenuation coefficient α. But in case of pulse oximetry or our setup, Beer–Lambert law is not valid as the light is also affected by the scattering caused by tissue (difference in the refractive index between cellular organelles and cellular fluid and between intracellular and extracellular fluids) and blood (difference in refractive index between red blood cells and plasma).[19–21] For this reason, the Beer–Lambert law equation cannot be directly used to estimate the size of the blood vessel. A modified Beer–Lambert law was introduced for the scattering media[22] and since its introduction has been a common technique used in the field of NIR tissue spectroscopy. It uses a mean path length of the detected photons instead of a direct

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source–detector distance.[23] In our method, we show that the change in the signal amplitude relative to its average can be used to estimate the size of the absorbing medium (pulsing arteries).

As shown in Fig. 2, the transmitted light (I) contains both a pulsatile component (I_{AC}) i.e., periodic light absorption by the blood flow within the vessel, and a baseline component (I_{DC}), i.e., static light absorption and scattering mainly by the surrounding tissues. To quantify the amount of change and the baseline of the signal, we take standard deviation and the average of the received signal, respectively. We call the standard deviation as the AC and the average as the DC, which are commonly used terms in the field of pulse oximetry.[18] It is assumed that the larger the blood vessel, the higher the absorption and lower the DC will be; and since there is a higher amount of blood volume changes, the AC, at the same LED brightness, will be smaller. In short, the fraction AC/DC should be inversely proportional to the blood vessel diameter. The system uses

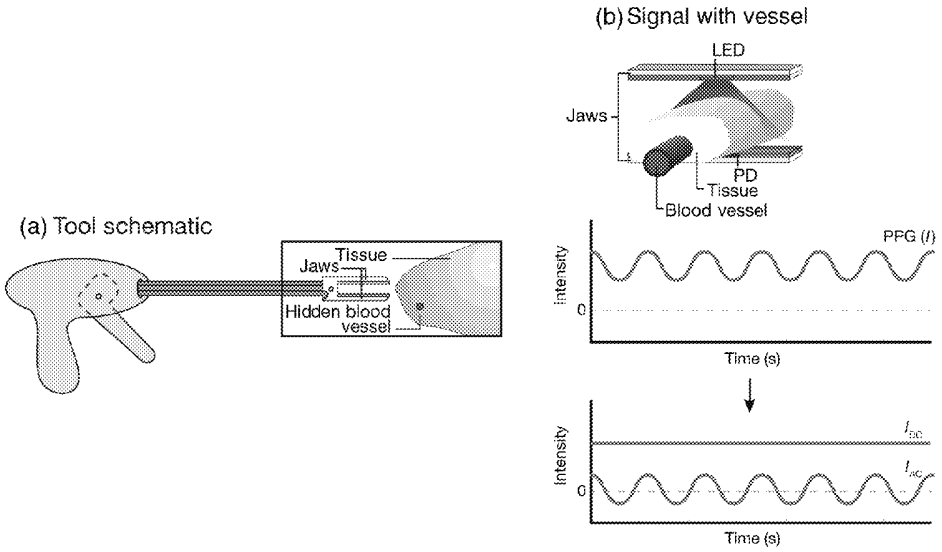


Fig. 2 The measurement setup used in this study. (a) An LED and a photodetector are added to the opposing jaws of a laparoscopic grasper. (b) The light received by the photodetector (PD) has both a pulsatile (I_{AC}, created by periodic blood flow) as well as a baseline (I_{DC}, mostly due to the tissue) component.

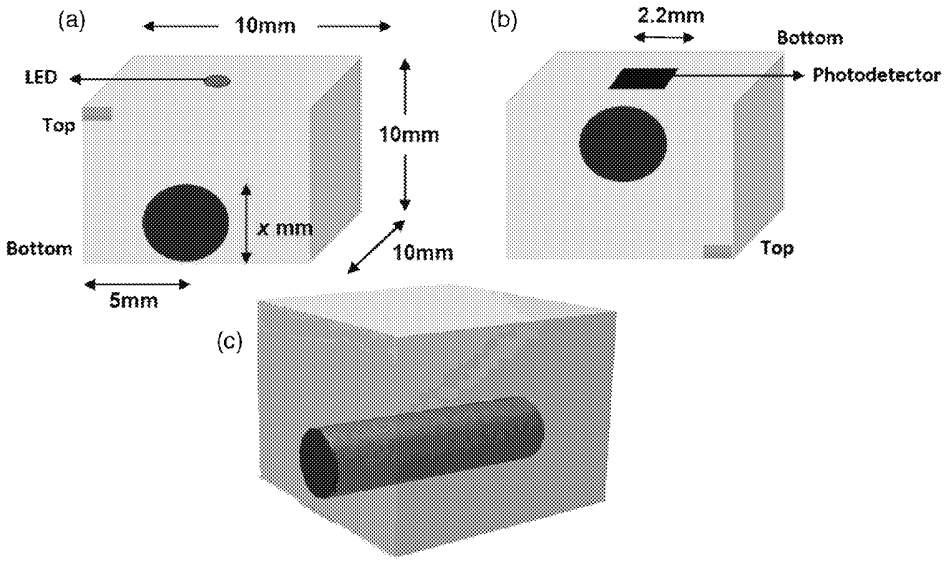


Fig. 3 A 3-D tissue block of size $10 \times 10 \times 10$ mm^3 was modeled. (a) An LED with wavelength $\lambda = 940$ nm was placed at center of the top surface of the block. The light from the LED undergoes some attenuation that is dependent on the optical characteristics of the tissue(s) and size of the blood vessel traversed by the photons. (b) The attenuated light that reaches the other side is recorded by the photodetector under the tissue block. The block is inverted upside down (b) to show the placement of the photodetector under the tissue block. The 3-D block in (c) shows how the cylindrical-shaped blood vessel runs through the tissue in a given depth.

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unique hardware and software to extract the I_{AC} and I_{DC} from the transmitted light and then analyze them to quantify the blood vessel size. Thus, our system is designed to selectively quantify the size of a blood vessel regardless of the type or thickness of tissue surrounding it. It is important to note here that the LED brightness plays a crucial role here. Too much or too little brightness can affect the resolution of I_{AC} and for that reason, the brightness of the LED should be within an optimal range. For that purpose, we have developed a custom automated algorithm that updates the LED brightness until the signal received by the photodetector is five times above the noise floor. The noise floor is defined as the reading of the photodetector when the LED is completely turned off.

2.4 *Monte Carlo Simulation Validation*

Monte Carlo simulations serve as the benchmark in understanding the probabilistic behavior of light traversal inside a biological medium. Being simulations, they are not corrupted by real-world artifacts and therefore provide an unbiased understanding of the system under consideration. To work on the simulations, we created a 3-D model, where a cylindrical blood vessel was embedded within a thick block of tissue. An LED and a photodetector were placed at the top and bottom of the tissue block, respectively. The setup shown in Fig. 3 was used for these simulations.

We launched 150-million photons into the tissue block, orthogonal to the top surface of the block, with and without the blood vessel to simulate the irradiated LED light. The photons were launched in packets, and each packet was tracked individually as it moved through different voxels. The direction and weight of the photon packet were updated at each iteration depending on the scattering and absorption properties of that voxel. The tracking was discontinued once the weight of the packet went below a predefined threshold or it escaped from one of the surfaces of the block. If the photon escaped from the bottom surface within the coordinate region of the photodetector, computed using basic geometry and trigonometry, it was added to the count of the detected photons. In the end, the total number of detected photons formed the photodetector output for a one-time snapshot. This process (Fig. 4) was

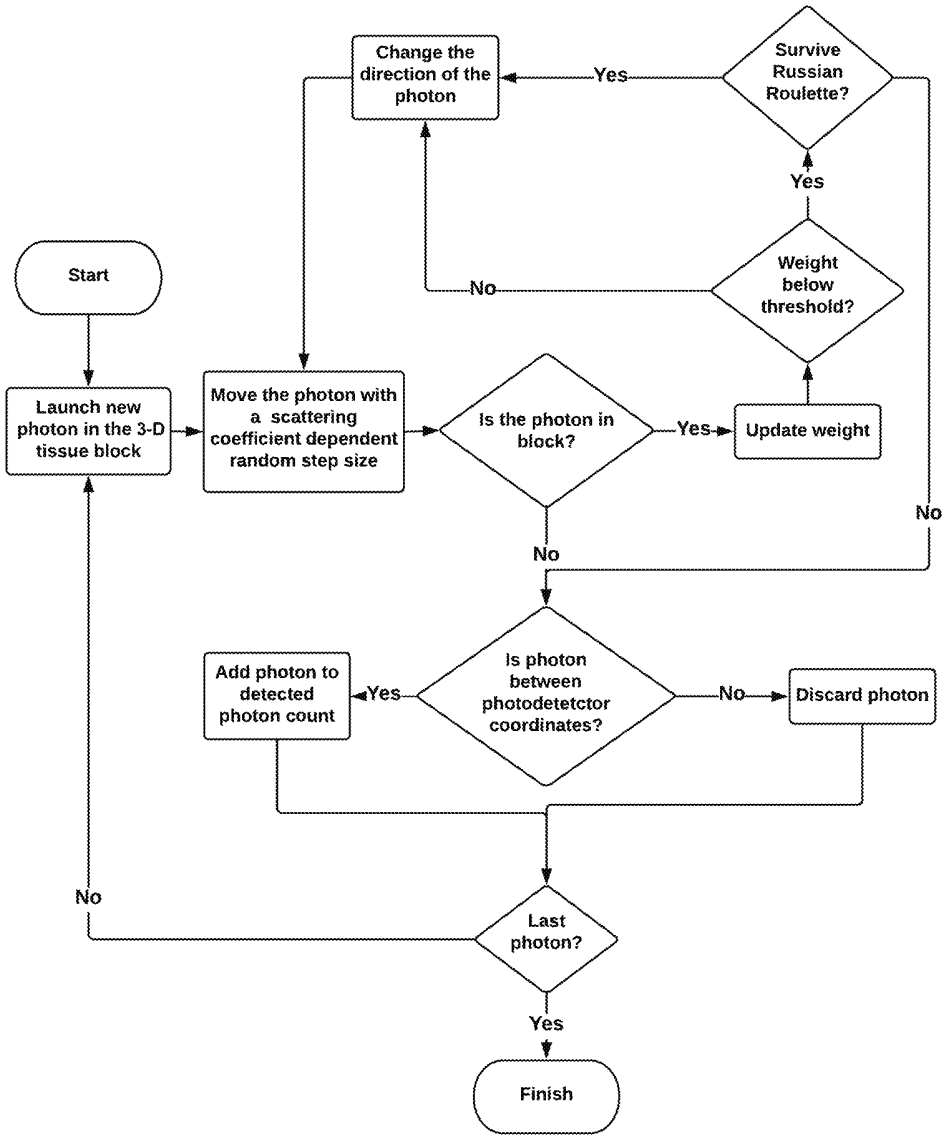


Fig. 4 Flowchart for the Monte Carlo simulations.

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repeated several times to create a signal received by the photodetector in time. The simulations were implemented in C based on the MCXYZ theory developed by Steven Jacques and Lihong Wang.[24,25] The optical properties of the simulated blocks were specified in a Cartesian grid. Being cylindrical in shape, a blood vessel does not fit very well within a square grid, and hence there will be artifacts. To minimize these artifacts, a grid with sufficient resolution ($50\ \mu m \times 50\ \mu m \times 50\ \mu m$) was chosen such that the blood vessel is essentially round.

3 Results and Discussion

3.1 *Monte Carlo Simulation Results*

The Monte Carlo simulations were performed for blood vessels with outer diameter ranging between 1 and 6 mm, with and without surrounding tissue. About 150-million photons were launched inside the tissue block. Adipose tissue ($\mu_s = 122.9\ cm^{-1}$, $\mu_a = 0.13\ cm^{-1}$, and $g = 0.9$, $n = 1.4$ at $\lambda = 940\ nm$[26]) was used for the initial analyses. An LED with wavelength $\lambda = 940$ nm was used as the light source. The detector used was a photodiode with dimensions of $2.2\ mm \times 2.2\ mm$. The blood vessel was placed on top of the photodetector. The optical properties for the blood used were $\mu_s = 53.2\ cm^{-1}$, $\mu_a = 6.62\ cm^{-1}$, $g = 0.9$, and $n = 1.3$ at $\lambda = 940\ nm$.[26] Each setup (a blood vessel of given diameter with or without tissue) was run 10 times to get one cycle of the periodic PPG signal. For each of these 10 simulations, the hemoglobin concentration was varied in a sinusoidal fashion to mimic the pulsatile flow of the blood through arteries. The following relation was used to create this periodic change in the hemoglobin concentration

$$H(t) = \frac{AH_0}{100}\ \sin\left(\frac{2\pi t}{T}\right) + H_0 \quad \forall\ t \in [0, T), \tag{1}$$

where $H(t)$ is the hemoglobin concentration at discrete time t, A is the amplitude of the sinusoidal variation, H_0 is the mean hemoglobin concentration (g/L), and T is the period. In our simulations, we used $H_0 = 150g/L$, $A = 10$, and $T = 10$.

Figure 5 shows the PPGs of blood vessels that these simulations yielded. As can be seen in the figure, different blood vessels have a different rate of change of the pulsatile signals, which could be quantified and used as a marker to determine the size of the blood vessels. Figure 5(a) shows the normalized pulsatile signals recorded. These signals were normalized by the reading obtained from a simulation with same air block without a blood vessel. The signals were further normalized by their respective means to compare their shapes and amplitudes. Figure 5(b) shows these signals when normalized by the corresponding DCs.

As the amount of absorption depends on the amount of blood, which is directly related to the size of the blood vessels, the absorption is higher for blood vessels with larger diameters. As a result, the average light intensity received by the sensor for the larger blood vessels (DC) is lower. Normalizing the signals by their corresponding DCs shows that the pulse for the larger blood vessels is bigger indicating that the rate of change of blood flow is higher in the blood vessels with larger diameters. Plotting this normalized variation against the blood vessel diameter shows a clear relation between the two (Fig. 6). This relation could be used as a marker to estimate the size of the blood vessels.

The simulations were repeated for a setup, where the same blood vessels were buried deep under adipose tissue. The thickness of tissue surrounding the blood vessels was 1 cm. The signals in Fig. 7(a) were obtained by normalizing the PPGs with the reading obtained from a simulation with same adipose tissue block without a blood vessel. These signals were further divided by their DCs to compare their shapes and amplitudes on the same scale. Figure 7(b) shows these signals when normalized by the corresponding DCs. Figures 5 and 7 show that the relative strengths of the signals received with and without tissue remain the same. They also demonstrate that the normalized signal variability of a blood vessel is directly proportional to its diameter.

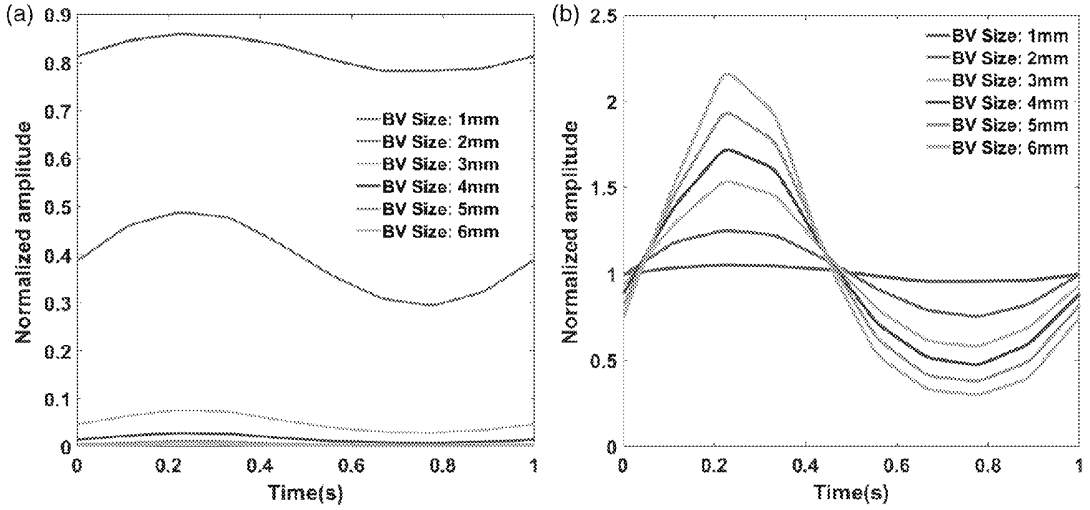


Fig. 5 The attenuated signal plotted over time is sinusoidal because of the pulsatile blood flow through the blood vessels. The absorption is higher for blood vessels with larger diameters as they contain more blood. (a) As a result the DC for the larger blood vessels is lower and the AC looks smaller because of the lower resolution. (b) Normalizing the signals by their DC values shows that the AC for the larger blood vessels is bigger. This suggests that the rate of change of blood flow is higher in blood vessels with larger diameters.

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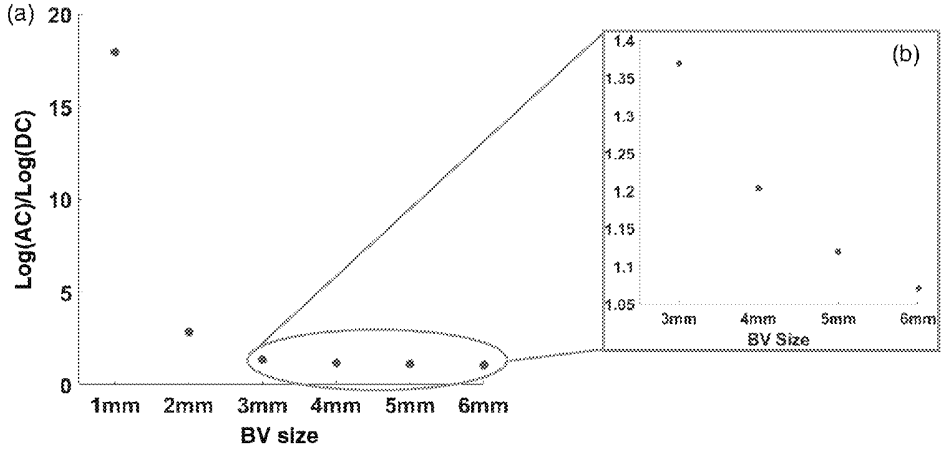


Fig. 6 (a) The plot between the ratio log(AC)/log(DC) and the blood vessel diameter demonstrates a clear relationship between the two. This plot is for the skeletonized blood vessels, i.e., the blood vessels that do not have any tissue surrounding them. The AC is computed by taking the standard deviation of the signal, and the DC is the mean of the signal. (b) Zoomed in to show the ratio profile for blood vessels of size 3 to 6 mm.

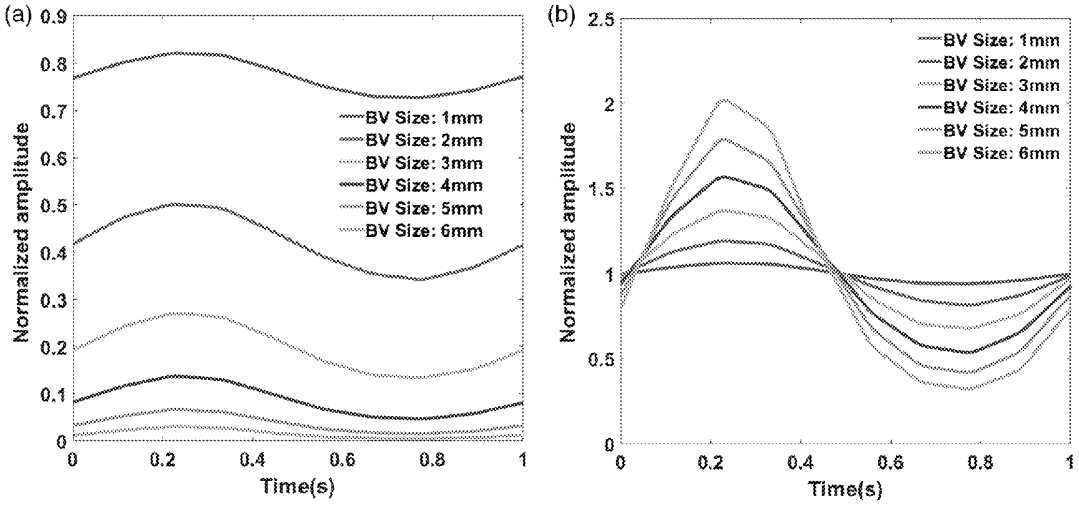


Fig. 7 The blood vessels were embedded in a 1-cm block of adipose tissue. (a) The signals for these simulations do not differ from those obtained using blood vessels alone [shown in Fig. 5(a)] when the PPGs are normalized with the reading obtained from a simulation with the adipose tissue block alone. (b) These signals were further normalized by their corresponding DCs to compare their shapes and amplitudes on the same scale, which highlights the same trend seen with blood vessel alone [shown in Fig. 5(b)].

Figure 8 shows that there is clear relationship between the ratio, log(AC)/log(DC), and the diameter of the blood vessel even if the vessel is buried under 1 cm of tissue.

3.2 *Results of Blood Vessel Phantom Experiments*

After validating the base theoretical concepts of the technology, we performed experiments with blood vessel mimicking tubes. The diameters of the tubes used varied from 3 to 6 mm. The goal of this experiment was to determine whether the pulsatile component of the transmitted light (I_{AC}) could be used to quantify different vessel sizes. We tested the system using pulsatile blood in optically clear tubing, which served as the *in-vitro* vessel phantom (control experiments showed no optical artifacts from the tubing material). The diameter of each size of tubing was provided by the manufacturer. A direct correlation between the I_{AC} and vessel size was observed, indicating a strong proof of concept for blood vessel size quantification by the system. To get the pulsatile blood flow inside these tubes, we developed a test system that closely mimics the pulsatile flow found in arteries. This system employs a VPII submersible DC pump and an Arduino Uno (R3) microcontroller board to regulate both the volumetric flow rate and pulse rate. In order to measure the light transmittance through the phantom, an adjustable test rig was created for modifying the distance between the LED and detector pair. The pulsatile flow system was designed for operation between 40 and 80 cycles/min based on user input (to mimic the physiological heart beat) as well as to vary the flow rate (similar to changing cardiac output). In all the experiments discussed below, heparinized whole bovine blood was

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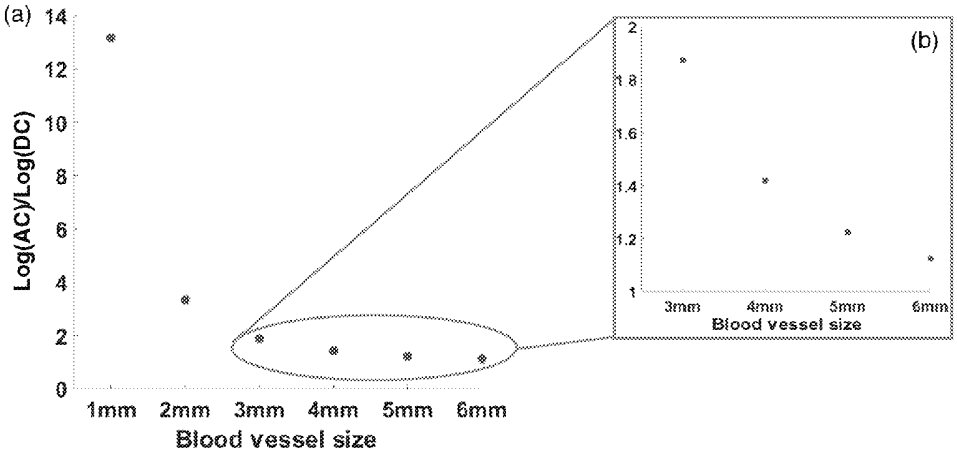


Fig. 8 (a) The log(AC)/log(DC) versus blood vessel diameter plot brings up a similar trend as seen with the skeletonized blood vessels. This validates the hypothesis that even for blood vessels buried in tissue, the trend will remain the same as seen in the case of no tissue. (b) Zoomed in to show the ratio profile for blood vessels of size 3 to 6 mm.

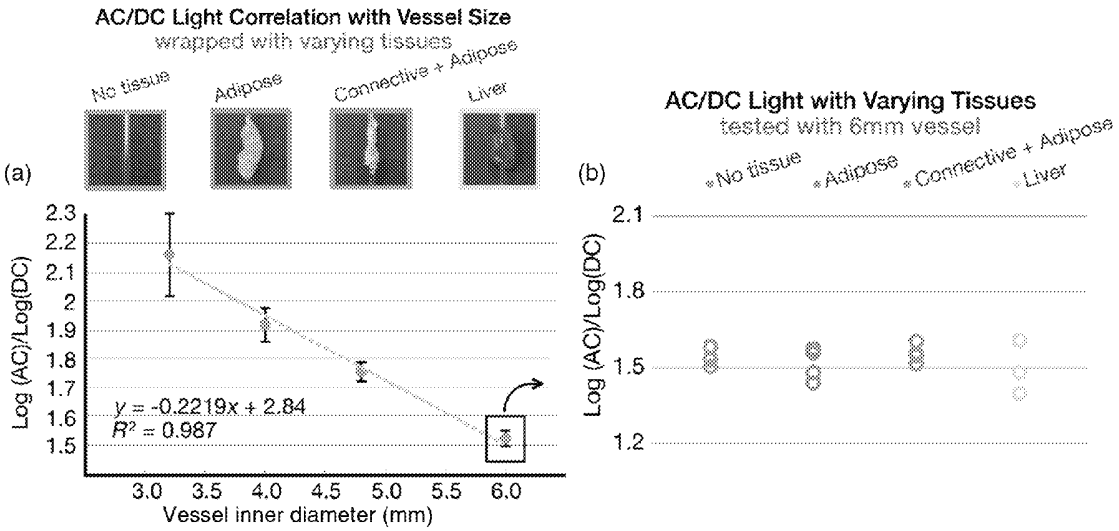


Fig. 9 (a) A linear correlation between the metric and the diameter of *in vitro* vessel phantoms (error bars are smaller than data symbols). (b) With various tissue types surrounding the vessel phantom, the metric was indicative of the actual vessel size. Each experiment was performed in triplicate.

pumped at 60 cycles/min and the flow rate was maintained at 500 mL/min (to mimic the blood flow of the hepatic artery). In addition, blood temperature was elevated to maintain physiological viscosity.

To check the effect of the added tissue on the signal characteristics, we wrapped the *in-vitro* vessel phantom (discussed above) with different types of porcine tissues. Sixty different samples were evaluated, including four vessel sizes, three tissue types, and one no-tissue control. In order to compensate for the scattering of light due to surrounding tissue, AC of the transmitted signal was normalized with DC and then correlated with vessel size. We found that regardless of tissue type or thickness, the log(AC)/log(DC) correlated very well ($R^2 = 0.987$) with the diameter [Fig. 9(a)]. In addition, when looking at a single vessel size (e.g., 6-mm inner diameter), the different tissue wrapping

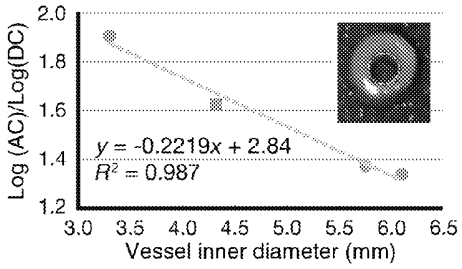


Fig. 10 A linear correlation between the metric and *ex vivo* porcine arteries (error bars are smaller than data symbols). Vessel diameter was quantified using NIH ImageJ (inset).

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samples had the same effective metric, indicating that the metric is independent of the surrounding tissue [Fig. 9(b)].

3.3 *Ex vivo Testing with Porcine Arteries*

We then used fresh porcine carotid arteries ($n = 5$ pigs) *ex vivo* in place of the PVC phantoms. The vessel size was obtained by quantifying the cross section of the vessels at the point of measurement using NIH ImageJ software (Fig. 10 inset). The results from the porcine blood vessel showed an excellent correlation ($R^2 = 0.987$) between vessel size and the metric.

4 Conclusion

We have demonstrated that by putting an LED and a photodetector across a blood vessel, it is possible to detect the vessel and quantify its diameter with sub-mm resolution. We presented the results obtained with Monte Carlo simulations to validate the theoretical concepts behind the technology. After the theoretical proof, we performed the *ex vivo* experiments on PVC phantoms mimicking blood vessels of different diameter with and without added tissue. These experiments showed a similar trend as seen with the Monte Carlo simulations. To check the applicability of this technology in real blood vessels, we repeated the experiments with fresh porcine arteries and were able to detect and quantify 3 to 6 mm blood vessels with high resolution. In the future, we will be developing a handheld prototype that could be used for *in vivo* testing. These *ex-vivo* experiments combined with the theoretical proof provide a strong indication that such a technology could be used in real world settings. Importantly, a single LED and sensor pair is small enough to be integrated into existing laparoscopic tools (i.e., Maryland, Right Angle, Endo GIA, Echelon GST), where the jaws have extremely small surface area. The concept could be further translated to LED and sensor arrays to be integrated into larger tools such as laparoscopic graspers and dissectors (i.e., Hunter graspers, Debakey graspers, bowel graspers, and dolphin-tipped dissectors). It should be noted that the currently available imaging modalities do not provide such resolution at low costs.

Disclosures

Dr. Chaturvedi, Dr. Gunn, and Dr. Subramanian have a patent "System for Determining Vessel Size using Light Absorption" pending. In addition, Dr. Subramanian reports personal fees from Northwestern University, personal fees from NanoCytomics, outside the submitted work. Dr. Shukair, Mr. Vijayvergia, and Mr. Le Rolland have nothing to disclose.

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Amal Chaturvedi is the lead signal processing engineer at Briteseed. He received his MS and PhD degrees in electrical engineering from the University of Cincinnati in 2012 and 2014, respectively.

Shetha A. Shukair is the lead research scientist at Briteseed. She received her PhD in life and biomedical sciences from Northwestern University in 2012. She has coauthored over 10 peer-reviewed articles.

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

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Mayank Vijayvergia is the head of business development and operations at Briteseed. He received his MS degree in biomedical engineering from Northwestern University in 2014.

Paul Le Rolland is the lead hardware engineer at Briteseed. He received his MS degree in electrical engineering from Illinois Institute of Technology in 2014.

Jonathan W. Gunn is the CEO at Briteseed. He received his PhD in biomaterials engineering and nanotechnology from the University of Washington in 2008 and his JD from Northwestern University in 2013. He has more than a decade of experience in the biomedical engineering field and has authored over 15 peer-reviewed articles in the biomedical engineering field.

Hariharan Subramanian is the VP of research and development at Briteseed. He received his MS degree in biomedical engineering from Texas A&M University in 2004 and his PhD in biomedical engineering from Northwestern University in 2009. His work has led to significant advancements in the fields of optical sensing systems and modern optical microscopy. He has authored over 40 peer-reviewed articles.

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Revision Level History

Document Number: (b)(4)

Version (b)(4)

2021/11/11

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2021-11-11

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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From: Mukibi, Sherifah * [Sherifah.Mukibi@fda.hhs.gov]
Sent: 5/9/2023 6:00:25 PM
To: (b)(6)
Subject: Corrected K222658/S002 Acknowledgment Notification
Attachments: Acknowledgment Letter-K222658_S002 (2).pdf

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

5/9/2023

Douglas Herrington, Official Correspondent
Herrington Consulting LLC
No 64, Haijing 3rd St
Sanzhi District
New Taipei City 252
TAIWAN

Dear Douglas Herrington:

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: K222658/S002
Received: 05/02/2023
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

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.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sincerely yours,

Center for Devices and Radiological Health

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Meaghan,

Thank you for the quick review. We think we can have a full response by Monday.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6); k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,

Meaghan

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov>

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E> Here

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov
<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

<mailto:Meaghan.Erlewein@fda.hhs.gov> >; 'Douglas HERRINGTON' (b)(6)
(b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6) ; k222658@docs.fda.gov
<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov
<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

From: (b)(6)
(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov> ; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software test report

Document Number: (b)(4)

Version: (b)(4)

2022/08/09

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2022-08-09

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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PULSE TRANSIT TIME BASED ON PIEZOELECTRIC TECHNIQUE AT THE RADIAL ARTERY

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Foo JYA, Lim CS. Pulse transit time based on piezoelectric technique at the radial artery.
J Clin Monit Comput 2006; 20: 185–192

ABSTRACT. Objectives. Pulse transit time (PTT) has shown its potential in relevant cardiovascular and cardiorespiratory studies. However, the use of photoplethysmography (PPG) in PTT measurement can be limited in events of poor peripheral perfusion. Uninterrupted PTT monitoring may also not be achievable when less cooperative patients distribute the PPG probe due to its prominent light source. Hence, there is a need for an alternative method to measure PTT in such incidents. **Methods.** In this study, the piezoelectric (PIEZO) technique to detect pulsations from a human wrist above the radial artery to estimate PTT is presented. 17 healthy adults (11 male; age range of 21–33 years) were recruited to compare PTT and heart rate (HR) differences between the PPG and PIEZO methods. These time-related derivations were made with respect to an electrocardiogram (ECG). **Results.** The timing consistency of the PIEZO transducer shows significant correlations ($p < 0.01$) to those derived from the ECG and a pulse oximeter. Particularly, there is a high level of agreement of <1beat per minute (bpm) difference in HR estimates observed when compared to the two commercial devices in the respective Bland-Altman plots. Comparison of PTT obtained from the PIEZO transducer against the PPG signal shows constantly lower values due to the shorter path length it requires to propagate. A regression equation was formulated to relate the PTT values acquired from both these signals. **Conclusions.** Preliminary findings herein suggest that the PIEZO technique can be useful as an alternative for PTT monitoring. This shows promise to be more accommodating for less cooperative patients or those with insufficient peripheral perfusion.

KEY WORDS. non-invasive monitoring, biosensors, transducers, cardiovascular measure.

INTRODUCTION

Cardiovascular diseases are one of the leading causes of death in the world and one of the traditionally known indicators is the cardiovascular pulsation. Previous studies have suggested that these diseases can be diagnosed depending on the shape, amplitude and rhythm of these pulsations [1, 2]. From this point of view, a sensor that can detect these pulsations and estimate physiological changes due to vascular diseases has great potential. Arterial pulse wave velocity (PWV) has shown its potential to indicate physiological changes due to peripheral vascular diseases. Over the recent decades, a simple and non-intrusive technique termed pulse transit time (PTT) was derived from the principle of PWV. It has also shown its clinical usefulness in cardiovascular studies [3, 4]. overnight respiratory sleep studies [5, 6]. and with more possible clinical applications being explored [7, 8]. PTT can be defined as the interval

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between ventricular electrical activity and the appearance of a peripheral pulsation.

The R-wave of the electrocardiogram (ECG) is generally used to indicate the start of the PTT computation. Other studies have established accurate estimation of the pulse arrival at the periphery by the direct derivation of raw photoplethysmographic (PPG) signals from pulse oximeters [5, 6]. However, the practical accuracy and application can be limited when its PPG signal-to-noise ratio (SNR) becomes inadequate. One principle factors that cause these occurrences is poor perfusion of the measured periphery [9]. Particularly, this can be common during vasoconstriction, low cardiac output or in a cold environment. During these circumstances, the peripheral perfusion can be poor and thus causing the PPG measure to be unreliable. Furthermore, this can occur when patients undergoing prolonged procedures such as cardiac, vascular or neurosurgery. These circumstances can transpire because conventional pulse oximeter sensors are usually placed on a periphery such as a finger. The pulsatile flow at these sites is most vulnerable when diversion of blood flow to more vital organs occurs. Measures from patients may also be fallacious at the time when the measurement may be clinically of most value [10]. In overnight sleep studies, less cooperative individuals and/or children may distribute the integrity of the PPG signals. This can occur when they are attracted to the bright and prominent light source of the PPG probe during any point of time in these studies. Hence, there is a need for an alternative technique to measure PTT besides the PPG method.

The piezoelectric (PIEZO) technique involves its effect in *polyvinyl dene fluoride* which produces an output voltage in response to the mechanical pressure on its material. This material converts the mechanical stress or strain it undergoes into proportionate electrical energy. It is a thin, flexible, lightweight, mechanically tough plastic film [11]. The PIEZO materials are known to have a wide frequency range, low acoustical impedance and moisture resistance. The application of PIEZO technique in studies related to PWV has been studied previously [12]. but not pertaining to PTT. Hence, the objectives of this study using the PIEZO technique were to: (1) compare its PTT estimate against that obtained from the PPG signals of the oximeter and (2) formulate a regression equation to relate PTT estimates from the PPG signal to those from the PIEZO transducer.

MATERIALS AND METHODS

Subjects

The study included the participation of 17 healthy adult subjects (11 male). Their mean age and standard deviation (SD) were 25.7 $\pm$ 3.7yr. Their mean weight and height were 62.6 $\pm$ 12.0 kg and 1704 $\pm$ 71 mm respectively. The inclusion criterion was only subjects with no clinically apparent arterial disease, no physical abnormality or peripheral injury, no strenuous exercise 24 h prior to the tests, and not on medication. The systolic and diastolic blood pressures of subjects involved in the study were less than 135 mmHg and 85 mmHg respectively. All measurements were performed in a tranquil environment at an ambient temperature of 25 °C. Institutional ethical approval and informed consent were attained before the commencement of the study.

Experimental materials

In this study, a side-by-side measurement of the three devices was adopted in order to facilitate comparison and calculation. The ECG signals which were used as the timing reference in this study were obtained from a single-lead commercial monitor (S & W Medico, Teknik, Denmark). The PPG signals were obtained from a conventional pulse oximeter (Oxypleth model 520A, Novametrix Medical Systems Inc, Wallingford, USA) and reusable proprietary finger probes (OxySnap) were used. The chosen anatomical position to monitor the pulsations using the PIEZO transducer was at the radial artery of the wrist. In order to measure these pulsations, a MP100 pulse transducer (ADInstruments Corporation, Sydney, Australia) was selected. It used a PIEZO element to convert force applied to the active surface of the transducer into an electrical signal. Moreover, a conditioning circuit was implemented to ensure easy detection of the signals from the transducer. This included a low-pass filter of 5 Hz with a gain of 50. All the three measurements were fed into a 16-channel analog-to-digital converter (PowerLab/16SP, ADInstruments Corporation, Sydney, Australia) and recorded in its proprietary software (Chart version 5.2). The recorded signals were sampled and stored at a rate of 1000 samples per second. All computational routines that performed time-related calculations were written in the Matlab Release 13 (the MathWorks Inc, Natick, USA) environment.

For the time-related computation, a slope detection algorithm was used to indicate the rising edge of the signal and a differentiator then detected its peak. Thereafter, a window of 100-recorded data following this detected peak was used for comparative validation. This was to minimise the false locating of peaks induced by high frequency ripples riding on the recorded signals. The described algorithm used in this study is as shown in Figure 1. Thereafter, 25% of each corresponding peak was recommended to be used as an arrival indication of pulsation at the finger [5, 6] and wrist accordingly. Transit time difference was calculated as the time delay between the pulses detected at

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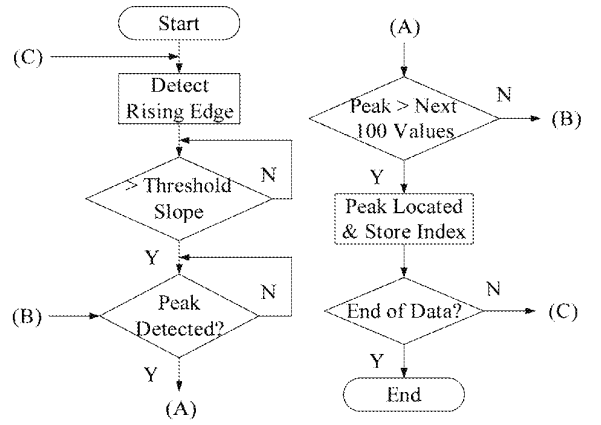


Fig. 1. The flowchart illustrates the algorithm used in the time-related calculation for this study. Particularly, a window of 100-recorded data following the detected peak is used to minimise the false location of peaks that can be induced by high frequency ripples riding on the recorded signals.

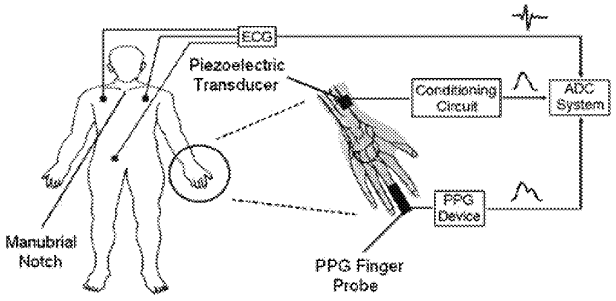


Fig. 2. The anatomical position of the recorded measurements which includes single-lead electrocardiogram (ECG) electrodes, a photoplethysmography (PPG) finger probe from a pulse oximeter and piezoelectric transducer. All path lengths in the study are measured with respect to the manubrial notch.

the wrist, finger and ECG as given in Figure 2. In this study, path lengths were measured with the manubrial notch as the anatomical reference.

Experimental protocol

After a given rest of 10 min to obtain cardiovascular stabilisation, the PPG finger probe was placed on the left middle finger of the subject. The PPG signals were recorded in conjunction with ECG signals that was measured using electrodes on the abdomen, left and right chest. Furthermore, the PIEZO transducer was secured comfortably on the left wrist with Velcro. The measured arm was placed on a provided table with the left arm and the back of middle finger held as straight as possible against a side wall. In addition, 2 more minutes were given to ensure that the subject was familiarised with the applied apparatus before the commencement of recording. This study was conducted in the sitting position in the wakeful state. A recording period of 2 min free from artefacts was obtained as part of the analysis in order to obtain a nominal value of an individual. All time-related derivations from the three devices were then computed for each of the subjects.

Statistical methods

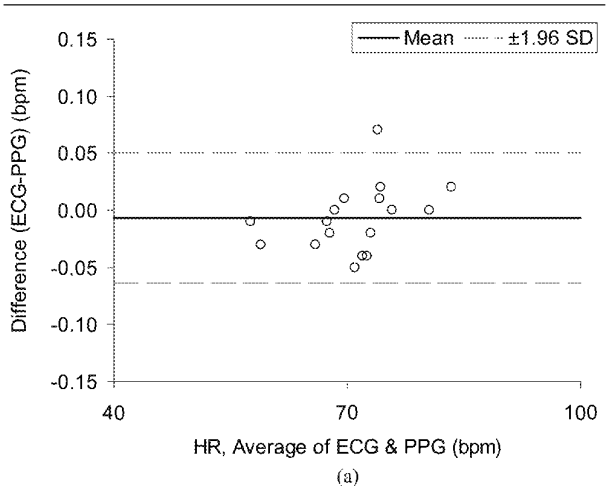
The analysis with correlations and least squares linear regression or calibration statistics was found to be fundamentally limited. It was recommended that a statistical method for assessing the agreement between two methods of measurement to be used [13]. Therefore, the Bland-Altman statistics were employed to compare the level of agreement in heart rate (HR) estimates between the PPG signal with the ECG, the PIEZO transducer with the ECG and the PIEZO transducer with the PPG signal. Furthermore, the same statistical treatment was applied to compare the differences in PTT estimates between the PIEZO transducer and PPG signal. It is recognised that due to the possible differences in arterial compliance, absolute PTT values by itself cannot be quantified [6]. Hence, PTT difference was only assessed as a relative measure between readings obtained from the PPG signal and PIEZO transducer. Descriptive statistics was also performed on all data including the ECG readings. Paired Student's t-test assuming equal variance was used to test for significant differences and correlations for discreet data among the two devices against the ECG data. Statistical analysis was performed using SPSS for Windows Student Version 12 (SPSS Inc, Illinois, USA) and Excel XP (Microsoft Corp, Seattle, USA) package. A value of $p < 0.01$ was considered here as statistically significant.

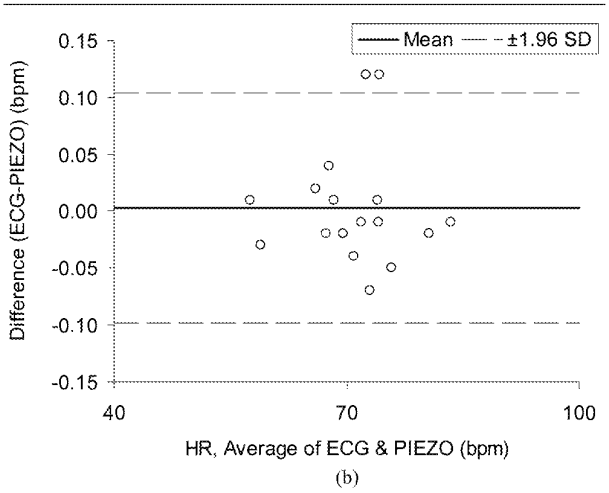
RESULTS

The required time-related measurements were successfully obtained from the group of subjects. From Table 1, it can be seen that HR derived by both the PIEZO transducer and oximeter were significantly correlated ($p < 0.01$) to those estimated by the ECG signals. This can suggest that the time-related measurements obtained from the PIEZO transducer device were consistent with both the commercial medical devices. From the Bland-Altman plot in Figure 3(a), it can better demonstrate the level of agreements in HR estimates between the PPG signal and the ECG (within $\pm$ 1beat per minute) (bpm). This plot served as the reference for comparison within the context of this study

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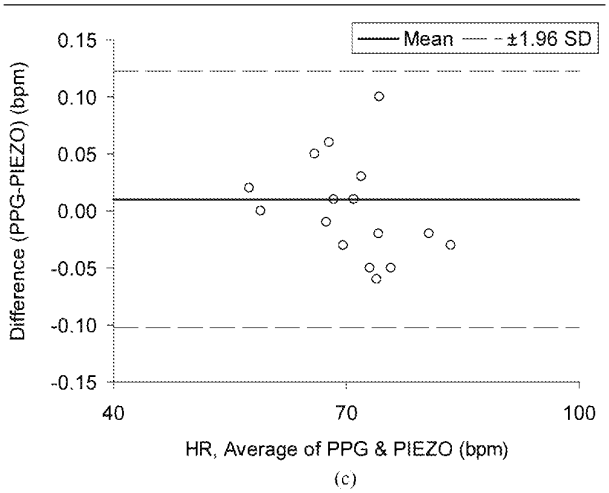


Fig. 3. (a) Bland-Altman plot of heart rate (HR) difference between the ECG monitor and PPG device versus the average of the two respective readings with 95% limits of agreement. This plot can be regarded as the reference (within ± 1 bpm difference) to compare with the remaining Bland-Altman plots on HR within the context of this study as all these recordings were obtained from two commercial devices. (b) The Bland-Altman plot shows that the level of agreement in HR estimates between piezoelectric (PIEZO) transducer and ECG is similar to that of the two commercial devices. This can signify the relative accuracy of the time-related derivation from the PIEZO technique in regards to a commercial ECG machine. (c) Similar level of agreement can be seen in this Bland-Altman plot of HR estimates between the PPG device and PIEZO transducer.

as both of these were commercial devices. The level of difference in HR between the PIEZO transducer and the two devices was also given in Figure 3(b) and 3(c) accordingly. By observation, the HR estimates attained from the PIEZO transducer were moderately accurate (±1 bpm difference) and can reflect cardiovascular timing characteristics.

From the obtained results in Table 2, it can be observed that PTT values obtained from the PIEZO transducer were generally lower than those acquired from the oximeter. This was expected due to the proximity of their anatomical position with respect to the ECG. Particularly, the pulses needed to travel a shorter path length to the wrist as compared to the middle finger. Likewise, Bland-Altman's statistics were applied to compare the PTT estimates obtained from the PPG signal and PIEZO transducer as shown in Figure 4. It can be observed that the greater PTT value (towards the right of the graph), the greater PTT difference between the two devices (an upward trend to the data). Using the mean PTT values obtained from the PPG signal and PIEZO transducer, a regression equation was formulated to relate the mean PTT values from these two devices as given in Figure 5.

$$\mathrm{PTT}_{\mathrm{piezo}}\,(\mathrm{ms}) = 0.85 * \mathrm{PTT}_{\mathrm{ppg}} + 18.05 \qquad (1)$$

It is worth noting that residual or random errors may still exist in the obtained PTT estimates. Since the contributors of these errors were not identified in this study, no correction factor was derived for the present regression equation. Furthermore, the arm and wrist path lengths of the subjects were recorded in Table 2 accordingly.

DISCUSSION

From the present study, it is observed that PIEZO transducer can be utilised to as a non-invasive method of measuring arterial pulsations at the wrist. Besides its utility

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Table 1. HR estimates derived from the three devices used in this study where () denotes the gender of the subject. Statistical HR comparison shows that there are significant correlations between the PIEZO transducer and the two commercial devices based on individual subject

Subject	ECG HR (bpm)	PPG signal HR (bpm)	PPG signal r^2 value	PPG signal p value	PIEZO transducer HR (bpm)	PIEZO transducer r^2 value	PIEZO transducer p value
1 (M)	65.97 ± 1.47	66.00 ± 1.47	0.95	<0.01	65.95 ± 1.68	0.89	<0.01
2 (M)	74.35 ± 3.58	74.33 ± 3.69	0.93	<0.01	74.23 ± 3.77	0.87	<0.01
3 (F)	72.57 ± 2.57	72.61 ± 2.65	0.97	<0.01	72.45 ± 2.27	0.90	<0.01
4 (M)	73.03 ± 3.14	73.05 ± 3.17	0.93	<0.01	73.10 ± 3.03	0.82	<0.01
5 (M)	68.40 ± 1.55	68.40 ± 1.90	0.91	<0.01	68.39 ± 1.62	0.91	<0.01
6 (M)	67.41 ± 2.78	67.42 ± 2.82	0.94	<0.01	67.43 ± 3.01	0.90	<0.01
7 (F)	69.59 ± 1.96	69.58 ± 2.05	0.96	<0.01	69.61 ± 2.07	0.86	<0.01
8 (M)	57.53 ± 2.09	57.54 ± 2.35	0.98	<0.01	57.52 ± 2.53	0.93	<0.01
9 (F)	58.92 ± 1.74	58.95 ± 2.00	0.93	<0.01	58.95 ± 2.03	0.88	<0.01
10 (M)	67.78 ± 2.08	67.80 ± 2.22	0.97	<0.01	67.74 ± 2.12	0.92	<0.01
11 (M)	80.63 ± 1.90	80.63 ± 1.98	0.95	<0.01	80.65 ± 1.86	0.92	<0.01
12 (M)	71.91 ± 2.26	71.95 ± 2.46	0.94	<0.01	71.92 ± 2.29	0.97	<0.01
13 (M)	70.90 ± 2.28	70.95 ± 2.85	0.84	<0.01	70.94 ± 2.55	0.94	<0.01
14 (F)	73.99 ± 3.56	73.92 ± 3.53	0.92	<0.01	73.98 ± 3.69	0.90	<0.01
15 (F)	83.44 ± 4.26	83.42 ± 4.51	0.98	<0.01	83.45 ± 4.44	0.99	<0.01
16 (F)	74.13 ± 4.50	74.12 ± 4.30	0.97	<0.01	74.14 ± 4.55	0.97	<0.01
17 (M)	75.78 ± 3.92	75.78 ± 3.97	0.99	<0.01	75.83 ± 4.29	0.97	<0.01

Table 2. The results show that mean PTT derived from the PIEZO transducer are generally lower than those obtained from the PPG device. This can be expected due to the shorter path length for the pulses to travel from the heart to the wrist. However, only slightly wider PTT variations from the PIEZO transducer can be observed from the results. The arm and wrist path lengths of the subjects are also tabulated accordingly with the number in () denotes the age of the subject

Subject	PPG Signal (ms)	Distance to Finger (mm)	PIEZO Transducer (ms)	Distance to Wrist (mm)
1 (33)	279.8 ± 7.1	882	256.0 ± 9.1	683
2 (31)	295.5 ± 6.2	949	268.9 ± 7.7	717
3 (25)	244.1 ± 4.7	767	226.3 ± 6.9	589
4 (23)	281.8 ± 5.6	846	263.0 ± 7.6	669
5 (27)	279.4 ± 7.5	932	255.1 ± 10.9	740
6 (26)	259.1 ± 5.5	881	238.0 ± 7.2	684
7 (25)	235.8 ± 6.3	832	219.8 ± 9.1	651
8 (24)	263.1 ± 8.0	896	241.7 ± 10.3	696
9 (31)	254.7 ± 7.0	756	237.6 ± 9.7	587
10 (25)	258.0 ± 6.8	885	235.7 ± 7.5	688
11 (25)	271.3 ± 3.4	875	248.0 ± 7.4	681
12 (26)	288.4 ± 5.3	884	261.9 ± 7.3	689
13 (23)	280.6 ± 6.8	853	257.8 ± 13.4	672
14 (26)	274.6 ± 4.3	855	252.6 ± 12.9	669
15 (21)	243.3 ± 3.8	840	223.0 ± 5.1	650
16 (21)	266.4 ± 3.8	860	239.6 ± 6.1	665
17 (25)	281.2 ± 6.3	854	254.9 ± 8.5	667

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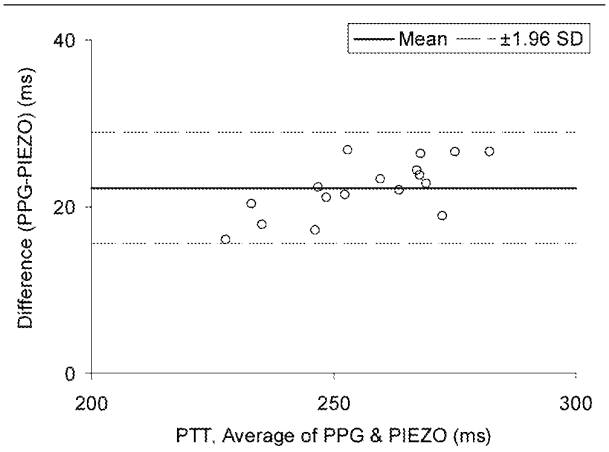


Fig. 4. This figure shows the Bland-Altman plot of pulse transit time (PTT) estimates between PPG signal and PIEZO transducer. From observation, this plot can suggest that higher PTT differences may be associated with higher PTT values. This may be due to that for a longer hand length, a longer PTT value is expected just as with a longer arm.

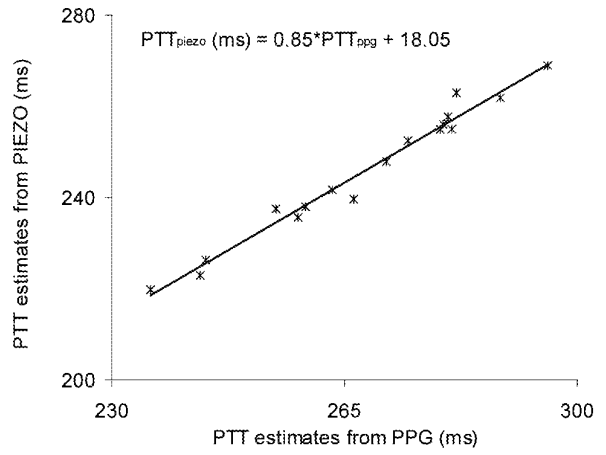


Fig. 5. A regression equation is formulated to relate the PTT values obtained from the PPG signal and PIEZO transducer. This can be useful to estimate the expected PTT values obtainable from a PPG source when measurements are acquired from a PIEZO transducer and vice versa.

in PWV [12] this simple device can be useful in other transit time-related clinical monitoring like PTT and HR measurements as demonstrated in this study. The importance of these parameters lies in the possible conversion of pulse timing characteristics to values that can be associated to local stiffness or elasticity of arterial walls in a non-intrusive manner. Hence, this technique can be beneficial for patient monitoring with cardiovascular abnormalities, pre-surgery or post-surgery patients. Moreover, it may be more unlikely to be removed by less cooperative patients or children as it can be placed on an anatomical position less visual than the PPG probe. PIEZO transducer also does not have prominent features like the light source from a PPG probe that can attract attention. However, it is acknowledged that further investigations are required to fully understand the relevance of PIEZO technique in clinical examinations.

The study of cardiovascular functions has shown to reveal the possible pathogenesis of diseases such as hypertension [14]. In adults, a decrease in arterial distensibility has adverse effects on the cardiac performance due to increased workload on the left ventricle and decreased coronary flow caused by a decrease in diastolic aortic pressure [15]. The measure of arterial distensibility has also shown its importance to determine the cardiovascular status in children [16]. Previous studies have also shown that PWV is inversely related to arterial distensibility [15] and PTT [5, 6]. Moreover, other studies have demonstrated the usefulness of PTT in clinical studies [7, 8]. Non-intrusive monitoring techniques are generally preferred for the comfort of patients especially when prolonged measurement is required. Therefore, it is essential that techniques used to monitor cardiovascular functions needs to be simple and accommodating to the patients.

In this study, a simple and non-invasive method to estimate pulse timing characteristics from the radial artery is presented. It involves the detection of the pulse pressure waves at the wrist through the use of PIEZO technique. These pulsations are detected by the changes in the mechanical movements experienced at the wrist. The accuracy of its time estimates is compared in its derived HR values against a commercial ECG monitor and pulse oximeter. The results herein show that there are significant correlations ($p < 0.01$) and high level of agreement (within ± 1 bpm) in its time-related derivations. This part of the study is essential to be performed to facilitate the utility of PIEZO technique in estimating PTT measurement. Furthermore, with its implementation in these cardiovascular monitoring, it may reduce the dependence on medical devices like the ECG and pulse oximeter.

In the second part of the study, the use of the PIEZO transducer on PTT measurements is being investigated. Generally, the assessment of PTT is based on the relative variations from its baseline and its absolute value by itself cannot be quantified [6]. Based on this understanding, the absolute difference in PTT values observed in the PPG signal and PIEZO transducer should therefore not have any clinical implications. It is also observed that PTT variations from the PIEZO transducer are generally higher but with appropriate technological applications, this can be improved significantly. From Figure 4, it can be seen that when the average PTT value derived from the two devices

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increases, their obtained relative PTT difference also tends to become higher. This is expected as PTT is related to the path length and its difference is related to the distance from wrist to fingertip. Particularly, just as for a longer arm, it is likely to have higher PTT values and therefore with a longer hand, a higher PTT difference is also expected.

It is recognised that there are some limitations in the present study. Firstly, Doppler ultrasound or pulse wave analysis could have been used to better qualify the pulse timing characteristics obtained from the PIEZO transducer. However, it is worth noting that there is high coherence in its time derivations with those from two commercial devices; the ECG machine and pulse oximeter. Secondly, this can be seen as a preliminary study conducted with a small cohort of healthy adult subjects and can be considered as a platform for continuous investigations with a larger pool of healthy and/or clinical paediatrics populations to study its clinical relevance. This initial study does not involve children as its primary aim is to corroborate evidences that PIEZO technique has the capability to detect pulse timing characteristics off the human wrist with moderate accuracy.

Thirdly, it is acknowledged that the present study does not evaluate the usefulness of PIEZO technique on peripheral with poor perfusion. In order to conduct a study of this nature generally requires the use of cold peripheral test. However, such testing condition is not ethical to be performed as this involves painful stimulus and is mainly used to test sympathetic responses in pathological studies [17]. Thus, the grounds for ethnical approval were not convincing and could not be formed as part of the study. Moreover, it is worth noting that the underlying measurement principle of both the PPG and PIEZO technique are different. The former detects pulsations by the changes associated in the red blood cells volume in the peripheral microvascular bed and this is dependent on the perfusion of the measured periphery [18]. On the other hand, the latter detects the pulses in response to the mechanical pressure changes on its material. With these understandings, the reliability of the latter should not be affected by poor perfusion so long as pulsations can be monitored off the wrist. Lastly, pulse characteristics acquired from the PIEZO transducer like the PPG method, are also susceptible to the effects of motional artefacts.

CONCLUSIONS

The present study details the investigation of a PIEZO-based technique as a reliable and reproducible non-intrusive method for estimating pulse timing characteristics. From the results obtained, it was demonstrated that accurate PTT and HR measurements can be derived using this technique. The values attained are considered acceptable when compared to those derived from a commercial ECG monitor and/or pulse oximeter. The clinical usefulness of PIEZO technique lies in its simplicity, portability and non-intrusive nature. Hence, the findings herein suggest that there is potential for clinical studies involving less cooperative patients such as children under prolonged monitoring conditions.

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TEST REPORT
IEC 80601–2–30
Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Report Number.....:	(b)(4)
Tested by .....:	
Approved by.....:	
Date of issue.....:	
Total number of pages.....	
Testing Laboratory .....:	
Address.....:	
Applicant's name .....:	Accurate Meditech Inc.
Address.....:	8F-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd. Sanchong Dist., New Taipei City 241406, Taiwan
Test specification:	
Standard .....:	IEC 80601-2-30:2018 for use in conjunction with IEC 60601-1:2005/AMD1:2012
Test procedure.....:	(b)(4)
Non-standard test method……..:	
Test Report Form No. .....:	(b)(4)
Test Report Form Originator.....:	
Master TRF .....:	

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Test item description.....:	Accurate 24 Non-invasive blood pressure monitor
Trade Mark.....:	Accurate 24
Manufacturer.....:	Accurate Meditech Inc.
Model/Type reference.....:	Accurate 24_BPM
Ratings.....:	(b)(4)

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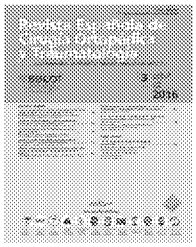
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ORIGINAL ARTICLE

Description and analysis of the dynamic and morphological flow pattern of the main arteries of the wrist and hand in a healthy Spanish population☆

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KEYWORDS
Radial artery;
Ulnar artery;
Doppler-colour ultrasound;
Digital arteries;
Reference values

Abstract
Background and aim: The vascular anatomy of the hand has already been widely described macroscopically. However, there are very few papers that study the pattern of normality of *in vivo* vascularisation that describe and analyse the main arteries of the hand. The aim of this paper was to carry out a study to serve as a reference for the normal values of size and flow of the radial and ulnar artery at the level of the wrist, and the digital radial and ulnar arteries at the level of the fingers.
Material and method: A descriptive observational cross-sectional study on 200 hands in 100 healthy volunteers aged between 20 and 30 years. Doppler-colour ultrasound was performed on the ulnar and radial arteries in the wrist, as well as on the radial and ulnar digital arteries in each finger. Once the measurements had been taken, a general comparative analysis was performed also taking laterality, dominance and gender into account.
Results: It was observed that the radial artery is larger in size than the ulnar at wrist level, however, it was the ulnar artery that showed flow dominance at this level. At finger level, the arteries are greater in size and flow in the areas of the fingers more protected from injury (digital ulnar artery in the first three and radial artery in the fourth and fifth digits).
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PALABRAS CLAVE
Arteria radial;
Arteria ulnar;
Ecografía
Doppler-color;
Arterias digitales;
Valores de referencia

Descripción y análisis del patrón de normalidad de flujo dinámico y morfológico de las arterias principales de la muñeca y mano en población sana española

Resumen

Antecedentes y objetivo: La anatomía vascular de la mano ya ha sido ampliamente descrita a nivel macroscópico. Sin embargo, existen muy pocos trabajos que estudien el patrón de normalidad de la vascularización *in vivo* y describan y analicen las arterias principales de la mano. El objetivo de este trabajo es realizar un estudio que sirva de referencia para los valores normales de tamaño y flujo de la arteria radial y ulnar a nivel de la muñeca y de las arterias digitales radiales y ulnares a nivel de los dedos.

Material y método: Estudio descriptivo observacional de corte trasversal sobre 200 manos en 100 voluntarios sanos entre 20-30 años. Se realizó ecografía Doppler-color de las arterias ulnar y radial en la muñeca, así como de las arterias digitales radial y ulnar de cada dedo. Una vez tomadas las medidas se llevó a cabo un análisis comparativo de forma general y también teniendo en cuenta la lateralidad, la dominancia y el género.

Resultados: Se observó que existe un mayor tamaño de la arteria radial sobre la ulnar a nivel de la muñeca; sin embargo, es la arteria ulnar la que presentó dominancia de flujo a este nivel. A nivel de los dedos, en los tres primeros fue la arteria digital ulnar la que presentó un mayor tamaño y mayor flujo. No obstante, en el cuarto y quinto dedos fue la arteria digital radial la que presentó un mayor tamaño y dominancia de flujo.

Conclusión: Ha quedado confirmado que la dominancia de flujo, pero no de tamaño, a nivel de la muñeca es de la arteria ulnar. A nivel de los dedos, existe un mayor tamaño y flujo de las arterias en las zonas de los dedos más protegidas de las lesiones (arteria digital ulnar en los tres primeros y radial en el cuarto y quinto).

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Introduction

The vascular anatomy of the hand has already been widely described macroscopically. The main arteries providing blood supply to the hand are the radial artery (RA) and the ulnar artery (UA); once they reach the hand they give rise to the superficial palmar arch, which in turn emits the common and own palmar digital arteries.[1] There are many anatomical variations,[2] but the presence is constant of the radial and ulnar artery at the wrist and the ulnar and radial digital arteries at the level of each finger.

In recent years, dynamic *in vivo* vascular study has been added to macroscopic vascular anatomical study thanks to ultrasound and Doppler ultrasound.[3–5] This technique has generally been used to study vascularisation in impaired situations – e.g. in smokers – or to assess vascular changes when performing the Allen test.[6–8] Despite all the studies carried out in impaired situations, there are very few papers that study the pattern of normality of vascularisation of the hand or vascular dominance between different arteries in a healthy population to serve as a reference.[3,5,9]

This study aims to describe, in a healthy Spanish population, the morphological pattern and dynamic flow of the radial and ulnar arteries at the level of the wrist and of each of the digital arteries. We will also analyse the dominance of one artery (radial or ulnar) over the other in the wrist and in each of the fingers and we will analyse the influence of the laterality of the hand (right or left), dominance (right or left) and gender. In this way we expect to achieve normal values that can serve as a reference for the study of different conditions.

Material and method

The study is cross-sectional, descriptive, and observational in design. To assess the variables studied by ultrasound in a healthy Spanish population, a population of 100 volunteer subjects was selected. The participants were randomly selected in different locations, mainly in the areas near the Hospital Universitario Infanta Leonor; this includes facilities such as sports centres, university centres, public offices, shops and the health facilities themselves.

For the selection of the healthy population to serve as a reference and in whom a normal pattern could be estimated, people between the ages of 20 and 30 were taken as the inclusion criteria with no exclusion criteria.

The exclusion criteria were the following: patients under 20 years of age or over 30, a history of high blood pressure and/or diabetes, smoking habits in the last 5 years, vascular pathology, connective tissue disease, history of inflammatory disease, systemic metabolic diseases, Raynaud's disease and a history of trauma in the forearm or hand, including from the elbow joint to the proximal interphalangeal joints.

The chosen age range of the sample was between 20 and 30, since at this age growth is complete and there are usually no vascular conditions (such as arteriosclerosis) that could alter normal arterial flow. Of the 100 patients selected, 50

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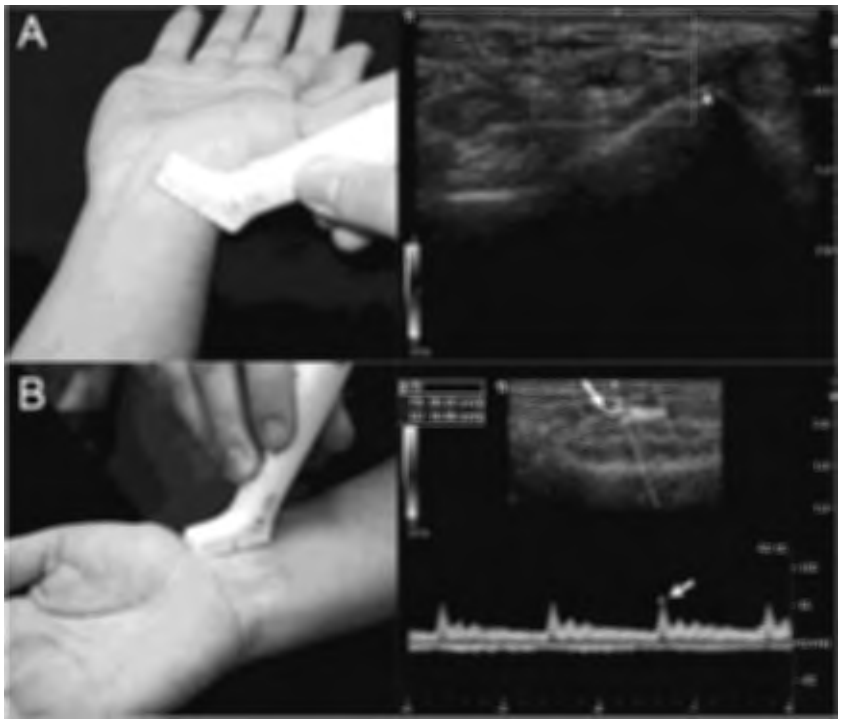


Figure 1 (A) Procedure for measuring the diameter of the radial artery of the right wrist. Measured at the level of the proximal palmar fold. The probe is placed transversely to locate the artery (arrow) and the measurement is taken using the styloid of the radius as a reference (asterisk). (B) Procedure to measure the flow velocity of the radial artery of the right wrist. Measured at the level of the proximal palmar fold. The probe is placed longitudinally to locate the artery (white arrow) and the peak systolic value is taken if the pulse was regular (yellow arrow).

were men and 50 were women. The dominant hand was the right in 90 participants (45 women and 45 men) and the left in 10 (5 women and 5 men). The patients were first interviewed briefly, when they were informed of the study objectives and the reason for the questions about their medical history. After confirming that both inclusion and exclusion criteria had been met, all the participants were given an informed consent form to sign, as well as a patient information sheet referring to the research objectives and the subsequent handling of the data obtained. The study was approved by the Clinical Research Ethics Committee of the Hospital General Universitario Gregorio Marañón in Madrid (protocol code: HUIL-181025).

The variables studied were the following:

Epidemiological and general anthropometric variables: age, gender, height in cm, weight in kg, body mass index, dominant hand, considering the hand that the patient used to write as dominant.

Ultrasound study of the wrist and hand: the variables collected in each artery were the cross-sectional diameter of the artery in cm and the flow velocity in cm/s. These parameters were measured in the wrist in the radial artery and the ulnar artery, as well as in all the radial and ulnar digital arteries specific to each finger. The GE Logiq ultrasound system from GE Health Care® was used to take the measurements, with a GE i12L-RS probe, at a frequency range of 4.0–10.0 MHz, designed for the examination of vascular structures, among others. The patients' arms were first placed in a supination and elbow joint flexion position, with the wrist placed on a support surface to keep it relaxed.

All the patients underwent an ultrasound scan of first the right upper limb and then the left upper limb.

Once the hand was in position, the ultrasound settings were adjusted; mainly by activating the colour function to be able to locate the vessels and differentiate between vein and artery, and modifying the angle of the Doppler function, which should always be kept between 55° and 60°, never exceeding 60°.

First, the ultrasound study was performed on the right wrist, starting with the radial artery. The proximal palmar fold was taken as a superficial anatomical reference. The probe was placed on this fold perpendicular to the forearm, with the notch of the probe facing medially at all times (Fig. 1A). In this plane, the ultrasound scan showed the radial artery accompanied by the 2 veins and the styloid process of the radius, which was the anatomical reference at ultrasound level (Fig. 1B). Once the artery had been located, minimum pressure was exerted on the wrist to avoid reducing the diameter of the vessel and the transverse diameter was measured in cm. Once the diameter had been measured, in the same plane, the probe was rotated by 90°, the notch being orientated distally (Fig. 1C). Once the rotation had been made, the longitudinal section of the artery was observed, and the flow velocity was measured. First the colour function was activated, then the *Steer* function, at all times placing the angle in favour of the vessel (from 55° to 60°) and placing the centre of the vessel in the longitudinal section as a reference. Once all this had been done, the *Doppler* function was activated and the arterial flow velocity, in both systole and diastole, was observed on the screen.

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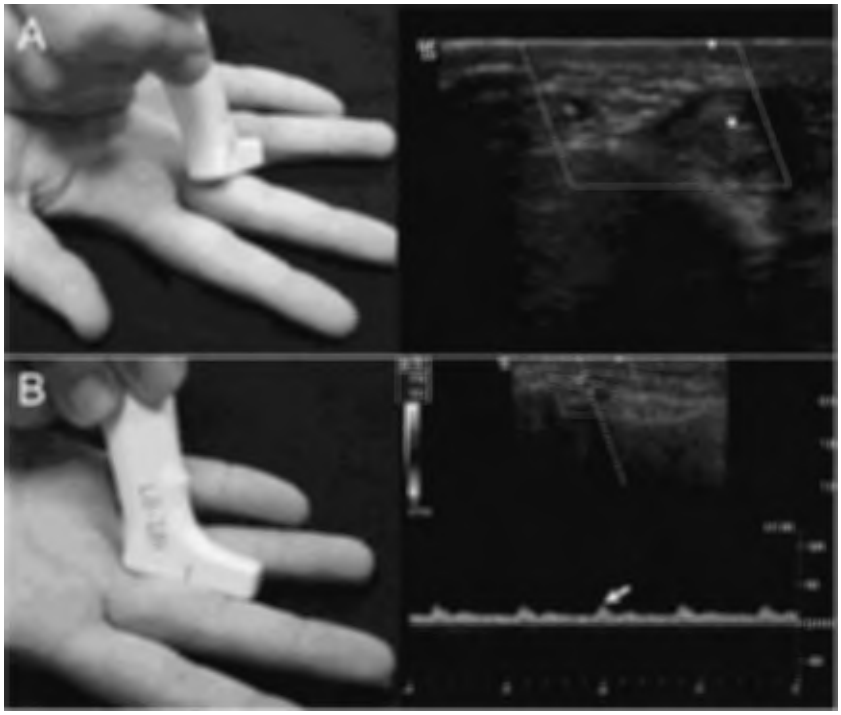


Figure 2 (A) Procedure for measuring the diameter of the ulnar digital artery of the third finger of the right hand. Measured proximal to the IFP joint. The probe is placed transversely to locate the artery adjacent to the flexor tendons (asterisk). (B) Procedure for measuring the flow velocity of the ulnar digital artery of the third finger of the right hand. Measured proximal to the IFP joint. The probe is placed longitudinally to locate the artery and the systolic peak value is taken if the pulse was regular (yellow arrow).

By freezing the screen, if the recorded pulse was regular, the ultrasound machine marked the arterial flow velocity at the time of the systolic peak, and this value was recorded for the study (Fig. 1D). If the recorded pulse was not regular, the manoeuvre was repeated.

After study of the radial artery, we continued with the ulnar artery; the superficial anatomical reference was the same as for the radial artery. The probe was placed over the fold, this time in the medial region of the wrist, perpendicular to the forearm, with the notch facing medially. However, at ultrasound level the reference was the distal epiphysis of the ulna. After taking the diameter of the artery in the transverse plane, the probe was rotated 90° and the notch was oriented distally to measure the flow velocity of the ulnar artery in the longitudinal section.

Once the data collection in the arteries of the wrist was completed, the ultrasound of the finger arteries was performed. We started with the first finger at all times and in each finger, we first collected the variables of the digital radial artery and then the ulnar.

To measure the arterial diameter of both the radial and the ulnar digital arteries, the proximal interphalangeal joint was taken as the anatomical reference, placing the probe proximal to it and in a perpendicular position to the proximal phalanx (Fig. 2A). In the radial digital artery (Rx, x being the finger) the probe was placed in the lateral half of the finger, while in the ulnar digital artery (Ux, x being the finger) the probe was placed in the medial half. In this plane, to facilitate locating the arteries, the colour function of the ultrasound machine was activated. Once located, the diameter of the artery was taken (Fig. 2B). For the flow velocity, the measurement was taken in the same position, proximal to the IFP joint, with the probe in a longitudinal direction (Fig. 2C). As with the arteries in the wrist, we took the flow velocity value at the systolic peak, a value indicated by the ultrasound machine (Fig. 2D).

After completing the measurements in the right hand, we proceeded to take samples in the left hand following the same method.

Once the abovementioned variables had been measured, the following comparative analysis was carried out:

- Comparative study of the size (transverse diameter) of the arteries in the wrist. The analysis was performed in 4 scenarios: in general; in relation to laterality; in relation to dominance, and in relation to gender.
- Comparative study of the flow velocity (systolic peak) of the arteries of the wrist. Conducted in the same 4 scenarios: generally, in relation to laterality, in relation to dominance, and in relation to gender.
- Comparative study of the size (transverse diameter) of the digital radial artery versus the digital ulnar artery in each of the five fingers generally; in each of the five fingers in relation to laterality; in each of the five fingers in relation to dominance, and in each of the five fingers in relation to gender.
- Comparative study of the flow velocity (systolic peak) of the radial digital artery versus the ulnar digital artery in each of the five fingers generally; in each of the five fingers in relation to laterality; in each of the five fingers in

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Table 1 Results of the diameter (in centimetres) and flow velocity (in centimetres/second) of the radial artery (radial) and ulnar artery (ulnar) in the wrist and of the radial and ulnar digital arteries of the five fingers.

	Transverse diameter (cm)	Flow velocity (cm/s)
Med radial (RIQ)	.24 (.22–.28)	48 (39.49–62.3175)
Med ulnar (RIQ)	.22 (.1875–.25)	54.2 (39.145–70.46)
Med U1 (RIQ)	.09 (.08–.11)	30.52 (19.2675–44.13)
Med R2 (RIQ)	.08 (.0775–.1)	17.57 (13.16–24.78)
Med U2 (RIQ)	.1 (.08–.11)	27.71 (17.615–37.3225)
Med R3 (RIQ)	.09 (.08–.1)	21.68 (15.31–30.97)
Med U3 (RIQ)	.1 (.08–.11)	25.55 (17.03–34.8325)
Med R4 (RIQ)	.09 (.08–.11)	25.17 (16.525–34.66)
Med U4 (RIQ)	.09 (.08–.1)	19.36 (13.94–26.32)
Med R5 (RIQ)	.09 (.08–.1)	21.68 (15.0275–21.184)
Med U5 (RIQ)	.08 (.07–.09)	15.3 (11.61–17.1041)

Rx: radial digital artery of finger x; Ux: ulnar digital artery of finger x.
Results of the 200 hands studied, shown as median (Med) and interquartile range (IQR).

relation to dominance, and in each of the five fingers in relation to gender.

R for Mac software (version 3.5.1; R, Vienna, Austria) was used for the statistical analysis. The descriptive values for the study of the arteries are always presented in terms of median and interquartile range (Q1–Q3). Given the large sample size available for the study and the fact that the main variables of analysis, diameter and arterial flow, are continuous quantitative, the Student's *t*-test for independent samples was used to carry out comparisons between paired groups of individuals (by gender). Similarly, when making comparisons in the same individual (in terms of side, in terms of dominance) the Student's *t*-test for paired samples was used. In all cases the level of statistical significance was set at $p < .05$.

Results

The results of the descriptive study of the transverse diameter and of the arterial flow velocity at the time of the systolic peak in each of the 12 arteries studied can be seen in Table 1.

The results of the same descriptive study broken down by right/left hand can be found in Table 2.

The following results were obtained for the comparative analysis of the variables studied:

1. In the comparative study of the size (transverse diameter) of the arteries of the wrist.
   - In general, that is, without considering laterality, dominance or gender, a larger (statistically significant) size of the radial artery is observed with respect to the ulnar artery (Fig. 3A).
   - In terms of laterality, the tendency is the same as described above, with a larger (statistically significant) size of the radial artery in both the right and left wrist (Fig. 3B).
   - In terms of dominance, there is no statistically significant difference between the size of the radial ulnar arteries of the dominant hand and the size of the same arteries in the non-dominant wrist (Fig. 3C).
   - In terms of gender, the two arteries in the wrist were found to be statistically significantly larger in the men than in the women (fig. 3D).
2. In the comparative study of the flow velocity (systolic peak) of the arteries of the wrist.
   - In general. A higher (statistically significant) flow was observed of the ulnar artery with respect to the radial artery (Fig. 4A).
   - In terms of laterality, the trend was the same, with greater flow of the ulnar artery (statistically significant) in both the right and the left wrist (Fig. 4B).
   - In terms of dominance, no statistically significant differences were observed between the radial and ulnar artery flow of the dominant hand with respect to the same arteries in the non-dominant hand (Fig. 4C).
   - In terms of gender, it was observed that in both arteries the flow is statistically significantly higher in the men than in the women (Fig. 4D).
3. In the comparative study of the size (transverse diameter) of the digital arteries in the fingers:
   - In general, it was observed that in the first, second and third fingers the digital ulnar artery was larger (statistically significant) than the digital radial artery. In the fourth and fifth fingers, the digital radial artery was larger (statistically significant) than the digital ulnar artery (Fig. 5A).
   - In terms of laterality, the trend was the same. Larger diameter of the digital ulnar artery in the first, second and third fingers, and larger diameter of the digital radial artery in the fourth and fifth fingers, both in the right and left hand (Fig. 5B).
   - In terms of dominance, no statistically significant differences were observed between the digital radial and ulnar arteries of each finger of the dominant hand compared to the digital arteries of the same fingers in the non-dominant hand (Fig. 5C).
   - In terms of gender, both the digital radial and digital ulnar arteries of the 5 fingers were found to be larger in the men than in the women (Fig. 5D).

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Table 2 Results of the diameter (in centimetres) and flow velocity (in centimetres/second) of the 100 right hands and 100 left hands.

	Right		Left	
	Transverse diameter (cm)	Flow velocity (cm/s)	Transverse diameter (cm)	Flow velocity (cm/s)
Med radial (RIQ)	.24 (.22–.28)	49.92 (40.0675–65.4275)	.25 (.2175–.27)	47.23 (38.71–61.0575)
Med ulnar (RIQ)	.22 (.1875–.25)	54.47 (39.49–70.5475)	.22 (.1875–.24)	53.88 (37.16–69.7175)
Med R1 (RIQ)	.08 (.08–.1)	19.91 (13.94–28.8425)	.08 (.07–.09)	19.38 (13.0675–26.42)
Med U1 (RIQ)	.09 (.08–.11)	31.74 (18.58–44.13)	.09 (.08–.1125)	29.81 (19.36–44.3125)
Med R2 (RIQ)	.09 (.08–.1)	17.81 (13.4975–24.78)	.08 (.07–.1)	16.72 (13.16–24.785)
Med U2 (RIQ)	.1 (.08–.11)	28.87 (18.3875–37.94)	.1 (.08–.1125)	27.1 (17.03–37.16)
Med R3 (RIQ)	.09 (.08–.11)	22.45 (16.26–31.0625)	.09 (.08–.1)	20.13 (14.71–29.705)
Med U3 (RIQ)	.1 (.09–.11)	27.99 (17.465–35.9625)	.1 (.08–.12)	24.78 (17.03–33.4975)
Med R4 (RIQ)	.09 (.08–.1)	24.39 (16.5–33.46)	.1 (.08–.11)	25.67 (16.8625–34-84)
Med U4 (RIQ)	.09 (.08–.1)	20.58 (14.71–26.5325)	.09 (.08–.1)	17.61 (13.7775–25.7425)
Med R5 (RIQ)	.09 (.08–.1)	21.68 (15.49–30.7)	.09 (.08–.1)	21.29 (14.5175–33.29)
Med U5 (RIQ)	.08 (.07–.09)	15.49 (12.39–21.095)	.08 (.07–.09)	14.59 (11.61–19.5425)

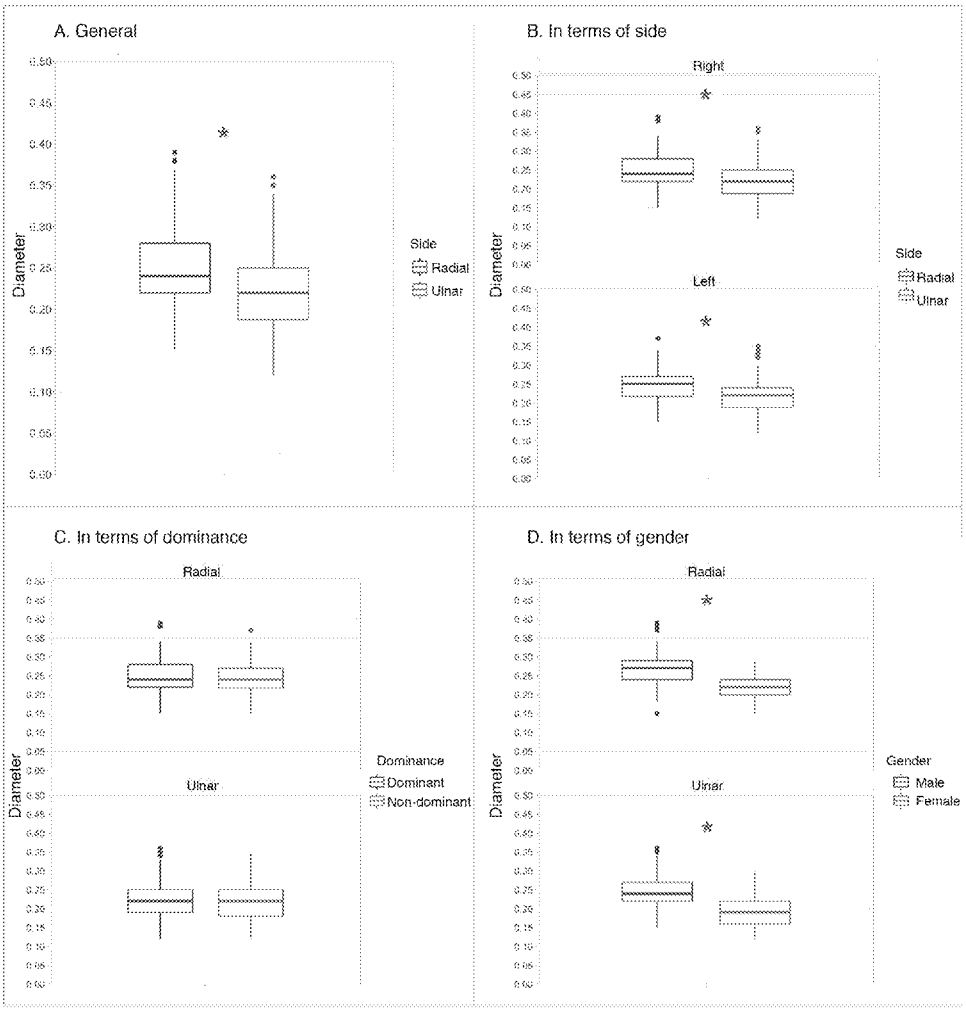


Figure 3 Comparative study of the size (transverse diameter) of the radial and ulnar arteries at wrist level shown in cm. (A) General comparison (with no discrimination). (B) Comparison in terms of side (right wrist/left wrist). (C) Comparison in terms of dominance (dominant hand/non-dominant hand). (D) Comparison in terms of gender (male/female). The asterisk indicates statistically significant differences at $p < .05$.

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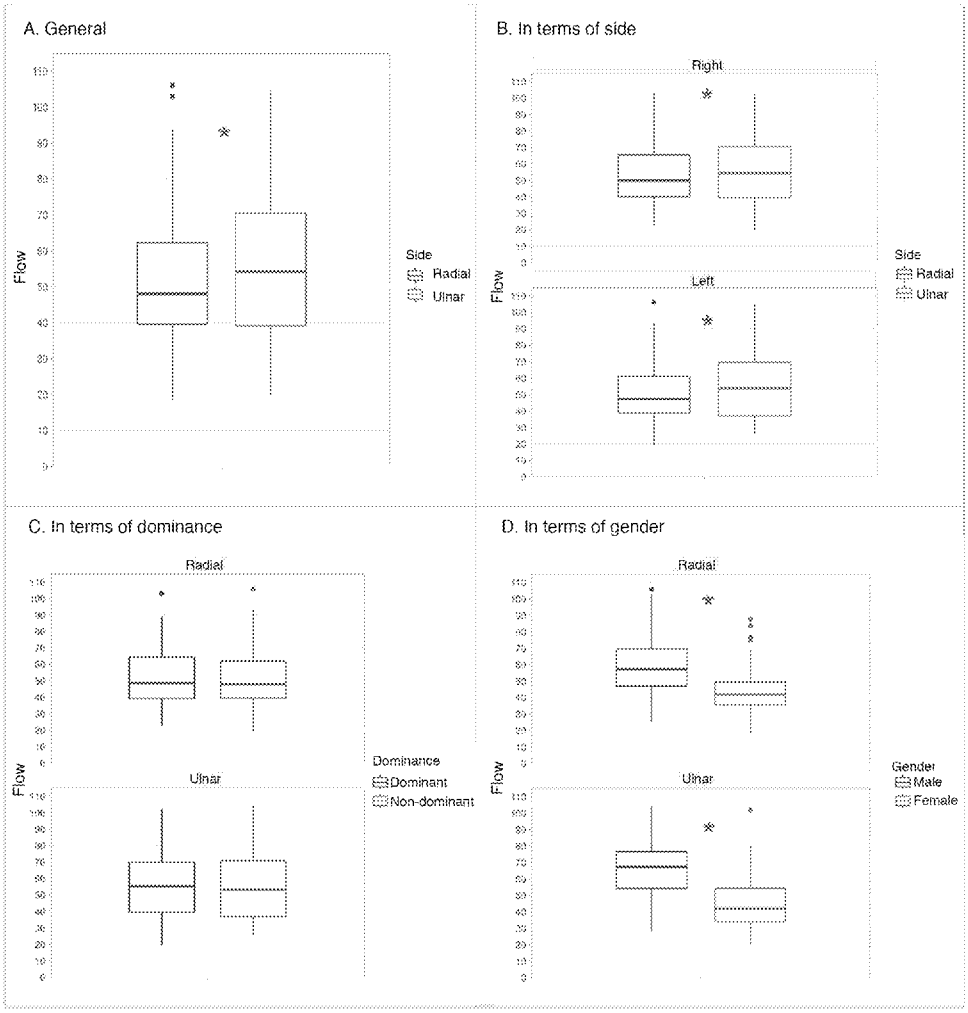


Figure 4 Comparative study of flow velocity (systolic peak) of the arteries of the wrist shown in cm/s. (A) General comparison (with no discrimination). (B) Comparison in terms of side (right wrist/left wrist). (C) Comparison in terms of dominance (dominant hand/non-dominant hand). (D) Comparison in terms of gender (male/female). The asterisk indicates statistically significant differences at $p < .05$.

4. In the comparative study of the flow velocity (systolic peak) of the digital arteries in the fingers:
   - In general, it was observed that in the first, second and third fingers the flow of the digital ulnar artery was greater compared to the digital radial artery. However, in the fourth and fifth fingers it was observed that the flow of the digital radial artery was greater in comparison to the digital ulnar artery, all of these results being statistically significant (Fig. 6A).
   - In terms of laterality, the trend was the same. With greater flow of the digital ulnar artery in the first, second and third fingers and greater flow of the digital radial artery in the fourth and fifth fingers, in both the right and left hand (Fig. 6B).
   - In terms of dominance, no statistically significant differences were observed between the digital radial and ulnar arteries of each finger of the dominant hand with respect to the digital arteries of the same fingers of the non-dominant hand (Fig. 6C).
   - In terms of gender, it was observed that the flow of the arteries, both digital radial and digital ulnar of the 5 fingers, was greater in the men than in the women (Fig. 6D).

Discussion

In this study describe the normal flow pattern of the radial and ulnar arteries of the wrist and the radial and ulnar digital arteries of each finger in a healthy Spanish population. In general terms, we observed that, regardless of the variables studied, at the level of the wrist the radial artery is of a greater size. However, it is the ulnar artery that presented flow dominance at this level. At finger level, we observed that in the first, second and third fingers it is the ulnar digital artery that presents a greater size, as well as flow dominance, over the radial digital artery. However, in the fourth and fifth fingers the digital radial artery was shown to be

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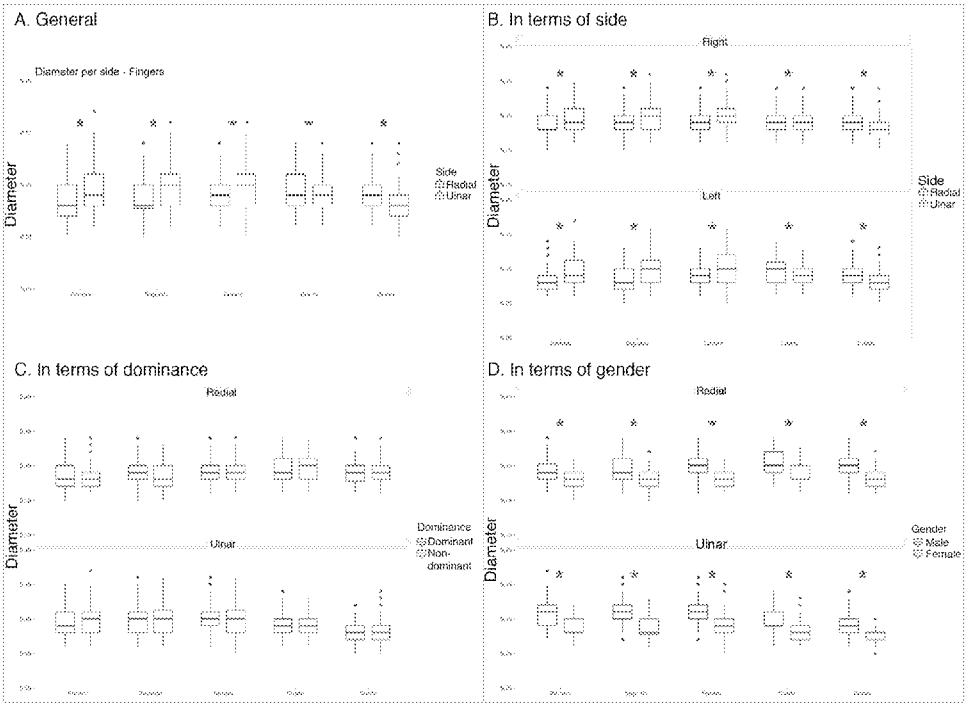


Figure 5 Comparative study of the size (transverse diameter) of the digital arteries in the fingers shown in cm. (A) General comparison (with no discrimination). (B) Comparison in terms of side (right hand/left hand). (C) Comparison in terms of dominance (dominant hand/non-dominant hand). (D) Comparison in terms of gender (male/female). The asterisk indicates statistically significant differences at $p < .05$.

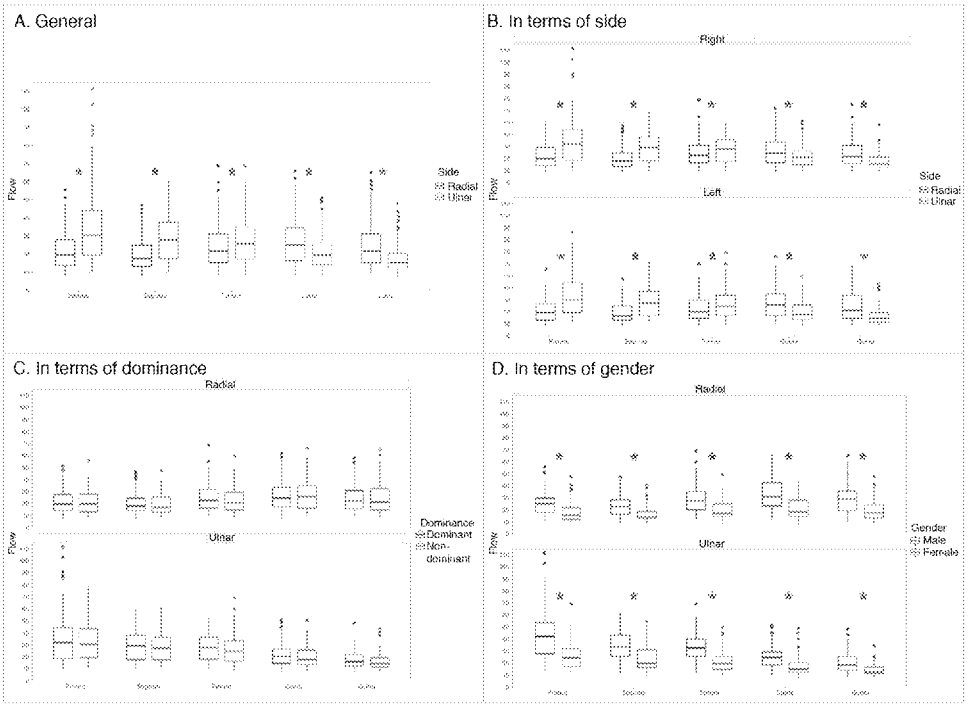


Figure 6 Comparative study of the flow velocity (systolic peak) of the digital arteries in the fingers shown in cm/s. (A) General comparison (with no discrimination). (B) Comparison in terms of side (right hand/left hand). (C) Comparison in terms of dominance (dominant hand/non-dominant hand). (D) Comparison in terms of gender (male/female). The asterisk indicates statistically significant differences at $p < .05$.

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of greater size and flow dominance compared to the digital ulnar artery.

Regarding the ultrasound study of the size of the arteries of the wrist, in the current literature there are several studies that focus on the comparative analysis between the radial and ulnar arteries, with different conclusions. Ashraf et al.[9] establish that the ulnar artery is larger in size than the radial. However, other studies conclude that the radial artery is larger at the wrist,[3–5] or that they find no significant differences in sizes.[10] Some of these studies also compared the size of these arteries according to laterality, and found no differences between the arteries of the right and left wrist,[3] or differences between the dominant and non-dominant hand,[4,10] but found a larger size of the radial artery in men compared to women.[4,10] In our study we observed that, regardless of the discriminated variable, the size of the radial artery is always larger than the ulnar artery, in contrast to some of the abovementioned studies. In terms of laterality, we also found no differences in arterial size when comparing right and left hands. Similarly, we found no differences in terms of dominance. Finally, on analysing size in terms of gender, we did find statistically significant differences in the size of both the radial and ulnar arteries, which were larger in the men. To explain the difference in the results, we should mention that our sample was obtained from completely healthy patients, with demanding exclusion criteria, while many of these studies included a populations with diseases that could impair vascularisation.

The arterial flow in the arteries of the wrist has also been studied in several papers. There are studies describing a flow pattern in which the ulnar artery is the dominant artery in the wrist[4,11]; however, we also found studies describing a pattern of radial dominance.[3,12] It seems that radial dominance is more likely in patients who smoke, since in smokers the ulnar artery is most affected.[12] The harmful effect of smoking on the circulation of the hand is known,[13,14] and finding radial dominance in patients who smoke does not go against our study, in which smoking was a criterion for exclusion. In our study it was observed that, in the wrist, the ulnar artery is dominant over the radial artery; our findings coincide with the first studies mentioned. If we take laterality into account, there are no marked differences between the flow of the left and right hand, the ulnar artery being the dominant artery in both hands. No previous studies of arterial flow in the wrist have been described that consider dominance, and in our study no statistically significant differences were observed between the flow from the dominant and the non-dominant hand. Finally, when considering gender, blood flow at the wrist was found to be higher in the men than in the women. Probably one of the most curious data of this study is the discrepancy between the size and flow of the radial and ulnar arteries, since, in spite of the larger size of the radial artery, the flow is less.

Regarding the size of the radial and ulnar digital arteries of each finger, the only article we found that studies the size of the digital vessels ultrasonically is the one by Trager et al.[11] on 20 patients. They describe that the ulnar artery of the first, second and third fingers is larger than the radial, while the radial artery of the fourth and fifth fingers is the largest. The same results were obtained in our study.

Finally, our last comparative analysis refers to the flow of the digital arteries in the fingers. Similarly, the only article we found that studies the flow velocity of the digital arteries is that of Trager et al.[11] They describe a greater flow in the arteries with a larger diameter, i.e. the ulnar of the first to the third fingers and the radial of the fourth and fifth fingers. In our study of 200 hands and 1000 fingers we found the same results. We were able to make a heat map in which the flow in each of the arteries of the fingers can be seen graphically (Fig. 7).

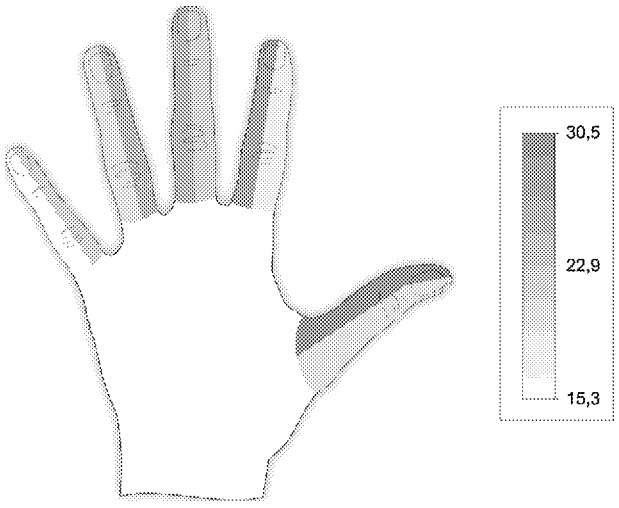


Figure 7 Heat map reflecting the flow for each digital artery. The colour shown is adjusted to the median obtained for the flow velocity of each artery.

As a limitation of the study, we should point out that the measurements were made by a single scanner (always the same one), but the measurements were not compared between two different scanners for interobserver validation.

As a curiosity, it is worth noting that the size and flow is less in areas of the fingers ''less protected from injury'' and where greater support is provided, such as the ulnar area of the fourth and fifth fingers and the radial area of the first, second and third fingers, while the arteries in the more protected areas provide greater vascular support. This has a completely logical evolutionary explanation in which the vascular contribution of the finger is protected, giving greater importance to the arteries that have less risk of injury.

Conclusion

The pattern of normal flow of the radial and ulnar arteries of the wrist and the radial and ulnar digital arteries of each finger in a healthy Spanish population has been described. In general terms, we observed that, regardless of the variables studied, at wrist level the radial arteries are greater in size. However, it is the ulnar artery that presented flow dominance at this level. At finger level, we observed that in the first, second and third fingers it is the ulnar digital artery that was larger in size, as well as flow dominance, than the radial digital artery of these fingers. However, in the fourth and fifth fingers we found that it is the digital radial artery that is larger in size and flow dominance compared to the digital ulnar artery of the same fingers. It can be concluded

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that there is a greater size and flow of the arteries in the areas of the fingers most protected from injury (ulnar area of the first, second and third fingers and radial area of the fourth and fifth) and a smaller size and flow in the areas of greater support and probability of injury (radial area of the first, second and third fingers and ulnar area of the fourth and fifth).

Level of evidence

Level of evidence III.

Conflict of interests

The authors have no conflict of interests to declare.

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Validation of normalized pulse volume in the outer ear as a simple measure of sympathetic activity using warm and cold pressor tests: towards applications in ambulatory monitoring

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Abstract

Normalized pulse volume (NPV) derived from the ear has the potential to be a practical index for monitoring daily life stress. However, ear NPV has not yet been validated. Therefore, we compared NPV derived from an index finger using transmission photoplethysmography as a reference, with NPV derived from a middle finger and four sites of the ear using reflection photoplethysmography during baseline and while performing cold and warm water immersion in ten young and six middle-aged subjects. The results showed that logarithmically-transformed NPV (lnNPV) during cold water immersion as compared with baseline values was significantly lower, only at the index finger, the middle finger and the bottom of the ear-canal. Furthermore, lnNPV reactivities (ΔlnNPV; the difference between baseline and test values) from an index finger were significantly related to ΔlnNPV from the middle finger and the bottom of the ear-canal (young: $r = 0.90$ and 0.62, middle-aged: $r = 0.80$ and 0.58, respectively). In conclusion, these findings show that reflection and transmission photoplethysmography are comparable methods to derive NPV in accordance with our theoretical prediction. NPV derived from the bottom of the ear-canal is a valid approach, which could be useful for evaluating daily life stress.

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Keywords: normalized pulse volume (NPV), ear-canal, photoplethysmography, cold pressor test, stress monitoring

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1. Introduction

There have been sustained efforts, over several decades, to develop and improve non-invasive methods to investigate and monitor cardiovascular phenomena in various circumstances and such methods are of importance for clinical diagnosis and for monitoring therapies, as well as for research (Palatini *et al* 2011). Along with the development of non-invasive techniques for the measurement of blood pressure and blood flow, the investigation of pulse pressure (PP), pulse wave velocity (PWV) and pulse volume (PV) have also attracted considerable interest (Hamilton *et al* 2007, Millasseau *et al* 2000, 2006, Xin *et al* 2007). PP, PWV and PV are recognized as having potentially useful relationships with arterial blood pressure, stroke volume and vascular mechanical properties, especially arterial tone and stiffness. Furthermore, peripheral PV has been found to provide information on autonomic vascular control (Javed *et al* 2010, Miller and Ditto 1989, 1991, Nitzan *et al* 1994, Piepoli *et al* 1995).

PV can be measured quantitatively or detected qualitatively with a number of techniques, including air or water plethysmography, strain gauge plethysmography, electrical impedance plethysmography (EIP) and photoelectric plethysmography (PPG). Air and water plethysmography can provide relatively direct quantitative measurements of PV and, by performing venous occlusion, they also allow estimation of blood flow, for example in a limb or digit. Strain gauge plethysmography and EIP have also been shown to allow both PV and blood flow estimations. PPG has been particularly popular for the assessment of peripheral perfusion due to its simplicity and convenience, in its simplest form only requiring the attachment of a light emitting diode (LED) and a photodetector (PD) (Challoner 1979, Lindberg *et al* 1991). Although PPG has been shown to be capable of providing accurate quantitative data for heart rate and/or oxygen saturation, even under challenging conditions (Lopez-Silva *et al* 2012, Townshend *et al* 2006), the amplitude of the PPG signal hitherto has only provided predominantly qualitative data. There has therefore been significant interest in methods for normalizing the PPG amplitude and this interest continues.

The efforts to develop PPG have centred on the study of the component parts of the signals obtained by this technique, particularly their relationships with physical and physiological factors. Signals produced by PPG relate to the intensity of light, $\boldsymbol{I}$, that is detected following absorption and scattering processes as the incident light, $\boldsymbol{I}_o$, propagates within tissues, and the Beer–Lambert–Bouguer law can be used to describe the relationship between $\boldsymbol{I}$ and $\boldsymbol{I}_o$. The PPG signal, which arises from $\boldsymbol{I}$, contains two basic components: firstly, a cardiac-synchronous pulse, the ac component, $\boldsymbol{I}_{ac}$, resembling the arterial blood pressure waveform, which is produced by the absorption of light by pulsating arterial and arteriolar blood; secondly, a slowly varying background signal, the dc component, $\boldsymbol{I}_{dc}$, that is related to absorption of light by tissues and venous blood. The PV signal derived from $\boldsymbol{I}$ in this way certainly has a relationship with the true arterial PV in the region of tissue interrogated by the light emitter–detector pair, but the exact relationship varies according to a number of factors, including the emitter–detector spacing and configuration, the wavelength of light used and the anatomical site used for the measurement. Thus direct comparisons of PV signals between different sites and different subjects are not possible. In order to address this problem, at least in

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part, the very earliest reports of the method included approaches for the normalization of the PV-related plethysmogram signals, that is the ac component, for example by expressing the volume pulse amplitude, $\triangle \boldsymbol{I}_{ac}$, as a percentage of the total photoelectric signal, $\boldsymbol{I}$; thus normalized pulse volume, NPV, was calculated as $(\triangle \boldsymbol{I}_{ac}/\boldsymbol{I})$ 100% (Davis and Hertzman 1957). The total photoelectric signal, $\boldsymbol{I}$, is often rewritten as $\boldsymbol{I}_{dc}$ and this is a valid approximation since $\triangle \boldsymbol{I}_{ac}$ is very much smaller than $\boldsymbol{I}_{dc}$. Further approaches are to normalize the $\triangle \boldsymbol{I}_{ac}$ amplitude to the baseline $\triangle \boldsymbol{I}_{ac}$ amplitude, or to the dc component, $\boldsymbol{I}_{dc}$, (Sawada *et al* 2001, Tanaka and Sawada 2003, Xin *et al* 2007) or, to enable waveform changes to be perceived more easily, to normalize the $\boldsymbol{I}_{ac}$ pulse width to the baseline pulse width value (Allen and Murray 2003).

Traditionally, the photoplethysmogram has been obtained from the fingertip with the light source and detector in the transmission configuration. This site is particularly useful for studying autonomic control since the arteriolar vessels here are known to be very sensitive to vasoconstrictor stimuli (Sawada *et al* 2001). Other anatomical sites have also been used, in some cases, such as the toe and ear lobe, with transmission optodes and in other cases, including the forehead and oesophagus, using the reflectance configuration (Allen and Murray 2000). Of all of these possible sites, the different locations on and in the ear can have several advantages. The vessels of the deep auricular artery, which originates from either the maxillary or the superficial temporal artery, ascend through the bony wall of the ear-canal from the parotid gland under the ear-canal, with its branches providing a supply to the lining and periphery of the ear-canal (Gray and Lewis 1918, Wasicky and Pretterklieber 2000). Thus, the photoplethysmogram can be obtained from there with the reflectance configuration. Furthermore there is relative freedom from motion artefacts produced, for example, during walking (Brodersen *et al* 2007, Vogel *et al* 2009, Wartzek *et al* 2009). Therefore, the collection of PPG-derived measurements from different regions of the ear could be well suited to the task of monitoring stress during normal daily life, especially through the use of the normalized pulse volume index, NPV.

Despite these potential advantages, the NPV derived from the ear has not yet been validated. Although Vogel and colleagues have validated the measurement of heart rate using the PV recorded in the ear-canal, they did not validate NPV (Vogel *et al* 2009, Wartzek *et al* 2009). Therefore, the purpose of our present study was to validate the ear NPV for evaluating stress. We used NPV derived from an index finger with the transmission mode PPG configuration (NPVt_IF) as a reference. We then compared the reference data with NPV values derived from a middle finger (NPVr_MF), from the top and bottom of the ear-canal (NPVr_ECT and NPVr_ECB, respectively), as well as from the upper and lower parts of the ear-auricle (NPVr_EAU and NPVr_EAL, respectively), in all cases using the reflection mode PPG configuration. We used cold pressor tests (CPT) and warm water immersion (WWI) as physiological challenges.

2. Methods

2.1. Participants

Two groups of participants, without known cardiovascular disorders, took part in this study. In the 'young' group there were ten males, with a mean age of 21.9 $\pm$ 0.8 S.D. years, whilst the 'middle-aged' group contained six males, with a mean age of 48.8 $\pm$ 10.9 S.D. years. All subjects agreed to take part in this study voluntarily and signed an informed consent statement. The experimental design was approved by the ethics committee of the Faculty of Medicine of Kanazawa University.

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2.2. Principle

In this study we derived NPV data from the photoplethysmograph, which is based on the Beer–Lambert–Bouguer law that describes the relationship between the intensity of incident light ($\boldsymbol{I}_o$) and transmitted light ($\boldsymbol{I}$), when the light passes through a non-scattering medium. If it is assumed that this law can be applied for transmission measurements in the fingertip, the relationship between the pulsatile change in the arterial blood volume, $\triangle \boldsymbol{V}_a$, and the intensity of the transmitted light could be derived. Within this context, the use of the transmission PPG obtained from a finger to derive the NPV has been analysed theoretically with the application of the Beer–Lambert–Bouguer law (Sawada *et al* 2001, Tanaka and Sawada 2003). It was shown (Sawada *et al* 2001, Tanaka and Sawada 2003) that NPV could be derived simply by normalizing the magnitude of the ac component to the mean dc component, giving the following relationship:

$$\mathrm{NPV} = \Delta I_{\mathrm{ac}} \big/ I_{\mathrm{dc}} (\propto \Delta V_a). \tag{1}$$

Equation (1) shows that the peak-to-trough magnitude of the ac component ($\triangle \boldsymbol{I}_{\mathrm{ac}}$) is essentially corrected by the mean intensity of transmitted light, which is the mean dc component ($\boldsymbol{I}_{\mathrm{dc}}$) photoplethysmographically detected from the finger. Thus, NPV is in direct proportion to the pulsatile component of the arterial blood volume, $\triangle V_a$.

However, the validity of equation (1) must be questioned since it is based on the assumption of a non-scattering medium; in fact, when light passes through biological tissues it is extensively scattered as well as absorbed. Thus, the modified Beer–Lambert–Bouguer law, which includes the influence of light-scattering, should be considered (Nishimura *et al* 1996, Twersky 1962, 1970).

According to the modified Beer–Lambert–Bouguer law for light-scattering, the relation between $\boldsymbol{I}_o$ and $\boldsymbol{I}$, when the light passes through absorptive and scattering homogeneous media, can be expressed as

$$-\ln(\boldsymbol{I}/\boldsymbol{I}_o) = \varepsilon C k V + S, \tag{2}$$

where ε is the molar absorptivity of the medium, C is the molar concentration of the medium. k is a volume correction factor, which is defined as the average of the differential path-length of light caused by scattering in the medium between light source and PD. If the light passes through a non-scattering medium then $k = 1$, whilst when there is scattering, $k > 1$. V is the volume of the medium where there is non-scattering (i.e. $k = 1$), and S is the attenuation due to scattering. Equation (2) can be rewritten as

$$-\ln(\boldsymbol{I}/\boldsymbol{I}_o) = \varepsilon C V_c + S, \tag{3}$$

where V_c is the corrected volume: $V_c = kV$.

We now consider the fingertip being composed of three components: arterial blood, venous blood and ischemic tissue. If we assume that the modified Beer–Lambert–Bouguer law holds in the fingertip, the relation between $\boldsymbol{I}_o$ and $\boldsymbol{I}$ can be expressed by the following equation:

$$-\ln(\boldsymbol{I}/\boldsymbol{I}_o) = \varepsilon_a C_a V_{\mathrm{ca}} + \varepsilon_v C_v V_{\mathrm{cv}} + \varepsilon_t C_t V_{\mathrm{ct}} + S_{a+v+t}. \tag{4}$$

Here ε_a, ε_v and ε_t are the absorptivity of the arterial and venous blood, and combined tissue other than blood, respectively. Similarly, C_a, C_v and C_t are the haematocrit (i.e. concentration of haemoglobin) of the arterial and venous blood, as well as the concentration of the combined tissue absorbers, respectively. V_{ca}, V_{cv} and V_{ct} are the correction volume of the arterial blood, venous blood and bloodless tissue, respectively. S_{a+v+t} is the attenuation due to scattering under a normal circulatory state in which arterial and venous blood and bloodless tissue all contribute to scatter.

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Next, we consider the situation in which the finger is made to be ischemic, there then being only the bloodless tissue present. Now the relationship between $\boldsymbol{I}_o$ and the transmitted light intensity, $\boldsymbol{I}_t$, is given as

$$-\ln(\boldsymbol{I}_t/\boldsymbol{I}_o) = \varepsilon_t C_t V_{\mathrm{ct}} + S_t, \tag{5}$$

where S_t is the attenuation due to scattering by the bloodless tissue under an ischemic circulatory state.

Subtracting equation (5) from equation (4), and using the exponential transform yields the following equation:

$$\boldsymbol{I}/\boldsymbol{I}_t = \mathrm{e}^{(-\varepsilon C V_c + S)}, \tag{6}$$

where V_c is the corrected volume of the total blood, ε is the mean absorptivity of the total blood and S is the scattering attenuation of the total blood: $V_c = V_{\mathrm{ca}} + V_{\mathrm{cv}}$, $\varepsilon = (\varepsilon_a V_{\mathrm{ca}} + \varepsilon_v V_{\mathrm{cv}})/V_c$, and $S = S_{a+v+t} - S_t$, respectively. C_a and C_v are considered to be constant and equal to the mean concentration of the total blood (C) under a normal circulatory state, and these change only a few per cent from rest to a mental stress state (Muldoon *et al* 1992); thus $C = C_a = C_v$.

Taking the first derivative of $\boldsymbol{I}/\boldsymbol{I}_t$ with respect to V_c in equation (6) leads to

$$d(\boldsymbol{I}/\boldsymbol{I}_t)/dV_c = -\varepsilon C(\boldsymbol{I}/\boldsymbol{I}_t), \tag{7}$$

and this subsequently leads to

$$\Delta V_c = -(\varepsilon C)^{-1}\Delta \boldsymbol{I}/\boldsymbol{I}. \tag{8}$$

Here, $\triangle V_c$ consists of the volume correction factor and the pulsatile components of the total blood volume: $\triangle V_c = k\triangle V$. Although the total blood volume consists of the mean and pulsatile components of the arterial blood volume, as well as of the venous blood volume, pulsation is only observed in arterial and arteriolar blood, so $\triangle V$ and the corresponding $\triangle \boldsymbol{I}$ may be rewritten as $\triangle V_a$ and $\triangle \boldsymbol{I}_{\mathrm{ac}}$, respectively. Correspondingly, $\boldsymbol{I}$ may be rewritten as $\boldsymbol{I}_{\mathrm{dc}}$. Thus

$$\Delta V_a = -(k\varepsilon C)^{-1}\Delta \boldsymbol{I}_{\mathrm{ac}}/\boldsymbol{I}_{\mathrm{dc}}. \tag{9}$$

The NPV being equal to the ratio of the ac and dc PPG components, $\triangle \boldsymbol{I}_{\mathrm{ac}}/\boldsymbol{I}_{\mathrm{dc}}$, is therefore simply derived from equation (9). It can be seen that NPV is related to the pulsatile component of the arterial blood volume, $\triangle V_a$. Furthermore, there may be considered to be direct proportionality on the assumption that the mean absorptivity (ε), the haematocrit (C) and the volume correction factor (k) of the total blood are constant. Conditions under which the validity of such an assumption can be ensured will be relatively easily met by adopting short term mental stress testing (Muldoon *et al* 1992) or by using an isosbestic wavelength (e.g. 805 nm). Thus, from equation (9), we may state the modified NPV (mNPV):

$$\mathrm{mNPV} = \Delta \boldsymbol{I}_{\mathrm{ac}}\big/\boldsymbol{I}_{\mathrm{dc}} (\propto \Delta V_a). \tag{10}$$

This theoretical derivation, which utilizes the modified Beer–Lambert–Bouguer law, serves to validate the use of the mNPV mathematical relationship in real biological tissues where there are both absorptive and scattering processes. This provides more confidence in the use of the NPV index when the method is applied to reflection PPG, where multiple scattering events are key aspects of photon propagation.

It is noteworthy, however, that, regardless of the starting point, the final result as seen in equation (10) is the same as equation (1). Therefore, we are justified in using the term 'NPV' instead of 'mNPV'. Nevertheless, although the derivation described above confirms that there is no need to distinguish between the NPV using the transmission mode PPG (NPVt) and that using the reflection mode PPG (NPVr), for completeness in this paper we continue to specify NPVt and NPVr.

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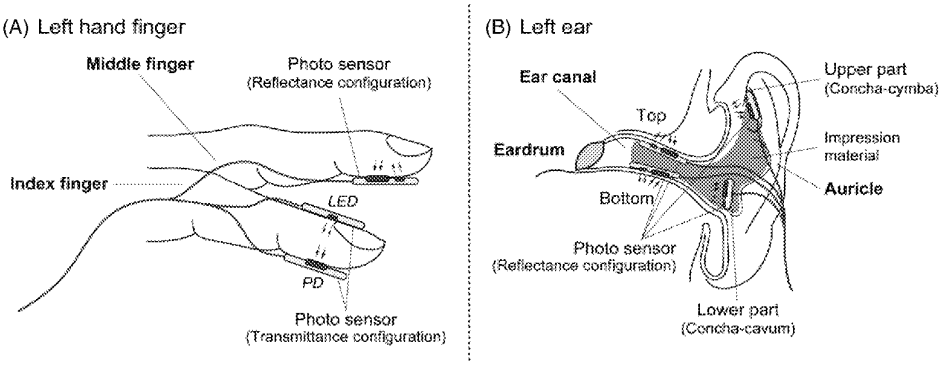


Figure 1. The placement of sensors for the measurement of NPV. Left hand finger: an index finger using the transmission type sensor as a reference; a middle finger using the reflection type sensor (panel A). Left ear: the top and bottom of the ear-canal, and the upper and lower part of the ear-auricle using the reflection type sensors (panel B).

2.3. Measurements and instruments

Near-infrared LEDs (940 nm, VSMB1940X01, Vishay, USA) were used as light sources and PIN photodiodes (BPW34FS, OSRAM, Germany) as the detectors. Figure 1 shows the attachment configuration of sensors for the measurement of NPV. An LED and a photodiode were placed on opposite sides of the distal part of the index finger of the left hand (IF), in the transmission mode PPG. For all other measurement sites the reflection mode PPG was used, with the LED and photodiode of each pair being placed side by side. The reflection sites were: at the distal part of the middle finger of the left hand (MF) (see figure 1 panel A), the top and bottom of the ear-canal (ECT and ECB, respectively), as well as the upper and lower part of the ear-auricle on the left ear (EAU and EAL, respectively) (see figure 1 panel B). The LEDs used in the ear were operated in the pulsatile mode, receiving 250 μs pulses at 16.6 ms intervals, to allow simultaneous measurement without interference among the four channels in the ear. The ac and dc photodiode outputs were amplified with gains of 150 and 100 respectively using a high precision OP-Amp. The signals were recorded by a data acquisition card (BNC-2111, National Instruments, USA) with 1 kHz sampling rate, for storage and off-line analysis using LabVIEW (National Instruments, Austin, USA). We carefully positioned the reflection type sensors in the ear-canal and the ear concha, and then secured them by infusing an impression material (detax addition, DETAX, Germany).

For calculating NPV, we measured PV and $\boldsymbol{I}_{\mathrm{dc}}$ at the index finger using the transmission PPG (PVt_IF and $\boldsymbol{I}_{\mathrm{dc}}$t_IF). Also, we measured PV and $\boldsymbol{I}_{\mathrm{dc}}$ at the MF (PVr_MF and $\boldsymbol{I}_{\mathrm{dc}}$r_MF), the ECT (PVr_ECT and $\boldsymbol{I}_{\mathrm{dc}}$r_ECT), the ECB (PVr_ECB and $\boldsymbol{I}_{\mathrm{dc}}$r_ECB), the EAU (PVr_EAU and $\boldsymbol{I}_{\mathrm{dc}}$r_EAU) and the EAL (PVr_EAL and $\boldsymbol{I}_{\mathrm{dc}}$r_EAL) using the reflection PPG.

2.4. Procedure

Participants were requested to refrain from drinking alcohol and carrying out vigorous exercise for at least 1 day before the experiment, and from smoking, eating and taking caffeinated beverages for least 2 h before. Participants were subjected to two challenges: CPT (4 °C) and WWI (37 °C) of the right hand up to the wrist to induce peripheral vasoconstriction (Allen *et al* 1992, 1997). The experiments were performed in a quiet, air-conditioned laboratory

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(temperature: 26 °C; humidity: 53%). At the start the participants sat on a chair to relax, and then the sensors were attached on the index and middle finger of the left hand, as well as the ear-canal and the auricle of the left ear. The stages of the experiment were carried out in the following order while the participants sat quietly: (a) adaptation for 10 min; (b) baseline (BS) for 5 min; (c) the CPT for 90 s; (d) rest for 5 min; (e) the WWI for 90 s.

2.5. Data analysis

All the stored data were equally subject to 30 Hz low pass digital filtering based upon the fast Fourier transform algorithm. Logarithmic transformation was applied to PV, $\boldsymbol{I}_{dc}$ and NPV to normalize the distribution (lnPV, ln$\boldsymbol{I}_{dc}$ and lnNPV, respectively). lnPV, ln$\boldsymbol{I}_{dc}$ and lnNPV values were averaged over 10 s, and these values further averaged to produce BS, first (0–30 s), second (30–60 s) and third (60–90 s) parts of the CPT as well as WWI values, respectively. These values were separated into two series: the CPT series and the WWI series. Each series was compared statistically by means of the one-way analysis of variance (ANOVA), and then Ryan's method applied for the comparisons.

Furthermore, lnPV and lnNPV reactivities (ΔlnPV and ΔlnNPV) were calculated by subtracting the BS values from the CPT and WWI values. Then, Pearson's correlation analysis was performed between ΔlnNPVt_IF as a reference and ΔlnNPVr_MF, ΔlnNPVr_ECT, ΔlnNPVr_ECB, ΔlnNPVr_EAU and ΔlnNPVr_EAL, respectively, as well as, between ΔlnNPVt_IF as a reference and ΔlnPVr_ECT, ΔlnPVr_ECB, ΔlnPVr_EAU and ΔlnPVr_EAL, respectively.

3. Results

3.1. lnPV and ln$\boldsymbol{I}_{dc}$, as well as lnNPV in the young group

Mean and S.D. values of lnPV and ln$\boldsymbol{I}_{dc}$, as well as lnNPV, during the CPT, are summarized in table 1 for the index finger, the middle finger, the top of the ear-canal, the bottom of the ear-canal, the upper part of the ear-auricle and the lower part of the ear-auricle, respectively. In the same way, mean and S.D. values of lnPV and ln$\boldsymbol{I}_{dc}$, as well as lnNPV, during the WWI, are summarized in table 2.

3.1.1. Index finger. During the CPT, the one-way ANOVA revealed the main effect of period: F (3,27) = 75.44, $p < 0.001$ for lnPVt_IF; F (3,27) = 79.48, $p < 0.001$ for ln$\boldsymbol{I}_{dc}$t_IF; F (3,27) = 107.80, $p < 0.001$ for lnNPVt_IF. Furthermore, significant differences among each period were found by Ryan's method: BS > CPT1, CPT2 and CPT3 for lnPVt_IF and lnNPVt_IF; BS < CPT1, CPT2 and CPT3 for ln$\boldsymbol{I}_{dc}$t_IF. Additionally, during the WWI, ANOVA revealed the main effect of period: F (3,27) = 11.46, $p < 0.001$ for lnPVt_IF; F (3,27) = 16.51, $p < 0.001$ for ln$\boldsymbol{I}_{dc}$t_IF; F (3,27) = 16.57, $p < 0.001$ for lnNPVt_IF. Significant differences among each period were found by Ryan's method: BS > WWI1 for lnPVt_IF and lnNPVt_IF; BS < WWI1, WWI2 and WWI3 for ln$\boldsymbol{I}_{dc}$t_IF.

3.1.2. Middle finger. During the CPT, the one-way ANOVA revealed the main effect of period: F (3,27) = 80.77, $p < 0.001$ for lnPVr_MF; F (3,27) = 17.74, $p < 0.001$ for ln$\boldsymbol{I}_{dc}$r_MF; F (3,27) = 80.68, $p < 0.001$ for lnNPVr_MF. Furthermore, significant differences among each period were found by Ryan's method: BS > CPT1, CPT2 and CPT3 for lnPVr_MF and lnNPVr_MF; BS < CPT1, CPT2 and CPT3 for ln$\boldsymbol{I}_{dc}$r_MF. Also, during the WWI, ANOVA revealed the main effect of period: F (3,27) = 18.58, $p < 0.001$ for lnPVr_MF;

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Table 1. Mean (S.D.) values of lnPV and lnI_{dc}, as well as lnNPV for different anatomical positions in the 'young' group, during baseline and while performing the CPT.

		Cold pressor test (CPT)		
	Baseline (5 min)	CPT1 (0–30 s)	CPT2 (30–60 s)	CPT3 (60–90 s)
Index finger				
lnPVt (mV)	2.57 (0.21)	1.69^{***} (0.26)	1.42^{***} (0.23)	1.55^{***} (0.27)
lnI_{dc}t (mV)	5.38 (0.18)	5.66^{***} (0.19)	5.76^{***} (0.19)	5.76^{***} (0.20)
lnNPVt (a.u.)	− 3.20 (0.26)	-4.40^{***} (0.26)	-4.77^{***} (0.31)	-4.63^{***} (0.38)
Middle finger				
lnPVr (mV)	2.62 (0.26)	1.33^{***} (0.31)	0.98^{***} (0.37)	1.15^{***} (0.42)
lnI_{dc}r (mV)	8.39 (0.09)	8.41^{***} (0.09)	8.42^{***} (0.09)	8.42^{***} (0.09)
lnNPVr (a.u.)	− 6.20 (0.23)	-7.55^{***} (0.36)	-7.85^{***} (0.41)	-7.68^{***} (0.45)
The top of the ear-canal				
lnPVr (mV)	0.54 (0.25)	0.36^{*} (0.35)	0.36^{*} (0.35)	0.41 (0.32)
lnI_{dc}r (mV)	8.42 (0.08)	8.42^{*} (0.08)	8.42^{*} (0.08)	8.43^{*} (0.08)
lnNPVr (a.u.)	− 8.29 (0.26)	− 8.40 (0.31)	− 8.46 (0.38)	− 8.42 (0.38)
The bottom of the ear-canal				
lnPVr (mV)	0.80 (0.35)	0.62^{**} (0.37)	0.54^{***} (0.39)	0.57^{**} (0.39)
lnI_{dc}r (mV)	8.39 (0.08)	8.39 (0.08)	8.39 (0.08)	8.39 (0.09)
lnNPVr (a.u.)	− 8.01 (0.37)	-8.18^{**} (0.39)	-8.27^{***} (0.44)	-8.24^{**} (0.44)
The upper part of the ear-auricle				
lnPVr (mV)	− 0.25 (0.22)	− 0.24 (0.21)	− 0.24 (0.16)	− 0.13 (0.17)
lnI_{dc}r (mV)	8.39 (0.07)	8.39 (0.07)	8.39 (0.07)	8.39 (0.07)
lnNPVr (a.u.)	− 9.06 (0.18)	− 9.06 (0.21)	− 9.05 (0.16)	− 8.90 (0.26)
The lower part of the ear-auricle				
lnPVr (mV)	0.29 (0.35)	0.18 (0.29)	0.12^{*} (0.26)	0.18 (0.23)
lnI_{dc}r (mV)	8.40 (0.07)	8.40 (0.07)	8.40 (0.08)	8.40 (0.07)
lnNPVr (a.u.)	− 8.52 (0.34)	− 8.64 (0.29)	-8.70^{*} (0.28)	− 8.64 (0.22)

Note. PV = pulse volume (gain = 150); I_{dc} = intensity of PPG signal (gain = 100); PPG = photoelectric plethysmography; NPV = normalized pulse volume; PVt, I_{dc}t, NPVt = PV, I_{dc} and NPV using the transmission mode PPG, respectively; PVr, I_{dc}r, NPVr = PV, I_{dc} and NPV using the reflection mode PPG, respectively; a.u. = arbitrary unit.

The comparisons between 5 min mean during baseline and CPT mean for each 30 s block by Ryan's method.
$^{*}p < 0.05$. $^{**}p < 0.01$. $^{***}p < 0.001$.

F (3,27) = 3.53, $p < 0.05$ for lnI_{dc}r_MF; F (3,27) = 18.52, $p < 0.001$ for lnNPVr_MF. Significant differences among each period were found by Ryan's method: BS > WWI1 for lnPVr_MF and lnNPVr_MF.

3.1.3. The top of the ear-canal. During the CPT, the one-way ANOVA revealed the main effect of period: F (3,27) = 4.10, $p < 0.05$ for lnPVr_ECT; F (3,27) = 4.33, $p < 0.05$ for lnI_{dc}r_ECT; F (3,27) = 4.33, $p < 0.1$ for lnNPVr_ECT. Significant differences among each period were found by Ryan's method: BS > CPT1 and CPT2 for lnPVr_ECT; BS < CPT1, CPT2 and CPT3 for lnI_{dc}r_ECT. Furthermore, during WWI, ANOVA revealed the main effect of period: F (3,27) = 5.13, $p < 0.05$ for lnI_{dc}r_ECT. Significant differences among each period were found by Ryan's method: BS < WWI1, WWI2 and WWI3 for lnI_{dc}r_ECT.

3.1.4. The bottom of the ear-canal. During the CPT, the one-way ANOVA revealed the main effect of period: F (3,27) = 8.43, $p < 0.001$ for lnPVr_ECB; F (3,27) = 8.44, $p < 0.001$

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Table 2. Mean (S.D.) values of lnPV and $\ln I_{dc}$, as well as lnNPV for different anatomical positions in the 'young' group, during baseline and while performing the WWI.

		Warm water immersion (WWI)		
	Baseline (5 min)	WWI1 (0–30 s)	WWI2 (30–60 s)	WWI3 (60–90 s)
Index finger				
lnPVt (mV)	2.57 (0.21)	2.34^{***} (0.20)	2.56 (0.26)	2.55 (0.23)
$\ln I_{dc}$t (mV)	5.38 (0.18)	5.56^{***} (0.19)	5.48^{**} (0.17)	5.47^{**} (0.19)
lnNPVt (a.u.)	− 3.20 (0.26)	-3.64^{***} (0.23)	− 3.32 (0.27)	− 3.32 (0.31)
Middle finger				
lnPVr (mV)	2.62 (0.26)	2.14^{***} (0.27)	2.52 (0.38)	2.48 (0.38)
$\ln I_{dc}$r (mV)	8.39 (0.09)	8.40 (0.09)	8.39 (0.09)	8.39 (0.09)
lnNPVr (a.u.)	− 6.20 (0.23)	-6.71^{***} (0.24)	− 6.29 (0.35)	− 6.34 (0.38)
The top of the ear-canal				
lnPVr (mV)	0.54 (0.25)	0.48 (0.29)	0.47 (0.27)	0.50 (0.25)
$\ln I_{dc}$r (mV)	8.42 (0.08)	8.42^{*} (0.08)	8.42^{*} (0.08)	8.42^{*} (0.08)
lnNPVr (a.u.)	− 8.29 (0.26)	− 8.36 (0.33)	− 8.37 (0.31)	− 8.33 (0.28)
The bottom of the ear-canal				
lnPVr (mV)	0.80 (0.35)	0.73 (0.37)	0.72 (0.38)	0.74 (0.36)
$\ln I_{dc}$r (mV)	8.39 (0.08)	8.39 (0.09)	8.39 (0.09)	8.39 (0.09)
lnNPVr (a.u.)	− 8.01 (0.37)	− 8.08 (0.41)	− 8.08 (0.43)	− 8.06 (0.41)
The upper part of the ear-auricle				
lnPVr (mV)	− 0.25 (0.22)	− 0.24 (0.20)	− 0.31 (0.21)	− 0.26 (0.19)
$\ln I_{dc}$r (mV)	8.39 (0.07)	8.39 (0.07)	8.39 (0.07)	8.39 (0.07)
lnNPVr (a.u.)	− 9.06 (0.18)	− 9.05 (0.19)	− 9.12 (0.19)	− 9.07 (0.17)
The lower part of the ear-auricle				
lnPVr (mV)	0.29 (0.35)	0.23 (0.35)	0.21 (0.32)	0.24 (0.31)
$\ln I_{dc}$r (mV)	8.40 (0.07)	8.40 (0.07)	8.40 (0.08)	8.40 (0.08)
lnNPVr (a.u.)	− 8.52 (0.34)	− 8.59 (0.36)	− 8.61 (0.34)	− 8.58 (0.34)

Note. For details, see the legend of table 1.

The comparisons between 5 min mean during baseline and WWI mean for each 30 s block by Ryan's method.
$^{*}p < 0.05$. $^{**}p < 0.01$. $^{***}p < 0.001$.

for lnNPVr_ECB. Significant differences among each period were found by Ryan's method: BS > CPT1, CPT2 and CPT3 for lnPVr_ECB and lnNPVr_ECB.

3.1.5. The upper part of the ear-auricle. During the CPT, the one-way ANOVA revealed the main effect of period: $F(3,27) = 3.05$, $p < 0.05$ for lnPVr_EAU; $F(3,27) = 2.79$, $p < 0.1$ for $\ln I_{dc}$r_EAU; $F(3,27) = 2.55$, $p < 0.1$ for lnNPVr_EAU.

3.1.6. The lower part of the ear-auricle. During the CPT, the one-way ANOVA revealed the main effect of period: $F(3,27) = 3.47$, $p < 0.05$ for lnPVr_EAL; $F(3,27) = 3.61$, $p < 0.05$ for lnNPVr_EAL. Significant differences among each period were found by Ryan's method: BS > CPT2 for lnPVr_EAL and lnNPVr_EAL.

3.2. lnPV and $\ln I_{dc}$, as well as lnNPV in the middle-aged group

Mean and S.D. values of lnPV and $\ln I_{dc}$, as well as lnNPV, during the CPT, are summarized in table 3 for the index finger, the middle finger, the top of the ear-canal, the bottom of the

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Table 3. Mean (S.D.) values of lnPV and lnI_{dc}, as well as lnNPV for different anatomical positions in the 'middle-aged' group, during baseline and while performing the CPT.

		Cold pressor test (CPT)		
	Baseline (5 min)	CPT1 (0–30 s)	CPT2 (30–60 s)	CPT3 (60–90 s)
Index finger				
lnPVt (mV)	1.87 (0.47)	1.03*** (0.35)	1.15*** (0.32)	1.40*** (0.43)
lnI_{dc}t (mV)	5.03 (0.35)	5.26*** (0.33)	5.32*** (0.30)	5.29*** (0.32)
lnNPVt (a.u.)	− 3.57 (0.27)	− 4.64*** (0.28)	− 4.58*** (0.23)	− 4.30*** (0.35)
Middle finger				
lnPVr (mV)	2.60 (0.24)	1.45*** (0.16)	1.59*** (0.18)	1.86*** (0.26)
lnI_{dc}r (mV)	8.44 (0.03)	8.47*** (0.02)	8.47*** (0.03)	8.46*** (0.03)
lnNPVr (a.u.)	− 6.27 (0.23)	− 7.45*** (0.13)	− 7.29*** (0.20)	− 7.02*** (0.27)
The top of the ear-canal				
lnPVr (mV)	0.40 (0.23)	0.33 (0.22)	0.37 (0.15)	0.45 (0.16)
lnI_{dc}r (mV)	8.46 (0.04)	8.46 (0.04)	8.46 (0.04)	8.46 (0.04)
lnNPVr (a.u.)	− 8.48 (0.26)	− 8.55 (0.25)	− 8.51 (0.18)	− 8.43 (0.20)
The bottom of the ear-canal				
lnPVr (mV)	0.66 (0.35)	0.51 (0.42)	0.46* (0.43)	0.59 (0.40)
lnI_{dc}r (mV)	8.46 (0.02)	8.46 (0.02)	8.46 (0.02)	8.46 (0.03)
lnNPVr (a.u.)	− 8.21 (0.36)	− 8.36 (0.44)	− 8.42* (0.45)	− 8.29 (0.43)
The upper part of the ear-auricle				
lnPVr (mV)	0.08 (0.27)	0.14 (0.15)	0.30 (0.24)	0.30 (0.29)
lnI_{dc}r (mV)	8.44 (0.03)	8.44 (0.03)	8.43 (0.04)	8.43 (0.03)
lnNPVr (a.u.)	− 8.78 (0.26)	− 8.73 (0.14)	− 8.56 (0.27)	− 8.56 (0.30)
The lower part of the ear-auricle				
lnPVr (mV)	0.11 (0.30)	0.05 (0.29)	0.08 (0.31)	0.20 (0.17)
lnI_{dc}r (mV)	8.43 (0.02)	8.43 (0.02)	8.43 (0.02)	8.43 (0.02)
lnNPVr (a.u.)	− 8.75 (0.34)	− 8.81 (0.30)	− 8.78 (0.30)	− 8.66 (0.21)

Note. For details, see the legend of table 1.

The comparisons between 5 min mean during baseline and CPT mean for each 30 s block by Ryan's method.
$^{*}p < 0.05$. $^{**}p < 0.01$. $^{***}p < 0.001$.

ear-canal, the upper part of the ear-auricle and the lower part of the ear-auricle, respectively. In the same way, mean and S.D. values of lnPV and lnI_{dc}, as well as lnNPV, during the WWI, are summarized in table 4.

3.2.1. Index finger. During the CPT, the one-way ANOVA revealed the main effect of period: $F(3,15) = 32.95$, $p < 0.001$ for lnPVt_IF; $F(3,15) = 76.24$, $p < 0.001$ for lnI_{dc}t_IF; $F(3,15) = 50.85$, $p < 0.001$ for lnNPVt_IF. Furthermore, significant differences among each period were found by Ryan's method: BS > CPT1, CPT2 and CPT3 for lnPVt_IF and lnNPVt_IF; BS < CPT1, CPT2 and CPT3 for lnI_{dc}t_IF. Additionally, during the WWI, ANOVA revealed the main effect of period: $F(3,15) = 4.40$, $p < 0.05$ for lnPVt_IF; $F(3,15) = 4.61$, $p < 0.05$ for lnI_{dc}t_IF; $F(3,15) = 4.63$, $p < 0.05$ for lnNPVt_IF. Significant differences among each period were found by Ryan's method: BS > WWI1 for lnPVt_IF and lnNPVt_IF; BS < WWI1 for lnI_{dc}t_IF.

3.2.2. Middle finger. During the CPT, the one-way ANOVA revealed the main effect of period: $F(3,15) = 45.65$, $p < 0.001$ for lnPVr_MF; $F(3,15) = 30.32$, $p < 0.001$ for lnI_{dc}r_MF;

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Table 4. Mean (S.D.) values of lnPV and lnI_{dc}, as well as lnNPV for different anatomical positions in the 'middle-aged' group, during baseline and while performing the WWI.

		Warm water immersion (WWI)		
	Baseline (5 min)	WWI1 (0–30 s)	WWI2 (30–60 s)	WWI3 (60–90 s)
Index finger				
lnPVt (mV)	1.87 (0.47)	1.47* (0.51)	1.69 (0.52)	1.74 (0.53)
lnI_{dc}t (mV)	5.03 (0.35)	5.20* (0.42)	5.14 (0.46)	5.10 (0.47)
lnNPVt (a.u.)	− 3.57 (0.27)	− 4.15* (0.57)	− 3.86 (0.68)	− 3.77 (0.69)
Middle finger				
lnPVr (mV)	2.60 (0.24)	1.95** (0.52)	2.32 (0.64)	2.41 (0.63)
lnI_{dc}r (mV)	8.44 (0.03)	8.46* (0.03)	8.45 (0.03)	8.45 (0.03)
lnNPVr (a.u.)	− 6.27 (0.23)	− 6.94** (0.53)	− 6.54 (0.66)	− 6.45 (0.65)
The top of the ear-canal				
lnPVr (mV)	0.40 (0.23)	0.35 (0.14)	0.30 (0.19)	0.35 (0.17)
lnI_{dc}r (mV)	8.46 (0.04)	8.46 (0.04)	8.46 (0.04)	8.46 (0.04)
lnNPVr (a.u.)	− 8.48 (0.26)	− 8.54 (0.18)	− 8.59 (0.21)	− 8.54 (0.20)
The bottom of the ear-canal				
lnPVr (mV)	0.66 (0.35)	0.61 (0.30)	0.60 (0.34)	0.61 (0.31)
lnI_{dc}r (mV)	8.46 (0.02)	8.45 (0.02)	8.45 (0.02)	8.45 (0.02)
lnNPVr (a.u.)	− 8.21 (0.36)	− 8.27 (0.32)	− 8.27 (0.35)	− 8.27 (0.33)
The upper part of the ear-auricle				
lnPVr (mV)	0.08 (0.27)	− 0.01 (0.20)	− 0.02 (0.22)	0.01 (0.24)
lnI_{dc}r (mV)	8.44 (0.03)	8.44 (0.03)	8.44 (0.03)	8.44 (0.03)
lnNPVr (a.u.)	− 8.78 (0.26)	− 8.88 (0.18)	− 8.88 (0.20)	− 8.86 (0.21)
The lower part of the ear-auricle				
lnPVr (mV)	0.11 (0.30)	0.04 (0.24)	− 0.05 (0.38)	0.02 (0.30)
lnI_{dc}r (mV)	8.43 (0.02)	8.43 (0.03)	8.43 (0.03)	8.43 (0.03)
lnNPVr (a.u.)	− 8.75 (0.30)	− 8.82 (0.26)	− 8.92 (0.41)	− 8.84 (0.31)

Note. For details, see the legend of table 1.
The comparisons between 5 min mean during baseline and WWI mean for each 30 s block by Ryan's method.
*$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.

F (3,15) = 49.38, $p < 0.001$ for lnNPVr_MF. Furthermore, significant differences among each period were found by Ryan's method: BS > CPT1, CPT2 and CPT3 for lnPVr_MF and lnNPVr_MF; BS < CPT1, CPT2 and CPT3 for lnI_{dc}r_MF. Also, during the WWI, ANOVA revealed the main effect of period: F (3,15) = 6.45, $p < 0.01$ for lnPVr_MF; F (3,15) = 4.84, $p < 0.05$ for lnI_{dc}r_MF; F (3,15) = 6.49, $p < 0.01$ for lnNPVr_MF. Significant differences among each period were found by Ryan's method: BS > WWI1 for lnPVr_MF and lnNPVr_MF; BS < WWI1 for lnI_{dc}r_MF.

3.2.3. The bottom of the ear-canal. During the CPT, the one-way ANOVA revealed the main effect of period: F (3,15) = 4.38, $p < 0.05$ for lnPVr_ECB; F (3,15) = 4.15, $p < 0.05$ for lnNPVr_ECB. Significant differences among each period were found by Ryan's method: BS > CPT2 for lnPVr_ECB and lnNPVr_ECB.

3.3. Correlation between the reactivities of lnNPV from an index finger as a reference and the reactivities of lnPVs and lnNPVs at the ear

During the CPT and WWI, Pearson's correlation coefficient between ΔlnNPV at the index finger as a reference and ΔlnPV and ΔlnNPV from the middle finger and the different

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Table 5. Pearson's correlation coefficient of △lnNPV from an index finger using transmission mode PPG as a reference and △lnPV and △lnNPV from the middle finger and the outer ear using reflection mode PPG in the 'young' and 'middle-aged' groups, respectively; during baseline and while performing cold and WWI.

	△lnNPVt_IF in young[a]		△lnNPVt_IF in middle-aged[b]	
	CPT	WWI	CPT	WWI
Middle finger				
△lnPVr (mV)	–	–	–	–
△lnNPVr (a.u.)	0.90**	0.96**	0.80**	0.99**
The top of the ear-canal				
△lnPVr (mV)	0.35	−0.12	0.13	0.15
△lnNPVr (a.u.)	0.45*	−0.10	0.14	0.17
The bottom of the ear-canal				
△lnPVr (mV)	0.60**	0.17	0.59*	−0.17
△lnNPVr (a.u.)	0.62**	0.18	0.58*	−0.19
The upper part of the ear-auricle				
△lnPVr (mV)	0.18	−0.08	−0.03	−0.17
△lnNPVr (a.u.)	0.23	−0.09	−0.04	−0.18
The lower part of the ear-auricle				
△lnPVr (mV)	0.18	0.08	0.56*	−0.02
△lnNPVr (a.u.)	0.18	0.08	0.56*	0.10

Note. △lnNPVt_IF = lnNPVt reactivities (the difference between baseline and test values) from an index finger using the transmission mode PPG as a reference; △lnPVr = lnPVr reactivities using the reflection mode PPG; △lnNPVr = lnNPVr reactivities using the reflection mode PPG; CPT = cold pressor test; WWI = warm water immersion; a.u. = arbitrary unit.

[a] $n = 30$.

[b] $n = 18$.

* $p < 0.05$. ** $p < 0.01$.

placements of the ear are presented in the young and middle-aged groups, respectively (table 5). In both age groups, significant relationships are observed between ΔlnNPVt_IF and ΔlnNPVr_MF, during the CPT and WWI. Furthermore, in the young group, significant relationships are observed between ΔlnNPVt_IF and ΔlnPVr_ECB, ΔlnNPVr_ECT and ΔlnNPVr_ECB, during the CPT. In the middle-aged group, significant relationships are observed between ΔlnNPVt_IF and ΔlnPVr_ECB, ΔlnPVr_EAL, ΔlnNPVr_ECB and ΔlnNPVr_EAL, during the CPT.

Figure 2 shows the two scatter plots for the correlation and the linear regression in the young and middle-aged groups during the CPT between ΔlnNPVt_IF (x-axis) and ΔlnNPVr_MF (y-axis) (see figure 2 panel A), and ΔlnNPVr_ECB (y-axis) (see figure 2 panel B).

4. Discussion

Peripheral PV has previously been used to provide information on autonomic vascular control (Miller and Ditto 1989, 1991) and the PPG has long been recognized as offering a convenient tool for the assessment of peripheral perfusion (Challoner 1979). However, NPV has been reported as being a more valid measure for the assessment of α-adrenergically mediated peripheral vascular tone (Sawada *et al* 2001). Whilst the finger has traditionally been used as the most appropriate anatomical site for measuring the PPG, other sites are clearly possible (Allen and Murray 2003), and the ear could be advantageous in certain situations. The vessels of the deep auricular artery pass between the tragus and eardrum, with its branches providing

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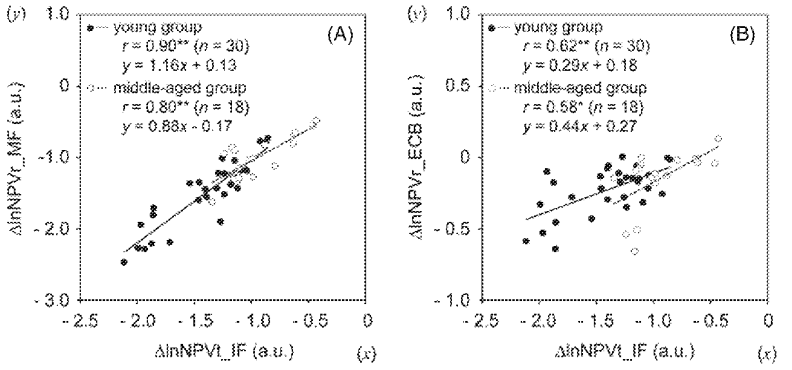


Figure 2. The scatter plot for Pearson's correlation analysis and the linear regression in the 'young' and 'middle-aged' groups between ΔlnNPV from an index finger using transmission mode PPG (ΔlnNPVt_IF) to *x*-axis and ΔlnNPV from the middle finger using reflection mode PPG (ΔlnNPVr_MF) to *y*-axis (panel A), and ΔlnNPV from the bottom of the ear-canal using reflection mode PPG (ΔlnNPVr_ECB) to *y*-axis (panel B). During baseline and while performing CPT, ΔlnNPV is the reactivity (the difference between baseline and test values) of lnNPV. ΔlnNPV is expressed in arbitrary units (a.u.). $^{*}p < 0.05$, $^{**}p < 0.01$.

a supply to the skin of the cartilaginous ear-canal (Gray and Lewis 1918). As compared with measurements in the finger or the limbs, PPG recorded from the ear can be relatively free from motion artefacts (Vogel *et al* 2009). Thus, the collection of PPG-derived measurements from the ear could be well suited to the task of monitoring stress during normal daily life, for example through the use of the NPV index (Sawada *et al* 2001). However, the NPV derived from the ear has not yet been validated and this was the purpose of the work described herein. In order to attempt to validate the NPV derived from PPG measurements at different sites in the ear, we have compared lnPV, $\ln \boldsymbol{I}_{\mathrm{dc}}$ and lnNPV with reference data derived from transmission PPG measurements in an index finger during CPT and WWI as physiological challenges. Specifically we have compared the reference NPV values with the reflection PPG measurements, lnPVr and lnNPVr at different locations of the ear.

We have calculated NPV by dividing PV by the so-called dc component of the PPG. Naturally, if the dc component is essentially constant, NPV values will be directly proportional to the PV and the calculation of NPV is seemingly unnecessary. However, PV itself is affected by several instrumental and anatomical factors, including amplifier gain and skin colour, and the normalization process to derive NPV minimizes the adverse influence of these factors (Sawada *et al* 2001). In the present study, we kept these variables constant, so the correlation coefficient of ΔlnNPVt_IF versus ΔlnNPVr_ECB was comparable to that of ΔlnNPVt_IF versus ΔlnPVr_ECB (table 5) during the CPT. However, not all measurements can be carried out under such controlled conditions, especially if the system is to be used during normal daily life. Therefore, NPV derived at the ear could be more suited to the task of monitoring stress than PV.

Our results show that, among the ear sites considered, the NPV values derived from reflection PPG measurements at the bottom of the ear-canal (NPVr_ECB) have the closest relationships with the reference data regardless of age group. This is judged, firstly, by the significant decreases that are observed in lnNPVr_ECB and lnPVr_ECB from the baseline values to the values obtained during the CPT in both age groups (tables 1 and 3). These decreases of lnNPVr_ECB and lnPVr_ECB indicate vasoconstriction by sympathetic activity

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during the exposure to the stressful stimuli (Sawada *et al* 2001, Tanaka and Sawada 2003). Secondly, good relationships were observed during the CPT between ΔlnNPVt_IF as the reference and ΔlnNPVr_ECB, and ΔlnPVr_ECB in both age groups (table 5). These relationships could be explained by the reported location of the origin of the deep auricular artery on the lining of the ear-canal. The vessels of the deep auricular arteries ascend through the bony wall of the ear-canal from the parotid gland under the ear-canal, with branches providing a supply to the lining of the ear-canal (Gray and Lewis 1918). That is, the change of the blood volume at the bottom of the ear-canal is larger than the change of the blood volume at the different locations in and around the ear. Taken together, these findings suggest that NPVr_ECB could be used as an alternative to NPVt_IF for evaluating physiological and psychological stress regardless of age.

The results for NPV values derived from measurements at the top of the ear-canal (NPVr_ECT) were somewhat inferior to those from the bottom of the ear-canal, NPVr_ECB. Although lnNPVr_ECT and lnPVr_ECT fell from baseline to CPT (table 1), the decreases were smaller than those of lnNPVr_ECB and lnPVr_ECB. These findings indicate that the sensitivity of NPVr_ECT during CPT was lower than that of NPVr_ECB. Furthermore, during the CPT, the correlation of ΔlnNPVt_IF versus ΔlnNPVr_ECT was lower than ΔlnNPVt_IF versus ΔlnNPVr_ECB as demonstrated by both analyses (table 5). Therefore, although NPVr_ECT could also be used as an alternative to NPVt_IF, if NPVr_ECB is available then it is to be preferred.

In contrast to the NPV data derived from the top and bottom of the ear-canal, NPVr_ECT and NPVr_ECB respectively, the indices derived from measurements at the upper (EAU) and lower (EAL) regions of the ear-auricle gave poorer results. Although the CPT induced changes in the PV and NPV indices the magnitudes of these changes were much less pronounced than those seen with the ear-canal measurements. Falls in both PV and NPV indices measured at the lower ear-auricle were produced by the CPT, but these were much smaller than those obtained in the ear-canal (table 1). For upper ear-auricle measurements, during the CPT lnNPVr_EAU and lnPVr_EAU did not fall significantly from the baseline values (table 1). Furthermore, the CPT did not produce any statistically significant relationships between ΔlnNPVt_IF and either ΔlnNPVr_EAU, or ΔlnNPVr_EAL (table 5). These results suggest that the NPV and PV indices derived from PPG measurements at the upper and lower regions of the ear-auricle, NPVr_EAU and NPVr_EAL respectively, are not ideally suited to the task of monitoring stress. This could imply that the supply to the auricle regions is more sparse; there is perhaps an insufficient arterial supply to allow the measurement of NPV from those regions (Gray and Lewis 1918).

It is of significance that the results show that the pattern of the autonomic vascular control in the ear appears to be more complex than that in the finger. In general, autonomic control processes in the peripheral vasculature appear to mitigate the changes induced by stimuli (Miller and Ditto 1989, 1991, Xin *et al* 2007). For example, the PV and total blood volume in the finger decreased during an exposure to stressful stimuli (Sawada *et al* 2001, Tanaka and Sawada 2003). In the present study, the decreases seen in the lnPV and $\ln \boldsymbol{I}_{dc}$ indices derived from the finger during the CPT could be comparable to those findings. On the other hand, the lnPV in the ear-canal was found to fall during the CPT, while the $\ln \boldsymbol{I}_{dc}$ in the ear-canal was maintained nearly constant during the CPT, although a significant change of $\ln \boldsymbol{I}_{dc}$ at the top of the ear-canal was observed (table 1). The nearly constant $\ln \boldsymbol{I}_{dc}$ observed in the ear could be explained by the notion that the blood flow in the head and neck circulation is maintained relatively constant by cerebral autoregulation (Panerai 1998). So, the pattern of the autonomic vascular control in the ear-canal might be a mixture of the maintenance of total blood volume and vasoconstriction induced by exposure to stressful stimuli.

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In addition to these main results, there are other points related to ear NPV to consider. Firstly, we have performed the CPT and WWI in the right hand up to the wrist to induce peripheral vasoconstriction. As a result, lnNPVt_IF and lnNPVr_MF, as well as lnPVr_IF and lnPVr_MF were significantly decreased from BS to CPT (tables 1 and 3). In fact, the CPT has been frequently used to induce peripheral vasoconstriction (Allen *et al* 1992). Consistent with those findings, the same tendencies were observed from BS to WWI (tables 2 and 4), although the changes of lnNPVt_IF and lnNPVr_MF, as well as lnPVr_IF and lnPVr_MF were smaller than the change of those from BS to CPT. Therefore, these results suggest that the CPT and WWI successfully produced peripheral vasoconstriction.

Secondly, we have used the transmission mode PPG as well as the reflection mode PPG when measuring NPV. The transmission and reflection modes of PPG have been studied by others (Nijboer *et al* 1981, Uretzky and Palti 1971), who reported that the pulsatile and non-pulsatile changes in intensity of light were found to be very similar whether measured by transmitted or reflected light. In our study, although each absolute value of NPV is different due to the volume correction factor (k), CPT and WWI produced strong statistical relationships between transmission PPG measurements in the index finger, ΔlnNPVt_IF as a reference, and reflection measurements in the middle finger, ΔlnNPVr_MF (see figure 2 panel A). Taken together, these results support the view that the transmission mode PPG and the reflection mode PPG are indeed the comparable method to derive changes in NPV values.

Thirdly, of all of the possible methods for monitoring blood volume changes, such as air or water plethysmography, strain gauge plethysmography or EIP, we have concentrated on the use of PPG. Whilst PPG does not provide an absolute measure of blood volume it is simple and convenient to use as well as low in cost. More importantly, other methods, for example, strain gauge plethysmography, which is also known to be able to provide quantitative volume measures in limbs and digits (Whitney 1953), would be difficult, if not impossible, to use for measurements in the ear. As we have shown, PPG can be applied quite simply for measurements at different regions of the ear, with the attachment of small and lightweight optical sources and detectors. Despite its simplicity our results show that PPG is a viable method for the assessment of peripheral perfusion at the ear.

Fourthly, regardless of age group, the same tendencies in the results were observed; not only the significant decrease in lnNPVr_ECB from the baseline values to the values obtained during the CPT (tables 1 and 3), but also the significant relationship during the CPT between ΔlnNPVt_IF as the reference and ΔlnNPVr_ECB are observed (table 5), though the reactivities of each lnNPV during CPT in the middle-aged group is marginally smaller than those in the young group. These results mean that the pattern of the autonomic vascular control is very similar regardless of age. These findings provide more confidence in the NPVr_ECB as an alternative to NPVt_IF for evaluating physiological and psychological stress.

Finally, in our experiment subjects were required to remain still with the effect that their central blood oxygen levels were assumed to be approximately constant and so the absorptivity (ε) could also be assumed to be essentially constant. This consideration is necessary when using the 940 nm wavelength light source. However, the peripheral oxygen levels can be changed in various circumstances, especially during exercise and it would therefore be preferable to use an isosbestic wavelength, such as 805 nm, to avoid this problem.

4.1. Limitation of this study

In this study, we have only used the CPT and WWI as challenges. To evaluate stress with NPV, however, there are several stress tasks that may initiate peripheral vasoconstriction, examples including mental arithmetic, mirror tracing and social speech (Allen *et al* 1997, Matsumura

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et al 2011a, 2012, Sawada *et al* 2001). Therefore, further laboratory studies using other kinds of stressors are needed to examine ear NPV more fully.

We have not yet shown that the ear NPV measurement carried out with our methodology can actually be applied to the investigation of stresses experienced in normal daily life. This is because the stressful tasks used in laboratory experimentation do not necessarily reflect daily life situations, for example during working and sporting activities (Matsumura *et al* 2011b, Yamakoshi *et al* 2010). Therefore, further studies are also needed to examine ear NPV under normal daily life situations.

5. Conclusions

The NPV derived from reflection mode PPG at the bottom of the ear-canal, NPVr_ECB, was found to be a valid measure when compared with reference measurements made in an index finger under CPT and WWI to produce peripheral vasoconstriction. We conclude that NPVr_ECB might be suitable as a practical index for evaluating physiological and psychological stress in daily life.

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Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Cc: (b)(6) k222658@docs.fda.gov

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

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Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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Bi-Modal Arterial Compliance Probe for Calibration-Free Cuffless Blood Pressure Estimation

Nabeel P M, *Member, IEEE*, Jayaraj Joseph, Srinivasa Karthik, Mohanasankar Sivaprakasam, and Chenniappan M

(Invited Article)

Abstract*— *Objective: **We propose a calibration-free method and system for cuffless blood pressure (BP) measurement from superficial arteries. A prototype device with bi-modal probe arrangement was designed and developed to estimate carotid BP – an indicator of central aortic pressure. *Methods:* Mathematical models relating BP parameters of an arterial segment to its dimensions and local pulse wave velocity (PWV) are introduced. A bi-modal probe utilizing ultrasound and photoplethysmograph sensors was developed and used to measure diameter values and local PWV from the carotid artery. Carotid BP was estimated using the measured physiological parameters without any subject- or population-specific calibration procedures. The proposed cuffless BP estimation method and system were tested for accuracy, usability and for potential utility in hypertension screening, on a total of 83 subjects. *Results:* The prototype device demonstrated its capability of detecting beat-by-beat arterial dimensions and local PWV simultaneously. Carotid diastolic BP (DBP) and systolic BP (SBP) were estimated over multiple cardiac cycles in real-time. The absolute error in carotid DBP was < 10 mmHg in 82% cases, and root-mean-square-error = 8.3 mmHg. Consistent with the theory, estimated SBP at the carotid site was lower than the reference brachial SBP. ROC curves obtained for hypertension screening analysis revealed an area under the curve ≥ 0.8 for both carotid SBP and DBP values, illustrating the potential for using the developed method in hypertension screening. *Conclusion:* The feasibility of calibration-free, cuffless BP measurement at an arterial site of interest was demonstrated with a level of acceptable accuracy. The study also demonstrated the potential utility of the proposed method and system in hypertension screening and local evaluation of arterial stiffness indices. *Significance:* Novel approach for calibration-free cuffless BP estimation; a potential tool for local BP measurement and hypertension screening.**

This research was supported by Science and Engineering Research Board (SERB), Department of Science and Technology (DST), Government of India, under grant IUSSTF/NIBIB_DST/ABPM/2013-2014/EOI_12. *Asterisk indicates corresponding author.*

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***Index Terms*—Blood pressure, calibration-free, carotid BP, central BP, cuffless BP, hypertension screening, local PWV.**

I. Introduction

NON-INVASIVE assessment of blood pressure (BP) at the brachial artery by sphygmomanometry is the conventional method for prediction of various pathologies of clinical importance. Despite the wide use of brachial diastolic BP (DBP) and systolic BP (SBP) values in clinical diagnostic practice, these BP estimates are poor surrogates for central BP (aortic or carotid) that the most target organs experience [1] – [3]. It is recognized that the central BP values are more strongly related to future cardiovascular risk and outcome [4] – [7]. Emerging evidence now suggests that continuous and beat-by-beat measurement of arterial pressure could offer several prognostic information (independent of the brachial BP level), for diagnosis and treatment [8]. Direct measurement of central BP parameters using cuff-type manometers is impractical due to methodological issues and occlusiveness. Further, short-term continuous BP monitoring is fundamentally limited by its periodicity of measurement, while long-term measurements are not feasible due to frequent occlusion. Recent advancement in technology has enabled the evolution of cuffless techniques for arterial BP measurement in a continuous and non-invasive manner [8].

BP measurement using pulse transit time estimates are extensively studied in the area of continuous and cuffless BP evaluation. In this approach, BP estimation is often performed using theoretical or heuristic regression models that relate transit time estimates such as pulse arrival time (PAT), pulse transit time (PTT), and pulse wave velocity (PWV) with arterial pressure [9], [10]. These transit time estimates are typically measured over larger segments (regional estimates) composed of arteries with different mechanical characteristics and involves error due to a coarse approximation of pulse propagation distance [11]. Consequently, regional transit time measures provide only an average estimate over the measurement sites, and cannot be directly used in biomechanical equations relating transit estimates and BP.

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Therefore, model-based BP computation using transit time estimates requires subject- and/or population-specific calibrations [10], [12] – [14], and cannot provide central BP parameters with a level of acceptable accuracy. The necessity of frequent recalibration has withheld the widespread application of transit time-based continuous cuffless BP techniques. Recent evidence further challenges the accuracy and reliability of PAT based cuffless BP measurement due to the confounding behavior of pre-ejection period (PAT comprises of the pre-ejection period and PTT) towards BP [15], [16].

Arterial pressure waveforms vary continuously throughout the arterial tree due to the phenomenon of pulse pressure amplification [1], [17]. As a result, accurate evaluation of BP parameters without a pressure cuff may be possible only when the measurements are performed at a small arterial site of interest. In this work, we propose a calibration-free technique for cuffless evaluation of BP parameters from superficial arteries, without relying on the subject- or population-specific calibration procedures. Mathematical models were introduced to express the elastic behavior of arteries as a function of instantaneous pressure level, with closed-form solution and coefficients that are free from calibration. Simultaneously acquired arterial dimensions and local PWV (pulse propagation velocity through a small arterial segment) were used to solve developed models and yielded direct estimation of BP parameters at the measurement site. An application-specific bi-modal probe arrangement and a prototype device were developed to estimate BP at the carotid artery – an indicator of central BP. Arterial dimensions was measured with a single element ultrasound transducer using the ARTSENS® (ARTerial Stiffness Evaluation for Non-invasive Screening) technology – an image-free technique for arterial stiffness evaluation, that has been developed and clinically validated by our group [18] – [20]. Local PWV was measured by recording high-fidelity blood pulse signals from the two measurement sites with a custom designed dual-element photoplethysmograph (PPG) probe. The measurement accuracy and hypertension screening efficiency of the proposed technique were experimentally validated on a pool of hypertensive and normotensive patients.

The principle of the proposed calibration-free technique for cuffless BP evaluation is briefed in Section II of this paper. Design features of the bi-modal probe arrangement, physiological signal acquisition hardware, and associated measurement algorithm are summarized in Section III. In Section IV, the study materials and measurement protocol followed during the clinical validation of the developed device are mentioned. Validation study results and observations are discussed with the detailed statistical analysis in Section V, followed by conclusion in Section VI.

II. Principle of Calibration-Free Cuffless BP

The physiological process of instantaneous variation in arterial pressure within a cardiac cycle can be modeled using arterial dimensions (such as end-diastolic lumen diameter D_D, systolic-peak diameter D_S, and distension ΔD; $\Delta D = D_S - D_D$), stiffness indices and transit time estimates [21]. These models characterize the elastic behavior of small arterial sections in the absence of multiple pressure wave reflections within the segment [21], [22]. Consequently, the physiological parameters obtained from smaller arterial sections are desirable for direct application of theoretical models into the cardiovascular system.

Consider a near circular and rotationally symmetrical geometry for an arterial section of unit length. The stiffness index β of the given arterial section can be expressed as in terms of arterial pressure P and the corresponding lumen diameter D at any given instant in the systolic phase during a cardiac cycle as in (1) [23].

$$\beta = \frac{\ln\left(\frac{P}{P_D}\right)}{\left(\frac{D-D_D}{D_D}\right)} \tag{1}$$

Here, P_D is the end-diastolic pressure corresponding to the diameter D_D. For a given cardiac cycle, its β reflecting the local arterial stiffness was considered as an arbitrary constant, and independent of arterial pressure changes within the cycle during the measuring time [23] – [26]. Hence, the change in arterial pressure with respect to lumen diameter can be evaluated by differentiating (1) as follows:

$$\frac{dP}{dD} = \frac{P\beta}{D_D}. \tag{2}$$

The relative pressure change (dP) over the change in lumen area (dA) as expressed in (3) can be readily obtained by replacing the diameter terms in (2) with the cross-sectional area (A) of the artery ($A = \frac{\pi}{4}D^2$) [23].

$$\frac{dP}{dA} = \frac{2P\beta}{\pi D D_D} \tag{3}$$

According to the Bramwell-Hill model, the propagation velocity of pressure pulses through a given arterial section (local PWV; henceforth referred to as C in equations and expressions) can be expressed as a function of relative pressure change over the change in lumen area [27]. Hence, the derivative of arterial pressure to area can also be represented in terms of local PW as given in (4), where ρ is the blood mass density ($\rho \approx 1060$ kg/m^3).

$$C^2 = \frac{A}{\rho}\frac{dP}{dA} \tag{4}$$

This equation readily shows that the absolute value of local PWV varies within a cardiac cycle as a function of the arterial cross-sectional area gradient and the respective change in pressure level. Further, combining (3) and (4) with a mathematical rearrangement yielded

$$P = \frac{2\rho C^2 D_D}{\beta D}, \tag{5}$$

which is a formulation that relates instantaneous pressure level with arterial dimensions and stiffness indices. The diameter and local PWV values measured from the diastolic point (D_D and C_D), and from any other fiducial point Ψ in the early systolic region of the same cardiac cycle (D_Ψ and C_Ψ) corresponds to the arterial pressures P_D and P_Ψ respectively, which can be expressed as:

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$$P_D = \frac{2\rho C_D^2}{\beta}, \quad (6)$$

$$P_\Psi = \frac{2\rho C_\Psi^2 D_D}{\beta D_\Psi}. \quad (7)$$

By taking the ratio of (7) and (6), and combining with (1) yielded an estimate of β for the given cardiac cycle:

$$\beta = \frac{\ln\left(\frac{C_\Psi^2 D_D}{C_D^2 D_\Psi}\right)}{\left(\frac{D_\Psi - D_D}{D_D}\right)}. \quad (8)$$

Further, substitution of β and C_D in (6) gives P_D level of the given cardiac cycle. Subsequently, systolic-peak pressure P_S corresponding to D_S of the same cardiac cycle can be evaluated using P_D, β, and ΔD using (1), resulting in:

$$P_S = P_D e^{\beta\left(\frac{\Delta D}{D_D}\right)}. \quad (9)$$

These mathematical models (referred to as P–β model) were used to realize a calibration-free technique for the assessment of BP parameters. The arterial diameter and corresponding local PWV values from distinct fiducial points (characteristic identification points) within a cardiac cycle were obtained using a specifically developed measurement system. Furthermore, non-invasive assessment of these physiological variables from small arterial sections does not require the use of any bladder-type pressure cuff.

The proposed technique for simultaneous measurement of arterial diameter parameters and local PWV estimates has been illustrated in Fig. 1. The method involves assessment of arterial dimensions by ultrasound echo technique, and local PWV values by the two-point method from time-shifted blood pulse at distinct sites within an arterial section. A bi-modal probe arrangement with specific functional structure was designed for simultaneous acquisition of essential physiological waveforms from the arterial site of interest. A single element ultrasound transducer was preferred to acquire arterial diameter waveforms by tracking the ultrasound echoes arising from proximal and distal walls. This approach gives the diameter parameters (D_D, D_Ψ, and ΔD) required for BP evaluation. Two identical PPG sensors were symmetrically positioned on either side of the ultrasound transducer with a fixed center-to-center distance equal to ΔX (Fig. 1). This distance was used in the fundamental distance-time equation for local PWV calculation (refer Fig. 1). Local PWV values C_D and C_Ψ were respectively obtained from the diastolic fiducial point and a second fiducial point Ψ (defined in Section III.C) by measuring local pulse transit time (ΔT) corresponding to these points (ΔT_D and ΔT_Ψ). BP parameters were then evaluated using (6) – (9) without any calibration procedure. Continuous measurement of diameter and local PWV over multiple cardiac cycles allow beat-by-beat evaluation. The presented measurement principle, method, design of bi-modal probe, hardware/software features are patent-protected (or patented) [28].

III. Device Architecture Cuffless BP Monitor

A. Design of Ultrasound-PPG Bi-Modal Probe

The introduced bi-modal probe arrangement was realized with a mechanism to simultaneously acquire diameter parameters and local PWV from the carotid artery. The carotid artery was preferred since it is superficial and closely represents the central aortic conditions. Fig. 2 depicts the sensor arrangement and design features of the bi-modal probe. A custom designed single element piezo-electric ultrasound transducer (diameter = 5 mm) was housed in a custom probe enclosure (outer diameter = 9 mm, length = 80 mm). This was the source of sharp ultrasound pulses of very narrow beam width (spatial half angle < 1.3°) with a center frequency of 5 MHz. To perform arterial diameter measurement, the ultrasound transducer was kept on the skin surface above the artery and it was operated in pulse-echo modality. The incident ultrasound waves get reflect from various structures in the signal propagation path, as well as from the proximal and distal arterial walls. These ultrasound echo signals were

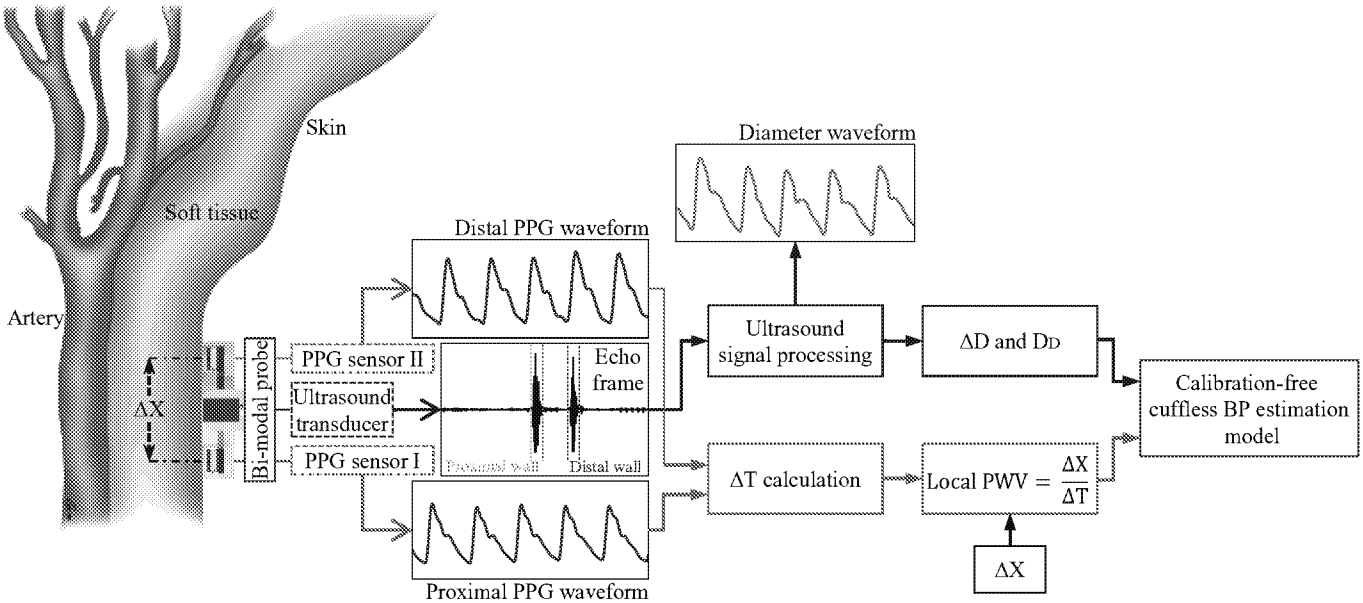


Fig. 1. Measurement principle of arterial dimensions and local PWV using the ultrasound-PPG bi-modal probe for calibration-free evaluation of cuffless BP.

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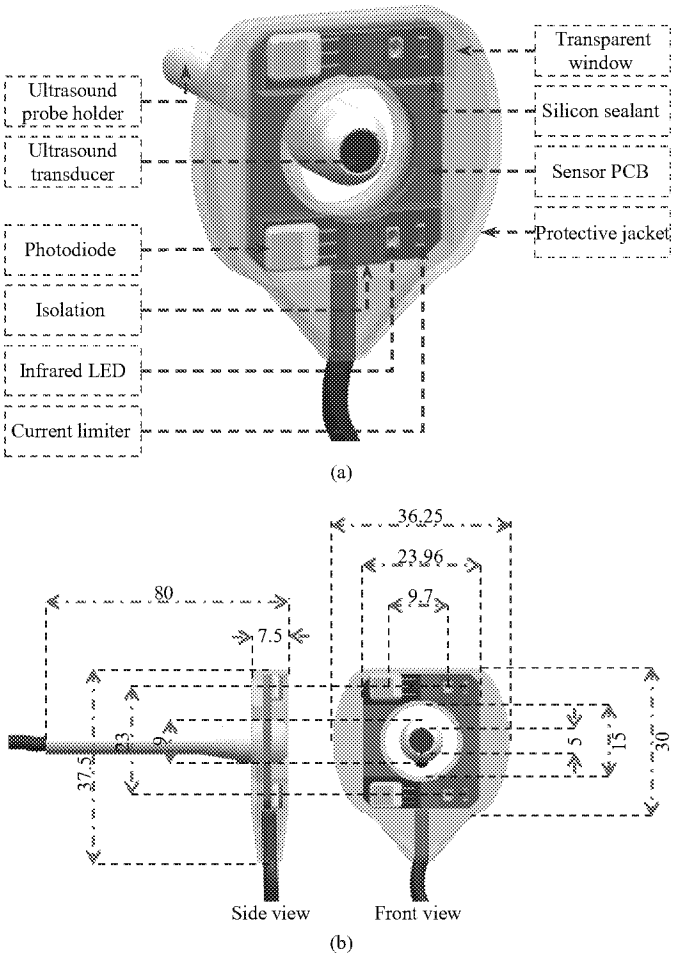


Fig. 2. (a) Sensor arrangement and design features of the proposed ultrasound-PPG bi-modal arterial compliance probe, (b) Front view and side view – illustrating the design dimensions (all dimensions are in mm).

received by the same transducer. In the proposed bi-modal arterial compliance probe design, an ultrasound transducer with maximum sensitivity along its central axis was preferred. Therefore, the amplitude of ultrasound echoes coming to the transducer along any direction at an angle to the central axis was insignificant. For a near circular cross section of the artery, the poor off-axis sensitivity and narrow half angle beam width of the transducer ensure measurement along a true diameter of the artery. This can be achieved by orienting the ultrasound probe to acquire strong and distinct echoes from both the proximal and distal arterial walls (reflection from normal surfaces of the arterial segment).

Local PWV was measured from the carotid artery using a dual-element PPG probe. The proposed probe consists of a pair of infrared light emitting diode (LED)–photodetector (PD) at the proximal and distal measurement sites to capture the time-shifted PPG pulses. These two PPG sensors were arranged with a center-to-center separation distance ΔX equal to 23 mm (refer Fig.1 and Fig. 2(b)). This sensor separation distance was considered as the propagation distance of blood pulse waves between the proximal and distal measurement sites. The LED (SFH4451 – OSRAM Opto Semiconductors, Regensburg, Germany) emits monochromatic infrared light of 850 nm wavelength. A highly sensitive PD (PIN-16-CSL – OSI Optoelectronics, California, United States) of window area 16 mm^2 was used to capture the blood volume modulated pulsatile waveforms. As illustrated in Fig. 2(b), the LED and PD were separated by 9.7 mm (center-to-center separation distance), which was an optimal separation for adequate penetration of infrared light at the carotid site for the prefixed LED drive current. The LED–PD separation was arrived at based on an initial set of experiments, to obtain PPG signals from multiple skin tones and tissue thicknesses. An optical isolation between them prevented any direct coupling. The LED and PD were soldered on a custom designed PCB and coated with silicone sealant for optical continuity. This assembly was housed in a transparent protective jacket (37.5 mm × 36.25 mm × 7.5 mm), which was 3D printed using a flexible rubber-like material. The dual-element PPG and ultrasound probes were physically decoupled, independently adjustable, and ensures synchronized signal acquisition. An opening of 15 mm diameter was provided at the center of the PPG probe to place the ultrasound probe. Such a design of bi-modal probe allows direct measurement of diameter parameters and local PWV from the same arterial segment.

B. Hardware and Software for Diameter Measurement

Fig. 3 depicts the basic system architecture of the developed prototype device. Ultrasound transducer excitation and pre-processing of echoes were performed by a custom analog front-end hardware. A 32-bit microcontroller (Arm® Cortex®-M4 Processor – NXP semiconductors, Eindhoven, Netherlands) was used for high-speed digital pulse generation. Generated pulse trains (a set of four 100 ns duration pulses, delayed by 1 ms) was fed to a high voltage pulser-receiver (STHV748 – STMicroelectronics, Geneva, Switzerland). High voltage (40 V) pulse generation by level translation, transmit-receive switching, protection of low voltage echo signals from transmit path were all performed by the pulser-chip, whose timing was controlled by the microcontroller. The received echo signals (LV_{out}) were initially filtered (cut-off frequency = 8 MHz) and dual stage amplification (gain = 40 dB) was performed by a high-speed amplifier (AD8058 – Analog Devices Inc., Massachusetts, United States), and subsequently sampled by a 12-bit 80 MSamples/sec analog-to-digital converter (ADC) of the microcontroller. One echo signal acquisition henceforth is referred to as a frame. The digitized frames were transferred to a tablet computer (Surface 3 Pro – Microsoft, Washington, United States) over a high-speed universal serial bus. A frame rate of 100 Hz was achieved because of high-speed processing and data transfer.

A custom program (measurement software) was developed in LabVIEW (National Instruments, Texas, United States) platform by incorporating a graphical user interface (GUI) to perform signal acquisition and conditioning in the digital domain, measurement of arterial dimensions and local PWV (hence to evaluate the BP parameters), and to guide the operator while acquiring signals using the bi-modal probe. Once the ultrasound echo and PPG signal were received in the digital domain, their signal quality determination [29], identification of the locations of arterial walls in the echo

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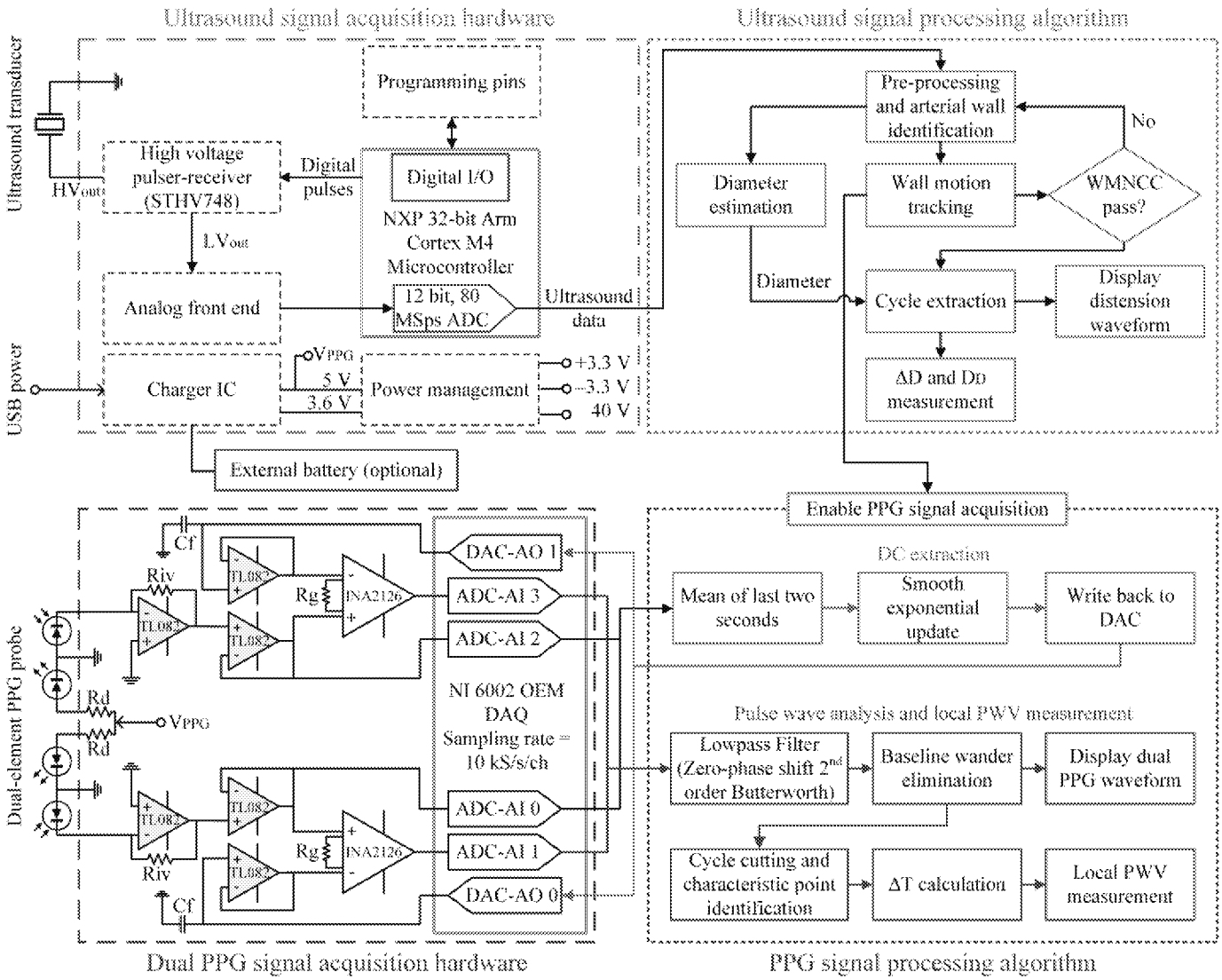


Fig. 3. System architecture of calibration-free cuffless BP device exhibiting basic electronics hardware and signal processing algorithm.

frame, tracking their instantaneous motion [30], capturing of end-diastolic diameter and distention waveforms [31], beat-by-beat evaluation of diameter parameters, and real-time elimination of non-ideal cardiac cycles were automatically performed by the developed measurement software. The digitized echo signals were initially filtered using a zero-phase Butterworth bandpass filter (4^{th} order, passband between 1 MHz ~ 8 MHz). Signal attenuation encountered on passage through the soft tissue (attenuation coefficient = 0.7 dB/cm/MHz) was compensated by implementing a time-varying gain compensation. After the initial signal conditioning, echoes were continuously displayed on the GUI (100 echo frames per second) like a real-time video graphic visualization of arterial wall motion. Developed measurement algorithms were efficient to identify the locations of proximal and distal arterial walls by analyzing the inherent out of phase motion of the wall echoes (as the artery contracts and relaxes during each cardiac cycle) using sliding window covariance-based method [19], [30]. Once the locations of both the walls were identified, two windows of approximately 2 mm width were defined around the echoes. The spatial movement in the position of these echoes was continuously tracked over successive ultrasound frames using a correlation-based motion tracking technique. The negative correlation between the proximal and distal wall movement was checked using wall motion negative correlation check (WMNCC) algorithm to ensure that both the walls were in opposite motion [18], [19].

Arterial distension waveform (temporal change in arterial diameter as a function of time) was captured from successive ultrasound frames as the sum of relative shift in location of proximal and distal walls with respect to the previous frame [18]. The obtained distension waveform was displayed on the GUI in real-time. A custom cycle-cutting algorithm was implemented in the measurement software to extract each distension cycle from this waveform and to calculate the absolute ΔD value (maximum change in a distention cycle from systole to diastole) in a beat-by-beat manner. The absolute value of end-diastolic lumen diameter D_D was further evaluated (from each distention cycle) as the distance between the intima layers of the proximal and distal walls. This was estimated as the absolute distance between the trailing edge of the near wall echo and leading edge of the far wall echo at the

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end of the diastole. A set of mathematical models and algorithms developed to define the wall-lumen interface of ultrasound echoes and to perform real-time D_D measurement has been detailed in our previous publication [31].

C. Hardware and Software for Local PWV Measurement

The carotid artery was illuminated by the infrared LED driven at a constant current, and the reflected blood pulse modulated light signal was received by the PD. The PPG from both the measurement sites were acquired independently and simultaneously by two separate channels (free from energy storage elements in the principal signal path) with a negligible inter-channel delay. As illustrated in Fig. 3, the current signal from PDs was initially converted to a voltage using the high gain transimpedance amplifier (TL082CP – Texas Instruments, Texas, United States). The signal at this stage consists of a large time-invariant DC component and a small time-varying component from the light passing through arteries. The DC component of this signal was calculated in real-time and subtracted from the original signal. The resulting pulsatile component was then amplified by an instrumentation amplifier with a gain of 40dB (INA2126P – Texas Instruments, Texas, United States) and digitized with a sampling frequency of 10 kSamples/sec using a data acquisition module (NI6002 OEM DAQ – National Instruments, Texas, United States).

As illustrated in Fig. 3, simultaneous recording of arterial diameter waveforms and dual PPG signals was ensured by synchronizing the 'wall motion tracking phase' and 'PPG signal acquisition phase' in the developed custom program. PPG signal acquired from proximal and distal sensors contains timing information about the onset of the pulse wave. They were simultaneously processed by the developed measurement software (along with the ultrasound signals). Initially, PPG signals from both the channels were filtered with a digital zero-phase Butterworth low pass filter (2^{nd} order, cut-off frequency = 10 Hz). Any baseline wander in the acquired waveforms was further removed with a suitable algorithm. The processed PPG signals from both the channels were then displayed on the GUI in real-time. Blood pulse cycle pairs (the pairs of consecutive proximal and distal blood pulse cycle) from the PPG pulse trains were collated using a custom cycle-cutting algorithm, followed by the determination of fiducial points in each pulse cycle. The amplitude of proximal and distal PPG cycles (in each pair) was normalized between 0 to 1 range before the characteristic point identification stage.

Determination of well-defined fiducial points in the acquired PPG cycle based on their physiological characteristic features was performed via a characteristic point identification technique. Typically, local ΔT (time taken by the blood pulse wave to travel between two distinct locations in a small arterial segment) is measured as the time difference between the occurrence of a fiducial point on the proximal and distal blood pulse cycle. Since the absolute value of local PWV is varying throughout a cardiac cycle (according to (4)), each point in a blood pulse cycle possess different propagation time (local ΔT). In the present prototype device, the second derivative maximum technique [32] was used to define a fiducial point near the end-diastolic region. In this approach, the maximum point of a PPG cycle's second derivative signal was considered as the diastolic fiducial point. This fiducial point corresponds to the maximal acceleration point at the foot of PPG wave's forefront. Then a second fiducial point Ψ was defined at a point 0.25 unit above the diastolic fiducial point in the normalized PPG cycle. This amplitude-based definition for the second fiducial point was based on a set of initial experiments using the bi-modal probe to ensure Ψ is in the early systolic region of PPG cycles. Local ΔT measures corresponding to both the fiducial points were obtained from each beat, and the respective local PWV values C_D and C_Ψ were evaluated using the fundamental distance-time equation (refer Fig. 1) with pulse propagation distance $\Delta X = 23$ mm.

D. Real-Time Evaluation of DBP and SBP

In order to solve the developed mathematical models (refer Section II), an intermediate estimate of diameter D_Ψ corresponding to the fiducial point Ψ was also required. Since the distension waveform and PPG waveforms were time synchronized, the position of Ψ in a distension cycle was identified as the point corresponding to the mean occurrence time of Ψ on the proximal and distal PPG cycles. Arterial distension δD_Ψ at this fiducial point was measured and D_Ψ estimated as; $D_\Psi = D_D + \delta D_\Psi$. The measured diameter and local PWV estimates were then directly used in the developed mathematical models (refer Section II) to evaluate BP parameters in real-time. Because β was considered as an arbitrary constant within a cardiac cycle, P_S and P_D were assessed from each cardiac cycle and their mean values were displayed on the GUI as SBP and DBP respectively. The mathematical models developed for calibration-free cuffless BP evaluation do not account for the influence of hydrostatic pressure caused by gravitational effects on the BP level [33]. However, it may be required to adjust the estimated BP

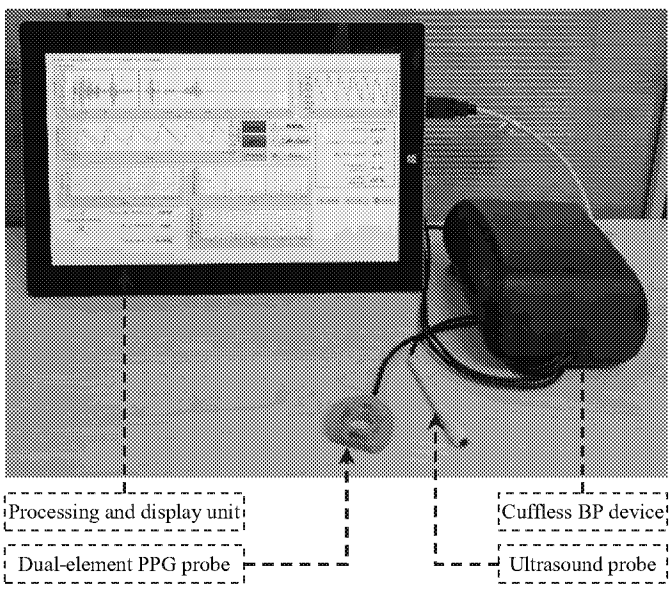


Fig. 4. The prototype device (DUT) with ultrasound and dual-element PPG probes (bi-modal probe system) developed for cuffless BP measurement. A screenshot of the software user interface is shown in the display unit.

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parameters for hydrostatic pressure difference whenever the measurements are performed in any posture other than the supine. This can be corrected by entering the pressure equivalent of the height difference between the heart and the cuffless BP measurement site, into the measurement software.

The proof-of-concept prototype device developed for carotid BP measurement along with the sensing elements is shown in Fig. 4. This prototype device will be henceforth referred to as the device under test (DUT). It was initially verified by conducting pilot studies in laboratory settings (data not presented) and further validated by an in-vivo study in a clinical setting.

IV. Validation Study Materials and Method

A. Subject Selection

The validation study of DUT was conducted at Ramakrishna Medical Centre, Woriyur, Trichy, India. The study protocol was reviewed and approved by the review committee of Healthcare Technology Innovation Centre (HTIC), IIT Madras and the procedures were performed in accordance with the guidelines of the review committee. This study was carried out in compliance with the Helsinki Declaration of 1975, as revised in 2000. Both male and female subjects were randomly selected, from those who were present at the clinic for a routine checkup. Subjects with age more than 90 years were excluded from the study. A total of 83 subjects from 24 to 85 years of age volunteered to participate and gave their informed consent. The recruited subject pool consisted of 40 normotensive subjects with suspected cardiac conditions and 43 subjects with hypertension. The baseline clinical characteristics of the recruited subjects are presented in Table I. Anthropometric measurements of every subject was obtained, and a unique subject identifier was assigned.

TABLE I
Subjects Characteristics

Parameters	Number	Mean ± SD	Range
Total subjects	83		
Male	63 (76%)		
Female	20 (24%)		
Hypertensives	43 (52%)		
Age (years)		57 ± 12	24 – 85
Height (cm)		166 ± 8.8	152 – 187
Weight (kg)		80 ± 14	64 – 98
Brachial BP (mmHg)			
SBP		144 ± 19	109 - 227
DBP		85 ± 12	65 - 132
Heartrate (bpm)		73 ± 10	50 - 101

B. Data Collection

1) Carotid BP Estimation: Measurements on all 83 subjects were performed by a single operator to avoid inter-operator variability. Subjects were requested to relax for 3 – 5 minutes before starting the data collection. Diastolic and systolic BP levels at the carotid artery (referred to as carotid DBP and carotid SBP respectively) were estimated from the left carotid artery of each subject at rest while being seated. The ultrasound probe was initially placed on the neck after locating carotid pulse by palpation. In order to guide the operator while placing the probe above the artery and to ensure placement along the center line of the artery for true diameter measurement, a custom signal quality evaluation algorithm was used in the measurement software. A numerical signal quality score was obtained in real-time and displayed in the GUI (along with the visuals of continuous ultrasound echo frames) as the signal-quality-indicator. The signal quality score was computed by considering the energy ratio and sharpness of the echoes recorded from both the proximal and distal walls of the artery [29]. Reliability of this technique to correctly position the single-element ultrasound probe has been experimentally validated in our previous study [29].

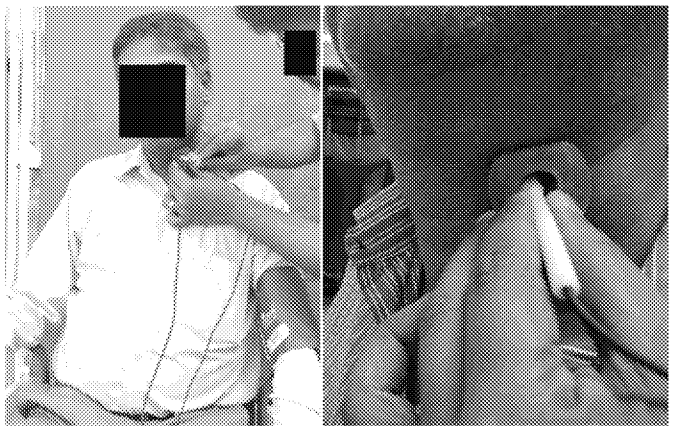


Fig. 5. (a) Operator performing cuffless BP estimation from the carotid artery of a subject. (b) A closer view of bi-modal probe placement at the carotid site.

According to the signal-quality-indicators, the operator adjusted the probe placement and orientation to acquire strong ultrasound echo signals from both arterial walls. This approach further helped the operator to identify the arterial segment. The dual-element PPG probe was then placed on the neck by placing both proximal and distal sensors along the carotid artery segment. Placement and orientation of both the probes were adjusted separately so as to get ultrasound echo and dual PPG signals simultaneously with desired quality. The recording was done for at least 30 seconds from each subject. A photograph showing BP measurement using the proposed device and a closer view of bi-modal probe placement at the carotid artery has been presented in Fig. 5.

2) Reference BP Measurement: Subjects were requested to continue being in the same state while recording reference BP parameters. The measurement was performed using a clinical grade automatic sphygmomanometer (SunTech® 247™, SunTech Medical, North Carolina, United States; resolution = 1 mmHg) in sitting position. A pressure cuff of suitable size was fastened to the left upper arm and kept at the same height as the heart to measure brachial DBP and brachial SBP. Average value of two consecutive measurements was recorded for data analysis.

Carotid BP parameters obtained via applanation tonometry is also a reference measurement technique. However,

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tonometer was not used in the present clinical validation study due to: (1) BP values obtained from the carotid artery using a tonometer is not a clinically accepted reference measure for hypertension screening. (2) It is time-consuming and requires a skilled operator to acquire reliable carotid pressure waveforms. (3) Practical limitations in using a tonometer at the carotid site along with the ultrasound and dual-PPG probes of DUT. Therefore, brachial BP parameters measured with a cuff-type manometer was used as the reference for accuracy evaluation and statistical comparisons.

C. Statistical Methods Used for Analysis

Statistical analyses were performed under the assumption that random errors were associated only with the DUT, and that the readings from the reference device were true values without random errors. All values are presented as mean ± standard deviation (SD). Repeatability of measured variables over continuous cardiac cycles is presented using beat-to-beat variation – the ratio of SD to mean value of a finite number of cycles expressed in percentage. The agreement between the readings from DUT and reference device was evaluated by linear regression and the resulting Pearson's correlation coefficient (r), a value of $p < 0.05$ was considered significant. The Bland-Altman analysis was performed to study inherent trends and degree of variation between the measurements from two devices, along with the root-mean-square error (RMSE). Group-wise analyses were performed by dividing the entire pool of subjects into normotensive and hypertensive groups based on their baseline BP values, with SBP $\geq$ 140 and/or DBP $\geq$ 90 considered as hypertensive [34]. The performance of hypertension screening was investigated using receiver operating characteristic (ROC) curves. An area under the ROC curve (AUC) $\geq$ 0.8 represents a reliable screening or diagnostic test.

It may be noted that the intermediate estimates of diameter, local PWV, and pressure from the fiducial point Ψ (D_Ψ, C_Ψ, and P_Ψ respectively) were not considered for statistical analyses. Therefore, in the forthcoming sections, the term 'local PWV' represents measurement from the diastolic fiducial point unless stated otherwise.

V. Results and Discussion

A. Simultaneous Acquisition of Physiological Waveforms

The in-vivo study comprised simultaneous recording of arterial diameter waveforms and dual PPG from the carotid artery. Fig. 6(a) presents a sample frame of the ultrasound echo (after the initial signal processing in analog and digital domains; refer Section III.B) obtained from the left carotid artery of a subject (age = 42 years, SBP/DBP = 130/90 mmHg). Both proximal and distal arterial walls are clearly defined in the echo frame (signal-to-noise ratio ≈ 26 dB). Fig. 6(b) illustrates sample carotid distension waveforms (from the same subject) obtained by continuously tracking the inherent out-of-phase motion of the wall echoes. Along with the diameter waveforms, time synchronized dual PPG signals were also acquired from the same arterial segment. Fig. 6(c)

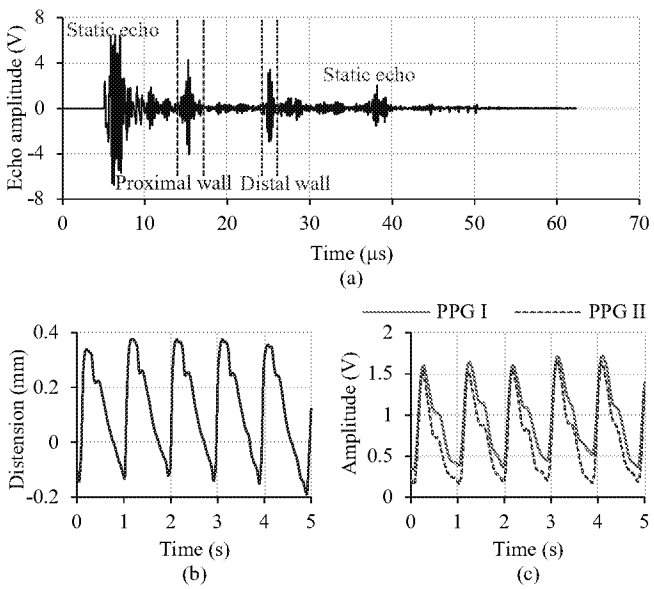


Fig. 6. A sample of simultaneously acquired physiological waveforms from the carotid artery of a subject. (a) Ultrasound echo frame illustrating proximal and distal arterial walls. (b) Carotid artery distension waveform. (d) Dual PPG acquired from the carotid artery with sensors positioned 23 mm apart.

depicts the proximal and distal PPG signals (PPG I and PPG II respectively) after initial signal processing. These signals were acquired along with the diameter waveform from the carotid artery (segment length = 23 mm). The pulsatile component of the PPG (peak-to-peak amplitude 6.5 mV – 24 mV) contains timing information about the onset of the pulse wave. Signal quality obtained from the DUT (signal-to-noise ratio ≈ 27 dB) was sufficient to identify the fiducial points and resolve local ΔT between proximal and distal cycles, thus determining the local PWV from multiple fiducial points. An absolute peak-to-peak amplitude difference of less than 5 mV was observed between the acquired raw proximal and distal PPG signals. This amplitude difference was typically observed due to minimal changes in the tissue structure at the measurement locations. However, any amplitude difference between the proximal and distal cycle in each pair was compensated using the normalization procedure before evaluating local PWV values (refer Section III.C).

The ultrasound-PPG bi-modal probe arrangement demonstrated its capability to simultaneously acquire strong and distinct echoes from the arterial walls and dual PPG waveforms from multiple subjects. The operator requires a moderate level of skill to orient the proposed bi-modal probe above the arterial segment to capture waveforms with the desired signal quality. However, the automated measurement algorithms and instantaneous visual feedback guided the operator to properly place and orient the probe for continuous signal acquisition.

B. Reliability of ΔD, D_D, and Local PWV Measurement

The prototype implementation of ultrasound–PPG bi-modal probe yielded a reliable measurement of carotid artery diameter and local PWV values from two fiducial points, synchronized with each heartbeat. Fig. 7 (a)–(c) depicts example plots of simultaneously measured beat-by-beat ΔD,

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D_D, and diastolic local PWV from the carotid artery of a subject (age = 35 years, SBP/DBP = 136/73 mmHg). Measurements were repeatable over multiple cardiac cycles. The range of absolute ΔD and D_D values assessed from the recruited subjects were 0.21 mm – 1.57 mm (beat-to-beat variation < 8.5%) and 3.65 mm – 9.37 mm (beat-to-beat variation < 10%) respectively. The resolution of D_D measurement (smallest luminal diameter that can be measured) using the present device is limited by the width of ultrasound echo pulses (3 dB pulse width) recorded from the arterial walls. Our initial experiments using the static phantom models of the carotid artery revealed that a minimum of approximately 379.6 ns echo pulse width can be obtained while using the present ultrasound transducer (center frequency = 5 MHz), which limits the threshold of D_D measurement to 285 μm [18]. This was found to meet the requirements of the current application. Measurements performed on the phantom further indicate that proposed single-element ultrasound transducer-based technique can continuously measure luminal diameter with a precision and accuracy better than 1% and 0.3% respectively [18]. The resolution of ΔD (smallest change in diameter that the system can detect) is determined by the smallest time shift of the echoes that can be measured using the tracking algorithm implemented in the prototype device. Any time shift of the recorded echoes that are smaller than the sampling time cannot be detected using the tracking algorithm. Since the ultrasound echo signals were sampled at 80 MHz (sampling time = 12.5 ns), the resolution of ΔD assessment would work out to be 9.6 μm (considering propagation speed of ultrasound signal through human tissue = 1540 m/s). However, resolution of ΔD measurement can be improved by digitizing the ultrasound echo signals with higher sampling frequencies.

Group average carotid diastolic local PWV of the recruited subjects was 3.04 ± 0.31 m/s. Consistent with the theory, local PWV obtained from the fiducial point Ψ was slightly higher than the diastolic local PWV. In 85% of subjects, the observed beat-to-beat variation in local PWV measures was less than 7.3% (range of local PWV beat-to-beat variation = 2.3% – 12.5%). Absolute values of local PWV measured at the carotid artery (elastic artery) was lower than the typical range of regional PWV assessed from muscular arteries and large arterial sections. Reduced values of carotid local PWV were also observed in our previous studies [35], [36], as well as by independent researchers working on various techniques to assess local PWV from elastic arteries [37], [38]. Potential error in measured local ΔT (from multiple fiducial points) was further investigated. Our initial experiments revealed a maximum inter-channel delay of less than 0.1 ms between the signal path of PPG analog front-end (inter-channel delay ≤ 0.05 ms in 77.3% test cases). This was measured by simultaneously feeding both the input channels with continuously acquired carotid PPG signal from a single sensor (single site) under different test conditions on multiple subjects. For the given pulse propagation distance of ΔX = 23 mm, the observed carotid local ΔT was approximately in the range of 5 ms – 12 ms. Therefore, the expected error in local

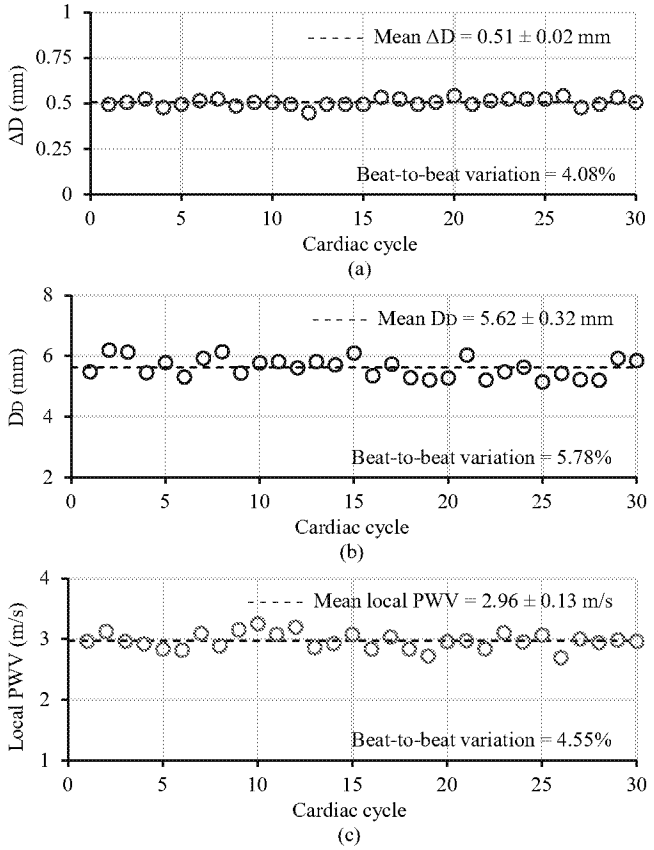


Fig. 7. Beat-to-beat variation of (a) Carotid ΔD, (b) End-diastolic lumen diameter D_D, and (c) Carotid diastolic local PWV obtained from a subject.

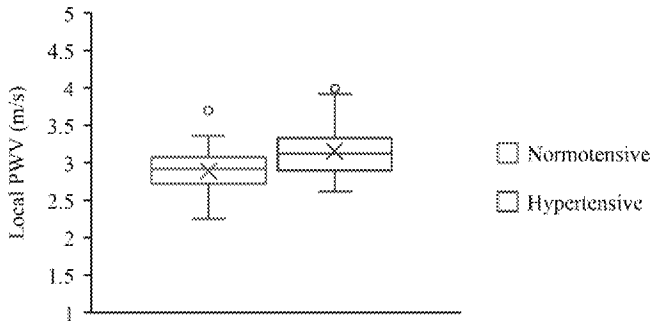


Fig. 8. Box-and-whisker diagram illustrating the grouping of carotid diastolic local PWV for normotensive subjects and hypertensive subjects.

ΔT measurement due to the hardware inter-channel delay is always less than 2%. It may also be noted that the measurement repeatability of DUT was attributed to the practical limitations in procuring quality signals simultaneously from ultrasound and dual PPG sensors. Relatively high beat-to-beat variation was observed in obese subjects and subjects with flaccid skin.

Statistical correlations of mean ΔD, D_D and local PWV versus brachial BP parameters pooled over all the subjects were evaluated. No significant correlation was observed for ΔD and D_D with brachial BP ($r < 0.5$). However, mean diastolic local PWV yielded statistically significant correlation with brachial DBP and brachial SBP, $r = 0.79$ ($p < 0.0001$) and $r = 0.74$ ($p < 0.0001$) respectively. Recorded mean carotid local PWV was further compared separately for the

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normotensive and hypertensive group, and the result is illustrated using a box-and-whisker diagram in Fig. 8. Group average diastolic local PWV values of normotensives (2.88 ± 0.29 m/s) were lower than the hypertensives (3.2 ± 0.33 m/s), marked × in the box-and-whisker diagram. Results indicate the ability of the proposed dual-element PPG probe to record carotid local PWV estimates from multiple subjects of different BP categories. Regression functions derived from these statistical analyses can also be used to predict arterial BP parameters. However, such prediction models and population-specific calibration coefficients are applicable only for the recruited population for a short period of time. For this reason, arterial wall properties and stiffness parameters (key indicators of arterial BP level) were also measured along with local PWV from multiple fiducial points to realize a calibration-free technique for cuffless BP measurement.

C. Accuracy of Calibration-Free Cuffless BP Estimation

The performance of the developed cuffless BP monitor was validated over 83 subjects seated at rest. Since all the measurements were performed in sitting posture, the estimated carotid BP parameters will be influenced by the hydrostatic pressure difference. In this present study, the vertical hydrostatic pressure gradient from the heart to the carotid was estimated using the height offset of the measurement site relative to the heart level, expressed in units of mmHg. The mean hydrostatic pressure difference for the recruited subjects was 21.6 ± 2.5 mmHg. The observed hydrostatic pressure offset was corrected in the directly measured carotid BP (obtained using DUT in sitting posture) for every individual in the measurement software. This offset adjusted BP is henceforth referred to as estimated carotid BP (estimated carotid DBP and estimated carotid SBP). During the statistical analyses, the estimated carotid BP parameters were directly compared with the reference brachial BP (measured at the heart level using sphygmomanometer). The estimated BP (hydrostatic offset corrected) is used in all the discussions and illustrations that follow.

A scatter plot of DBP readings from the reference device and DUT pooled over all the subjects is depicted in Fig. 9(a). Estimated carotid DBP and reference brachial DBP values correlated well ($r = 0.86$) with a statistically significant ($p < 0.0001$) relationship. Fig. 9(a) also shows a regression line (solid line; $y = 0.97x - 1.05$) for the measurements obtained from both devices as being close to the ideal regression line (dotted line; $y = x$). A histogram showing the distribution of absolute error in DBP measurement is presented in Fig. 9(b). It may be observed that the error in DBP estimation was less than 10 mmHg for 82% of total subjects, and 39% of the total measurements belongs to an error band of ±5 mmHg. Group average RMSE between estimated and reference DBP was equal to 8.3 mmHg. Maximum error (17.3 mmHg) was observed in a female subject of 67-years of age. The Bland-Altman analysis performed to evaluate the degree of agreement between DBP measurements resulted in a mean bias of 3.8 mmHg and SD of differences equal to 1.96 mmHg. It may be noted that carotid DBP estimated using the DUT

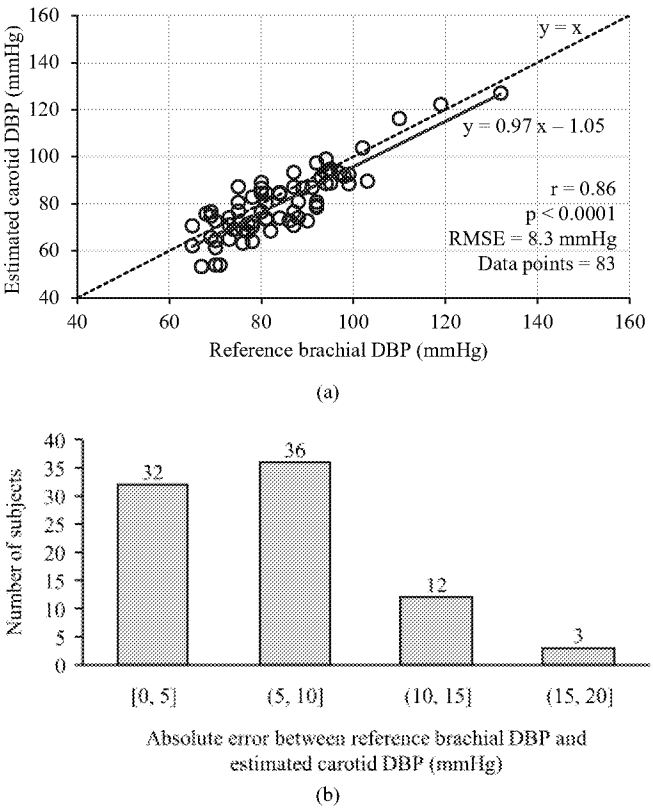


Fig. 9. (a) Scatter plot and linear regression analysis of estimated carotid DBP versus reference brachial DBP. (b) Distribution of the absolute differences between estimated mean carotid DBP and reference brachial DBP.

was compared against the reference brachial DBP by considering relatively constant nature of DBP throughout the arterial tree [1]. Study results demonstrate the feasibility of carotid DBP measurement using the proposed calibration-free cuffless BP technique. The introduced technique can be further explored to achieve local BP measurement from other superficial arteries with suitable bi-modal probe arrangement.

It may also be noted that the SBP level varies with the site in the arterial system due to pulse pressure amplification. Typically, SBP and pulse pressure at the carotid artery is lower than the corresponding values at the brachial artery [39]. Consistent with theory, SBP estimated at the carotid artery using the proposed calibration-free technique was lower than the brachial SBP. For this reason, absolute values of estimated carotid SBP could not be compared with the brachial SBP values. However, a statistically significant correlation ($r = 0.78$, $p < 0.0001$) existed between the carotid and brachial SBP pooled over all the subjects and yielded a regression line $y = 0.82x - 17.53$. The group average SBP of the recruited subjects at the carotid site was 101 mmHg, which is 43 mmHg lower than that of group average SBP of reference at the brachial site. This is relatively higher than the previously reported difference between brachial and carotid SBP level [17]. The large variation observed in some of the values could possibly be due to the real-time estimation error, and not caused by the physiological pulse amplification alone. Further studies are necessary to evaluate the accuracy of SBP estimation using the proposed calibration-free technique.

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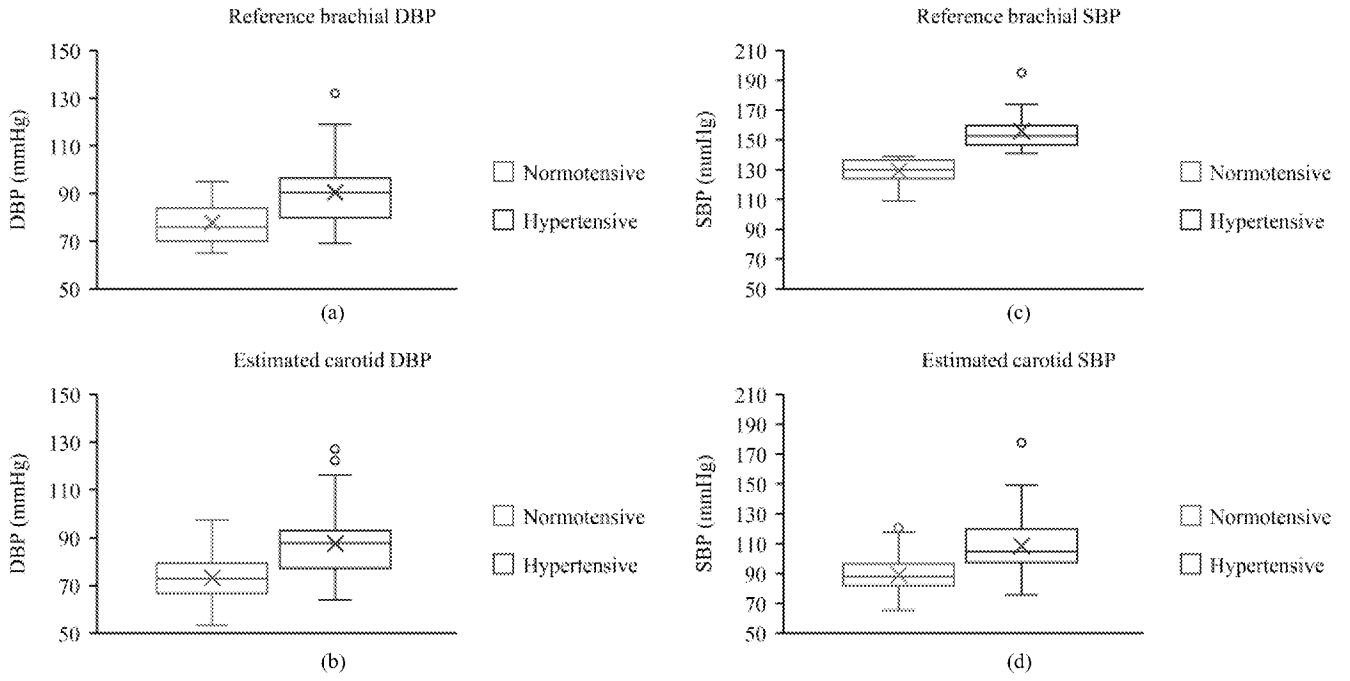


Fig. 10. Box-and-whisker diagrams exhibiting statistically significant difference in (a) reference brachial DBP, (b) estimated carotid DBP, (c) reference brachial SBP and (d) estimated carotid DBP during normotensive and hypertensive group analysis.

Arterial pressure needs to be obtained using an invasive catheter as the reference for such a study since other means of references are prone to limitations explained in Section IV.B.

D. Hypertension Screening Efficiency

The performance of the developed calibration-free cuffless technique in hypertension screening was also explored. Group-wise analysis of the recorded BP data from the reference device and the DUT was performed. Box-and-whisker diagrams presented in Fig. 10(a)–(d) exhibit the distribution of DBP and SBP values between normotensive and hypertensive groups. The group average values are marked as × in the box-and-whisker diagrams. Table II summarizes the performance of both the devices during normotensive and hypertensive group analysis. Statistical significance of the observations was confirmed via unpaired t-test of the respective BP values.

Reference brachial DBP values distinguished between normotensive and hypertensive groups as shown in Fig. 10(a). Group average brachial DBP of hypertensive subjects was 16.7% higher than that of normotensive subjects. Correspondingly, a significant difference in estimated carotid DBP was observed between normotensive and hypertensive subjects (Fig. 10(b)). There was 18.9% increase in the group average carotid DBP of hypertensives compared to the normotensives. The reference brachial SBP could clearly distinguish normotensive and hypertensive BP category as illustrated in Fig. 10 (c). Group average brachial SBP of hypertensive subjects was 22.5% more than the corresponding measure from normotensive subjects. Fig. 10 (d) depicts grouping of the carotid SBP obtained from normotensives and hypertensives. As discussed in Section V.C, the absolute value

TABLE II
NORMOTENSIVE VERSUS HYPERTENSIVE GROUP COMPARISONS

BP Parameters	Device	Group average of normotensives (mmHg)	Group average of hypertensives (mmHg)	Percentage change in group average
DBP	Reference	78	91	16.7
	DUT	74	88	18.9
SBP	Reference	129	158	22.5
	DUT	91	110	20.9

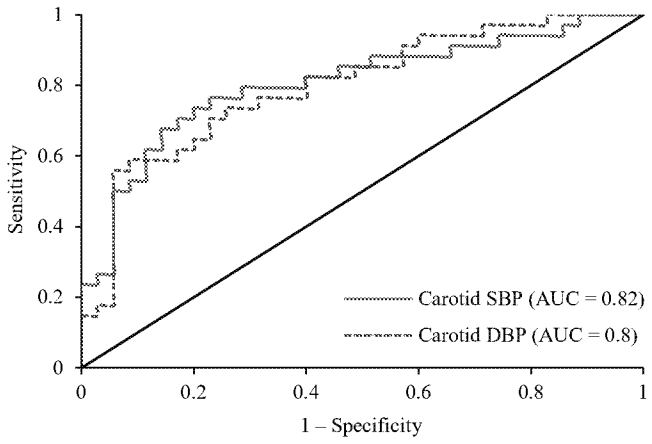


Fig. 11. ROC curves demonstrate the hypertension screening performance of DUT using carotid DBP and carotid SBP. An AUC ≥ 0.8 indicates reliability and efficiency of the screening device.

of carotid SBP was lower than the brachial SBP in both BP categories. However, the variation of carotid SBP level in these two groups was statistically significant. The group average carotid SBP of hypertensive subjects was 20.9% higher than that of the normotensive subjects; comparable to

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the corresponding quantitative metrics offered by the reference BP device.

Hypertension screening efficiency of the proposed device was further evaluated using ROC curves. Fig. 11 illustrates the ROC curves reflecting the data corresponding to carotid SBP and carotid DBP assessed using the DUT. Brachial SBP was considered as the reference to define the state variable of hypertensive status (brachial SBP $\geq$ 140 mmHg $\leftrightarrow$ hypertensive status = true). Interpretation of the AUC statistics revealed the hypertension screening efficacy of the proposed device. Resultant AUC values for carotid SBP and carotid DBP were 0.82 and 0.8 respectively, indicating the reliability of hypertension screening test using DUT. Carotid SBP was found to be a better indicator than the carotid DBP for hypertension screening during both group-wise analysis, and in ROC evaluation. Statistical analysis of this study demonstrated that the proposed calibration-free cuffless BP device has the potential for hypertension screening using carotid BP parameters. Further extensive clinical validation in diverse subjects including hypotensive patients is needed to evaluate the widespread applicability of the proposed system.

E. Local Estimation of Arterial Stiffness Indices

The cuffless BP monitor evaluated here effectively measures all the physiological parameters required for the calculation of various arterial stiffness indices. Estimate of stiffness indices such as pressure strain elasticity (E_P) and arterial compliance (AC) can be obtained using the arterial diameter and BP parameters alone as given in (10) and (11). Here, ΔP is the pulse pressure (numerical difference between SBP and DBP), expressed in units of kPa.

$$E_P = \frac{\Delta P}{\left(\Delta D / D_D\right)} \tag{10}$$

$$AC = \frac{\frac{\pi}{4}\left(D_S^2 - D_D^2\right)}{\Delta P} \tag{11}$$

Using the data recorded during the present in-vivo study, the carotid E_P and AC of the recruited population were also quantified. Mean values of the measured diameter values and estimated BP parameters from the carotid artery were used to compute these stiffness indices. Since the proposed bi-modal arterial compliance probe performs a direct evaluation of ΔD, D_D, DBP, and SBP from small arterial segments, this approach gives a local estimate of stiffness indices of the respective artery without the necessity of any calibration. For the whole study cohort, the absolute values of E_P (in units of kPa) and AC (in units of mm^2/kPa) were in the range of 12.68 kPa – 96.34 kPa, and 0.42 mm^2/kPa – 5.08 mm^2/kPa respectively. Obtained stiffness measures were comparable to similar estimates reported in previous studies [19], [40]. Since the recruited small study population was slightly skewed towards the younger age group and more than 75% of the subjects were under medication (it may affect stiffness), an extensive statistical analysis on the age-related changes in arterial stiffness was not feasible with the current data. However, relatively high E_P and low AC values were observed in hypertensive patients and in geriatric populations. Extensive clinical validation and field studies (like previous studies of our ARTSENS® device on arterial stiffness evaluation for vascular screening [19], [20]) are essential to investigate the ability of the proposed system to detect subtle changes in arterial stiffness that occur due to various cardiac conditions as well as vascular aging.

F. Limitations of Proposed Technique and Ongoing Work

Simultaneous, independent adjustment and orientation of both ultrasound and dual-element PPG probes on the artery is a limitation in our current bi-modal probe design. Typical time taken for initial probe placement to obtain reliable signals was 20 – 40 seconds. In 15% of subjects, placement and orientation of the probes at the correct location took more time, particularly in the geriatric population and subjects with flaccid skin. Further research is underway to overcome these limitations and to improve the usability of the proposed technique. Integrated multi-modal handheld probes and patches (mechanically integrated single element ultrasound transducer and PPG or magnetic plethysmograph [32] or accelerometric [41] sensing elements) are being developed with an aim to reduce the initial probe adjustment time, and to ensure continuous, long-term BP monitoring. Experimental verification and validation of calibration-free cuffless BP measurement using a multi-channel unimodal ultrasound probe (to capture arterial dimensions and local PWV at single and/or multiple arterial sites) with an inbuilt hydrostatic pressure correction unit are also in progress.

VI. Conclusion

We present a novel cuffless BP measurement technique to estimate BP at the carotid artery, using a bi-modal ultrasound-PPG probe-based device. It non-invasively measures the arterial dimensions and local PWV (from multiple fiducial points) at the same location on the carotid artery. DBP and SBP were estimated from these measurements using mathematical models without any subject- or population-specific calibration. The bi-modal probe and the measurement device were custom designed and tested on normotensive and hypertensive subjects, with brachial cuff-based BP monitor as the reference device. The DBP estimated from carotid and reference brachial DBP correlated well (r = 0.86), with the error in estimated DBP being less than 10 mmHg for 82% subjects. A statistically significant agreement (r = 0.78) was observed between carotid and brachial SBP. Absolute values of SBP at the carotid site were found to be lower than the respective reference brachial SBP, which was expected due to the physiological pulse amplification along the arterial tree. An invasive catheter may be used in future studies for better comparison. The utility of the developed device for hypertension screening was also explored. The subject population was grouped into normotensive and hypertensive categories based on the reference brachial values. The group average carotid DBP in hypertensive subjects was 18.9% higher than the normotensive group, while the brachial DBP showed 16.7% increase. Similar figures for carotid and brachial SBP were 20.9% and 22.5% respectively. The percentage increase in the group average carotid SBP and

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DBP values between the normotensive and hypertensive groups were statistically significant and comparable to the increase observed in the reference brachial SBP and DBP measurements. ROC curves resulted in AUC of 0.82 and 0.8 for carotid SBP and carotid DBP respectively, thereby illustrating the potential utility of the developed device in hypertension screening. The study results clearly indicate the potential of the developed bi-modal probe and measurement system in measuring BP and local arterial stiffness indices at the carotid artery in a cuffless, non-invasive manner, without the necessity for any subject- and/or population-specific calibration, and its potential for hypertension screening.

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RE: K222658/S003 SE letter change requested

Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Wed 7/26/2023 11:15 AM

To:510K Program <510K_Program@fda.hhs.gov>

Cc:Kazmierski, Robert <Robert.Kazmierski@fda.hhs.gov>;DeMarco, Angela <Angela.Demarco@fda.hhs.gov>;Wille, Elizabeth <Elizabeth.Wille@fda.hhs.gov>;Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

1 attachments (271 KB)
K222658.Letter.SE.FINAL_Addendum_20230726.pdf;

Hi Lisa,

Thank you so much for the assistance!

I have attached the signed letter. I am not able to access the designated folder. Are you able to add the file?

Thank you,
Meaghan

From: 510K Program <510K_Program@fda.hhs.gov>
Sent: Tuesday, July 25, 2023 5:35 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: Kazmierski, Robert <Robert.Kazmierski@fda.hhs.gov>; DeMarco, Angela <Angela.DeMarco@fda.hhs.gov>; 510K Program <510K_Program@fda.hhs.gov>; Wille, Elizabeth <Elizabeth.Wille@fda.hhs.gov>
Subject: RE: K222658/S003 SE letter change requested

Hi, Meaghan,

(b)(5)

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(b)(5)

Please let us know if you have any questions.

Elizabeth (*Lisa*) Fife Wille
Management Analyst

Premarket Notification and Classification Team (TRP1A)
Division of Submission Support (DRP1) | Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 2437
Tel: (301) 796-0769 | Elizabeth.Wille@fda.hhs.gov





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From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Sunday, July 23, 2023 1:24 PM
To: 510K Program <510K_Program@fda.hhs.gov>
Cc: Kazmierski, Robert <Robert.Kazmierski@fda.hhs.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003 SE letter change requested

Hello,

(b)(5)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Friday, July 14, 2023 7:03 AM
To: 510K Program <510K_Program@fda.hhs.gov>
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003 SE letter change requested

Hello,

(b)(5)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Friday, July 7, 2023 8:28 AM
To: 510K Program <510K_Program@fda.hhs.gov>
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003 SE letter change requested

Hello All,

(b)(5)

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(b)(5)

Thank you!

-Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 29, 2023 9:06 AM
To: 510K Program <510K_Program@fda.hhs.gov>
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003 SE letter change requested

Hello,

Just wanted to f/u.

Thanks!
-Meaghan

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

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From: Erlewein, Meaghan
Sent: Thursday, June 22, 2023 12:22 PM
To: 510K Program <510K_Program@fda.hhs.gov>
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: K222658/S003 SE letter change requested

Hello,

(b)(5)

Thank you,
Meaghan

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Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
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510(k) Cover Letter

K222658

FDA/CDRH/DCC
SEP 0 2 2022
RECEIVED

September 02, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional 510(k) Premarket Notification for the Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (As amended) and as required in 21 CFR § 807 - Subpart E, Accurate Meditech Inc submits this subject Premarket Notification for your review. In accordance with 21 CFR § 807.90(c), this document is submitted in duplicate with this original cover letter, and two additional copies of the cover letter are provided.

(b)(4)

Accurate 24 Non-Invasive blood pressure monitor(Model: Accurate 24 BPM) will be shown to be substantially equivalent to the BioBeat BB-613 WP(**K190792**). The purpose device(Accurate 24 BPM) is a Class II device per 21 CFR 870.1130, ProCode: DXN.

Accurate Meditech Inc considers the intent to market this device as confidential commercial information. Therefore, Accurate Meditech Inc. considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR § 20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

Sincerely,

(b)(6)

Kuan-Jen, Wang
Accurate Meditech Inc.
8F-10, No. 12, Ln, 609, Sec. 5, Chongxin Rd.,
Sanchong Dist. New Taipei City
241406 Taiwan

Phone: +886 2 2999-1596
Fax: +886 2 2999-1196
stanley@accurate-meditech.com

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

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(b)(4)

MODEL	(b)(4)
SPEC NO.	

(b)(4)

PRODUCT SPECIFICATION

(b)(4)

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 5/9/2023 5:45:38 PM
To: (b)(6)
CC: DCCLetters@fda.hhs.gov
Subject: K222658/A001 Acknowledgement Letter
Attachments: K222658-A001-Acknowledgement Letter.pdf

May 9, 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.

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

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Acknowledgement Letter

05/09/2023

Douglas Herrington, Official Correspondent
Accurate Meditech Inc.
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.,
New Taipei City,
241406 TAIWAN

Dear Douglas Herrington:

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: K222658/A001
Received: 05/09/2023
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

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

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Hi Megan,

Here is the second email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-May 2023 Response

(b)(4)

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ADMINISTRATION

(b)(4)

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Hi Megan,

There are two emails that were composed but are not listed in my email files. They contain files 006 – 010 and 026 – 029. I am resending them.

Also, file 021 was inadvertently sent twice.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

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Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

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If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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(b)(4)

TEST REPORT
IEC 62133
Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

Report Number. ..... :	(b)(4)
Date of issue ..... :	
Total number of pages	
Applicant's name ..... :	
Address ..... :	
Test specification:	
Standard ..... :	IEC 62133: 2012 (Second Edition)
Test procedure ..... :	(b)(4)
Non-standard test method ..... :	
Test Report Form No. ..... :	IEC62133B
Test Report Form(s) Originator .... :	(b)(4)
Master TRF ..... :	

(b)(4)

Test item description ..... :	Rechargeable Lithium-Ion Battery (Product name: Rechargeable Lithium Polymer Battery)
Trade Mark ..... :	(b)(4)
Manufacturer ..... :	
Model/Type reference ..... :	
Ratings ..... :	Rated Voltage: 3,7 V d.c. Rated Capacity: 250 mAh (0,925 Wh)

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

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Accurate Meditech Inc.-May 2023 Response

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Cc: k222658@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Attached please find our responses to the questions below (b)(4)

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

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

Records processed under FOIA Request 2023-10915, Released by CDRH on 07-09-2024

(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

[cid:image003.png@01D98C82.A36A4C70]<http://www.fda.gov/>

[cid:image004.jpg@01D98C82.A36A4C70]<https://www.facebook.com/FDA>
[cid:image005.jpg@01D98C82.A36A4C70] <https://twitter.com/US_FDA>
[cid:image006.jpg@01D98C82.A36A4C70] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image007.jpg@01D98C82.A36A4C70] <http://www.flickr.com/photos/fdaphotos/>
[cid:image008.jpg@01D98C82.A36A4C70]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
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 2023-10915; Released by CDRH on 07-09-2024

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas
HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

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

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From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Verification

And Validation Documentation

(Software Test Plan)

Document Number: (b)(4)

Version: (b)(4)

2021/07/05

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2021-07-05

Kuan Jen, Wang (General Manager)

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Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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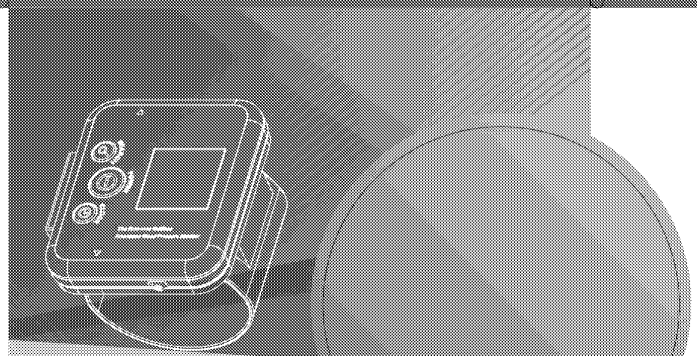
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Accurate 24 Non-Invasive Blood Pressure Monitor

Accurate Meditech Inc.
12, Ln. 609, Sec. 5, Chongxin Rd.,
Rm. 10, 8F., Sanchong Dist.,
New Taipei City 24161, Taiwan
www.accurate-meditech.com
+886-2-2999-1596

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2024-XX-XX
LOT ACC2XXXXB
SN ACC2400001



Accurate
MEDITECH

Accurate 24 Non-invasive Blood pressure monitor

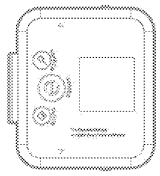
Made in Taiwan

Accurate
MEDITECH

Accurate 24 Non-Invasive Blood Pressure Monitor

FEATURES

- Non-invasive, cuff-less, fast, and automatic blood pressure and pulse rate measurement.
- Monitor measurement data with a real-time clock on the self-contained screen.
- Real-time power status, low battery alert and auto sleep for power saving.



Accurate

SPECIFICATIONS

- **Model Name**: Accurate 24 BPM
- **Weight**: 0.22lb / 100g
- **Dimension**: 70mm(H) x 60mm(W) x 14mm(D)
- **Measuring Range**:
  70~180mmHg(Sys) / 40~130mmHg(Dia) / Pulse 40~240bpm
- **Operating** : Internal Battery DC 3.7V / 250mAh
- **Recharge** : Power Input DC 5V, 1A MAX, Micro-USB

Operating Temperature: 41 °F ~ 104°F / 5 °C ~ 40 °C
Storage and Transportation Temperature: -4 °F ~ 131°F / -20 °C ~ 55 °C
Relative Humidity: 10% ~ 95% (non-condensing)
Atmospheric Pressure: 70.0 kPa ~ 106.0 kPa

In the box | 1 Accurate 24 Non-invasive Blood Pressure Monitor
1 Micro-USB charging Cable, 1 User Manual

→V1.1/20211106

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name:
Risk Management Report of Biological Evaluation Based on 10993-1:2018

Document Number: (b)(4)
Version: (b)(4)
2021/7/28

Presented by
Kuan Jen Wang / General Manager

Approved By (b)(6) *Date* 2021-07-28

Kuan Jen, Wang (General Manager)

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Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail: info@accurate-meditech.com

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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 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-June 19 2023, Response

(b)(4)

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

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5. 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 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

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Material Safety Data Sheet

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Date: June 7, 2023

From: Saryet Kucukemiroglu, Ph.D. (Mathematical Statistician)
CDRH/OCEA/DCEA2/TCEA2C

Subject: Statistical Review of K222658/S003 Accurate 24 Non-invasive blood pressure monitor by Accurate Meditech Inc. (DHP yes, SaMD no, not software only, SaMD AI/ML no, RWE no, data reuse no)

To: Meaghan Erlewein, PhD
CDRH\OHT2\DHT2A\THT2A1

(b)(5)

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

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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Statement of the Accurate 24 BPM's Essential Performance

Accurate 24 BPM is the blood pressure and pulse rate monitor.

The functions of the device are as follows:

1. Time and date setting
2. Storage of measurement results
3. Measurement of blood pressure
4. Heart rate measurement

According to clause 202.8.1.101 of IEC 80601-2-30:2018 shall not be allowed:

a) component failures.
b) changes in programmable parameters or settings.
c) reset to default settings; and
d) change in the reading for the measurement of the blood pressure at any point of the NOMINAL measurement range greater than 2 mmHg.

1) during and after exposure to non-transient phenomena; and

2) after exposure to transient phenomena.

(b)(6)

(Signature)

Kuan-Jen ,Wang

(Typed Name)

2023.4.12

(Date)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

(b)(4)

Product name :

Accurate 24 Non-invasive blood pressure monitor

Accurate Meditech Inc.

(b)(4)



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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.
Best

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Report Number: (b)(4)

(b)(4)

Skin Irritation Test of Reusable One-piece Blood Pressure Cuff Using ISO 10993-10:2010 Test Method 0.9% Sodium Chloride Injection Extract

Sponsor

(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 2023-10915; Released by CDRH on 07-09-2024

Hi Megan

Here is the seventh email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

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Heart Vessels (2000) 15:49–51 Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024 © Springer-Verlag 2000

SHORT COMMUNICATION

Motoaki Sugawara · Kiyomi Niki · Hiroshi Furuhata
Satoshi Ohnishi · Shin Suzuki

Relationship between the pressure and diameter of the carotid artery in humans

Received: April 11, 2000 / Accepted: April 15, 2000

Abstract The purpose of this study was to examine the assumption of similarity between pressure and diameter-change waveforms in humans. We measured carotid arterial pressure and diameter change, simultaneously, in six patients with heart disease. In all patients, the carotid arterial pressure–diameter relationship could, in practice, be regarded as being linear.

Key words Carotid artery · Pressure · Diameter · Echo tracking · Catheter-tipped micromanometer

Many animal experimental studies have demonstrated that arterial pressure waveforms and diameter-change waveforms are similar. Therefore, it is practical to obtain arterial pressure waveforms by measuring changes in the diameter of an artery and calibrating its peak and bottom values by systolic and diastolic blood pressure measured with a cuff-type manometer.[1,2] However, the assumption of the similarity between pressure and diameter-change waveforms in humans has been a target of much criticism. Since few reliable human data are available, most of the criticism is based not on real human data but on a stereotyped idea of the nonlinearity of vessel wall elasticity. The purpose of this study was to examine this issue.

We studied the relation between the intravascular pressure and the diameter of the carotid artery in six patients with heart disease (4 men and 2 women, age: 45 ± 9 years, systolic blood pressure: 103 ± 9 mmHg, diastolic blood pressure: 62 ± 9 mmHg). The study was approved by the ethical review committee of the Heart Institute of Japan, Tokyo Women's Medical University, and all subjects gave informed consent. The pressure was measured with a catheter-tipped micromanometer and the diameter was measured simultaneously with an echo-tracking system (QFM-1100, Hayashi Denki, Kanagawa, Japan).

Figure 1 shows simultaneous recordings of pressure and diameter for a single cardiac cycle from the left common carotid artery, superimposition of the pressure and diameter-change waveforms, and instantaneous relationships between the pressure and the diameter.

During systole, the pressure and diameter-change waveforms are very similar on the whole, but artifact-like differences in small parts of the contours, probably caused by an error in echo tracking, can be noted in some recordings (Fig. 1b,c,e). During diastole, the diameter change follows the pressure change, i.e., there is a slight delay between the decrease in pressure and the decrease in diameter. In all patients, the relationship between pressure and diameter was relatively linear throughout the cardiac cycle (goodness-of-fit $r^2 \geqq 0.97$).

In all six patients, the carotid arterial pressure–diameter relationship showed slight nonlinearity and hysteresis. However, the effects were not serious, and we can practically regard the carotid arterial pressure–diameter relationship as being linear.

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H. Furuhata
Medical Engineering Laboratory, Jikei University School of Medicine, Tokyo, Japan

S. Ohnishi · S. Suzuki
Department of Cardiology, Tokyo Women's Medical University School of Medicine, Tokyo, Japan

References

1. Watanabe H, Kawai M, Sibata T, Hara M, Furuhata H, Mochizuki S (1998) Noninvasive measurement of aortic pressure waveform by ultrasound. Heart Vessels 13:79–86
2. Niki K, Sugawara M, Uchida K, Tanaka R, Tanimoto K, Imamura H, Sakomura Y, Ishizuka N, Koyanagi H, Kasanuki H (1999) A noninvasive method of measuring wave intensity, a new hemodynamic index: application to the carotid artery in patients with mitral regurgitation before and after surgery. Heart Vessels 14:263–271

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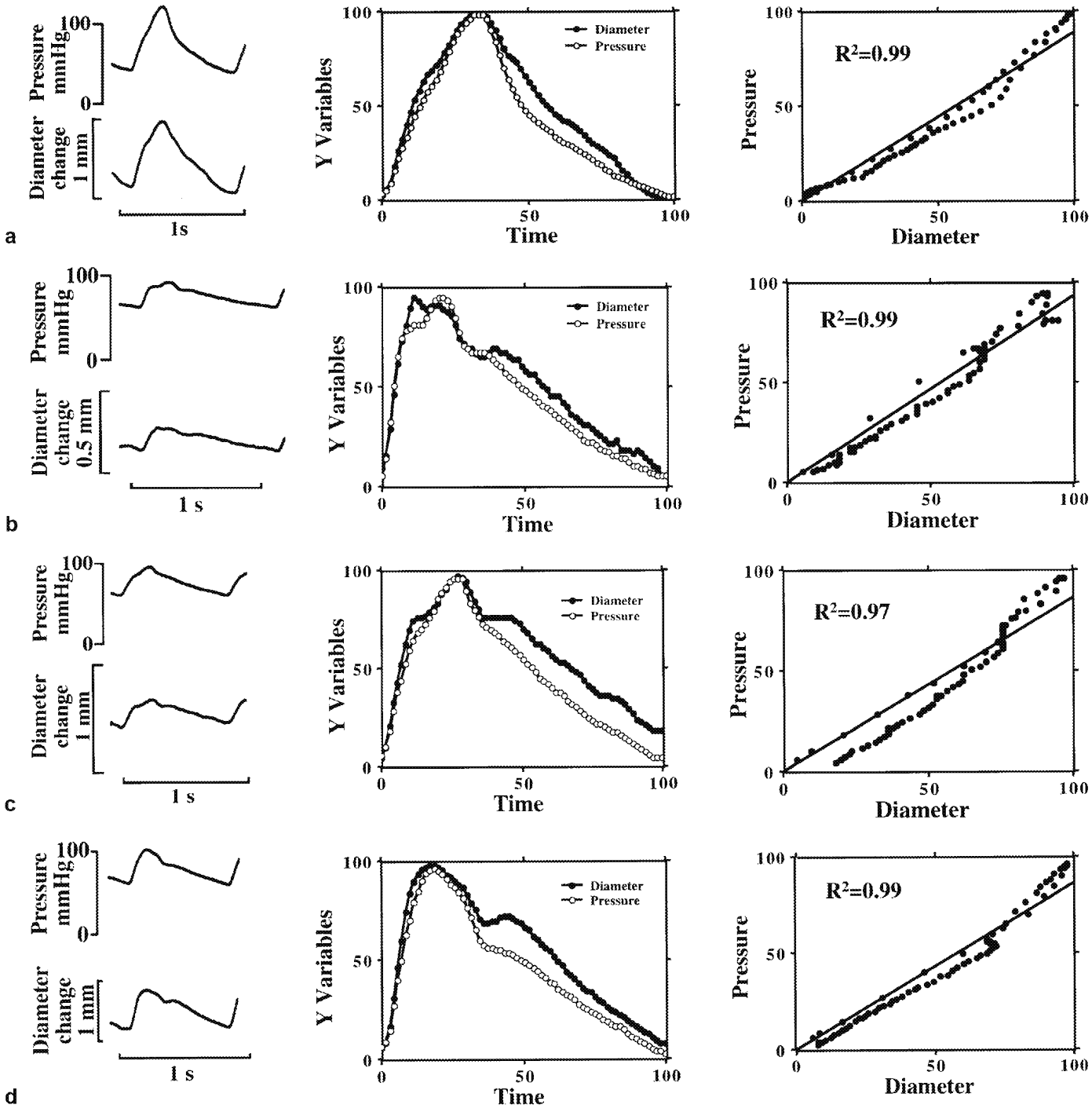


Fig. 1a–f. *Left panels*, simultaneous recordings of pressure and diameter for a single cardiac cycle from the left common carotid artery in six patients. *Middle panels*, superimposition of the pressure and diameter-change waveforms. The scales of the amplitudes of both waveforms have been adjusted so that the peak amplitudes are nearly the same (~100). The time scale was adjusted so that one cardiac cycle is 100. *Right panels*, instantaneous relationships between the pressure and diameter with the adjusted scales. **a** A 50-year-old man with aortic stenosis and regurgitation, and mitral regurgitation. **b** A 49-year-old man with aortic regurgitation and mitral stenosis. **c** A 35-year-old woman with aortic stenosis and regurgitation, mitral stenosis and regurgitation, and atrial flutter. **d** A 31-year-old woman after open mitral commissurotomy. **e** A 54-year-old man with Adams-Stokes syndrome. **f** A 49-year-old man with right heart failure

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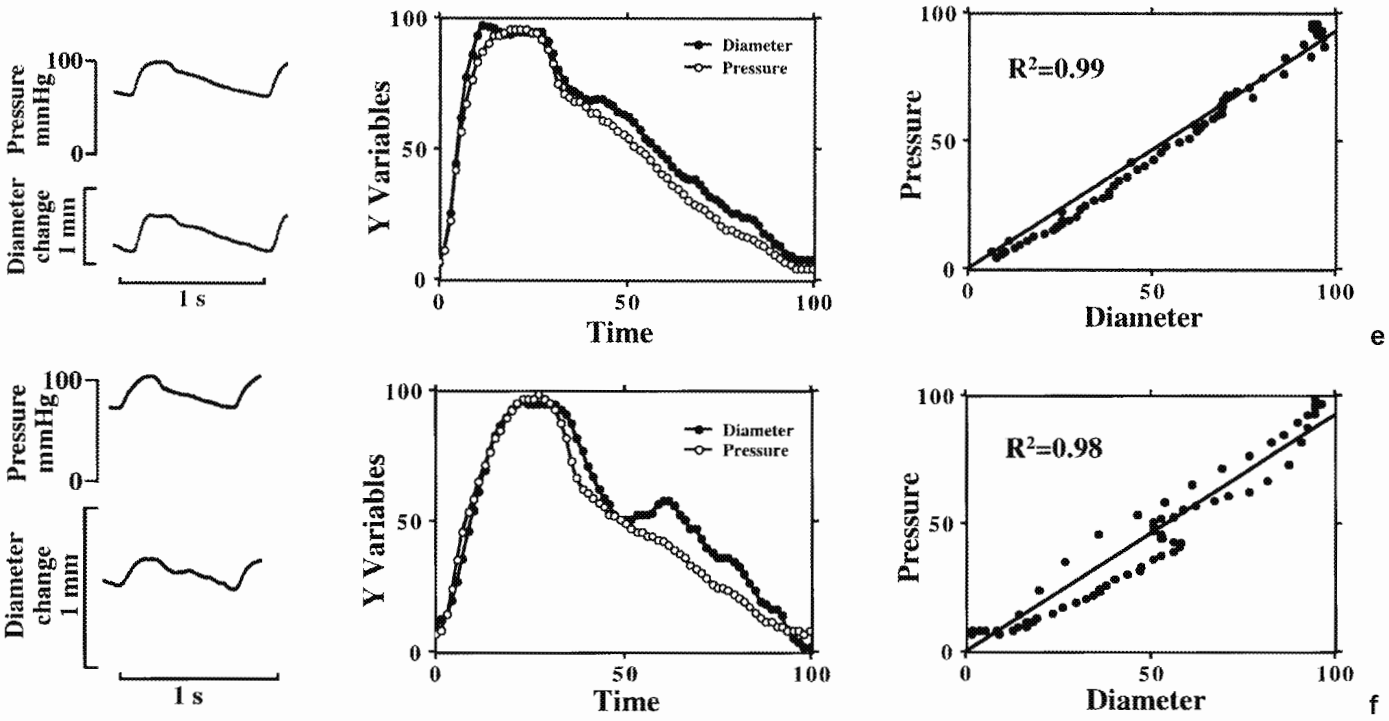


Fig. 1a–f. *Continued*

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Accurate Meditech Inc	Schematic Design	ISO Doc No	(b)(4)
		Doc Version	
		Form Page	
		Change record	
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U.S. FOOD & DRUG ADMINISTRATION

August 7, 2023

Accurate Meditech Inc.
% Douglas Herrington
Official Correspondent
Herrington Consulting LLC
No 64, Haijing 3rd St
Sanzhi District
New Taipei City, 252
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN

Dear Douglas Herrington:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 21, 2023. Specifically, FDA is updating this SE Letter to correct the official contact name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Stephen Browning OHT2: Office of Cardiovascular Devices, 240-402-5241, Stephen.Browning@fda.hhs.gov.

Sincerely,

Stephen C. Browning -S

Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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Report No. (b)(4)

TEST REPORT
IEC 60601-1-2
Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: ELECTROMAGNETIC disturbances – Requirements and tests

Report Number. ..... :	(b)(4)
Project Number ..... :	
Date of issue ..... :	
Total number of pages ..... :	
Name of Testing Laboratory preparing the Report ..... :	
Applicant's name ..... :	Accurate Meditech Inc.
Address ..... :	8F-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406, Taiwan
Test specification:	
Standard ..... :	IEC 60601-1-2:2014+AMD1:2020 EN 60601-1-2:2015+AMD1:2021 8.11 Proximity magnetic fields
Test procedure ..... :	Test Scheme
Non-standard test method ..... :	N/A

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Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2567
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: June 20, 2023

Reviewer: Meaghan Erlewein

510(k)# K222658/S003 Subject: Traditional

Applicant: Accurate Meditech Inc.	**Device Trade Name:** Accurate 24 Non-invasive blood pressure monitor
Contact Name: Wang Jen	**Contact Title:** General Manager
Correspondent Firm: Accurate Meditech Inc.	**Phone:** 886 (2) 299-91196 **Email:** stanley@accurate-meditech.com
Received Date: May 15, 2023	**Due Date:** June 21, 2023
Pro Code(s): DXN **Class:** II **Reg #:** 870.1130	**Reg Name:** Noninvasive Blood Pressure Measurement System

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K190792	DQA, DXN, DRG	Bb-613wp	BioBeat Technologies Ltd.

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.15.00)	
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.	
Reviewer Sign-Off	Meaghan Erlewein -S Date: 2023.06.20 11:47:49 -04'00'

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

Here is the sixth email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: (b)(6)

Sent: Monday, June 12, 2023 5:44 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, June 9, 2023 3:00 AM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Thursday, June 8, 2023 2:31 PM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have a few more questions. If possible, please respond by COB on Monday, 6/12.

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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(b)(4)

Thanks,

Meaghan

(b)(6)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Friday, June 2, 2023 9:30 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Please find attached our response to the question below.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 26, 2023 11:29 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Monday, May 22, 2023 10:24 PM

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Tuesday, May 23, 2023 3:17 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

[cid:image001.png@01D99D55.87080110]

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Monday, May 22, 2023 7:55 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

(b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

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

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[cid:image004.png@01D99D55.87080110]<http://www.fda.gov/>

[cid:image005.jpg@01D99D55.87080110]<https://www.facebook.com/FDA>
[cid:image006.jpg@01D99D55.87080110] <https://twitter.com/US_FDA>
[cid:image007.jpg@01D99D55.87080110] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image008.jpg@01D99D55.87080110] <http://www.flickr.com/photos/fdaphotos/>
[cid:image009.jpg@01D99D55.87080110]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

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

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Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7,

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

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2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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5. 510(k) Summary

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR Part 807.92

5.1 Submitter

Accurate Meditech Inc.
8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.,
Sanchong Dist., New Taipei City 241406, Taiwan

Phone: +886 2 2999 1596
Fax: +886 2 2999 1196
Contact Person: Kuan-Jen, Wang

Date Prepared: 2023/6/17

5.2 Subject Device Information

Trade/Device Name	Accurate 24 Non-invasive blood pressure monitor
Model	Accurate 24 BPM
Common Name	Non-invasive blood pressure monitor
Regulatory Classification	Class II 870.1130 Noninvasive blood pressure measurement system
Submission type	Traditional 510(k)
Product Code	DXN

5.3 Predicate Device Information

Predicate Device	Sponsor: Biobeat Technologies Ltd. Device: BB-613 WP 510(K) Number: K190792

5.4 Device Description:

Accurate 24 Non-Invasive blood pressure monitor device is a small, lightweight, handheld device intended to measure and display blood pressure trending (Systolic and Diastolic) and spot-check of pulse rate. Measurement is performed on the wrist of the radial artery. This blood pressure monitor uses the pulse wave transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and pulse rate of adults in a non-invasive manner.

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

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5.5 Indications for Use:

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and is able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

5.6 Comparison to the Predicate Device

The intended use of Accurate 24 BPM has the same intended use as predicate device BB-613 WP(K190792). The technological characteristics of Accurate 24 BPM are substantially similar to the technological characteristics of the predicate device BB-613 WP(K190792). The subject device and predicate device are considered NIBP monitors; both the subject device and predicate device are based on obtaining pulse wave transit time for blood pressure and pulse rate calculation. At a high level, the subject and predicate devices are based on the following same technological elements:

Functionality	New Device Accurate 24 BPM	Predicate Device BB-613WP
Indications for use	The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40. The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally. The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using oscillometric blood pressure monitor. The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.
Product Codes	DXN	DXN, DQA, DRG
Regulation No.	21 CFR 870.1130	21 CFR 870.1130
Classification	Class II	Class II
Classification Name	Noninvasive Blood Pressure	Noninvasive Blood Pressure

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

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	Measurement System	Measurement System
Use Population	Adults (age 20-70)	Adults
User Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use
Monitoring	Spot-checking	Spot-checking
Principle of Operation	Accurate 24 BPM estimates blood pressure based on the Moens-Korteweg equation. The dual piezo sensors obtain the pulse wave transit time by positioned in a fixed length on radial artery for PWV and pulse rate. By utilizing arterial changes captured by the first NIRS optic, hemodynamic process is able to conclude the pulse pressure for SBP and DBP.	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time which is obtained utilizing pulse measurements from the integrated skin attached SpO2 sensor
Internal Power supply	Rechargeable lithium-polymer battery	Rechargeable lithium-polymer battery
Measurement Site	Wrist area and skin	Wrist area and skin
Measurement type	Spot	Spot
Measurement Range, Pulse rate	40 to 250 bpm	40 to 250 bpm
Pulse rate	±5%	±3%(Arms)
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg
Accuracy blood Pressure	±5 mmHg	±5 mmHg
Contact material	Wrist Skin Cushion: Medical Silicone Wrist Holder: Nylon and Fabric Plastic Parts: ABS	Polycarbonate, photodiode window, silicone, adhesive patch
Data Display	PMOLED on device.	LCD on device or handheld display unit (e.g., mobile phone)
Screen	65K Full Color	Black and White
Data Storage	Yes, Storage in the NAND flash.	No, but can transmit the data to handheld device

5.7 Performance Data

Performance Data - Bench Tests

The performance evaluation of the proposed Accurate 24 BPM included testing conducted following the FDA Guidance Documents and international standards:

- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "major" concern since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
- Electrical safety and EMC testing were conducted on the Accurate 24 BPM device. The system complies with the IEC 60601-1、IEC 60601-1-11 and IEC80601-2-30 standards for safety and the IEC 60601-1-2 standard for EMC.

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- Cytotoxicity, sensitization, irritation, and systemic toxicity of Accurate24 BPM passed ISO 10993 standard.

Performance Data - Clinical Tests

Our clinical study is evaluated according to ISO 81060-2:2018 and IEEE 1708:2014 [Including: Amendment 1(2019). In total, 376 subjects were included in the clinical validation study. The subjects were included according to the subject selection criteria outlined in ISO 81060-2:2018 and IEEE 1708-2014 [Including: Amendment 1(2019)]. At least 85 subjects were included for the following confounding factors: (1) Fitzpatrick Scale Type 5 and 6, (2) Subjects Ages 51-70 years, (3) Body Mass Index Grade I & II. All confounding factor groups were assessed independently. All analysis met the accuracy requirements outlined in ISO 81060-2:2018. The obtained clinical results are as follows.

Characteristic		**Actual subjects**	
Subject, n		376	
overall results for all study subjects			
	Pass requirements	**Achieved**	
		SBP	***DBP***
Means (*mmHg*)	± 5	1.67	1.01
SD (*mmHg*)	≤ 8	4.04	5.32
Results		**pass**	**Pass**
Criterion 2			
SD (*mmHg*)	≤ 6.76/6.87	2.73	3.55
Results		**pass**	**pass**

General study participants (The subject requirements for ISO 81060-2:2018) of accuracy study:

This was a study of 114 subjects. Participants' age ranged from 20 – 70 and 73 were male and 41 were female. The study was conducted in accordance with ISO 81060-2:2018 standard. The Accurate 24 BPM accuracy was compared to "Welch Allyn DuraShock DS66 Trigger Aneroid".

Primary endpoint
The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid measurement in the accuracy validation data set were as follows: (1) mean bias of systolic BP: 2.00±2.97 and (2) mean diastolic bias: 1.33 ±4.17 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

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

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Confounding factors of the study participants accuracy study:

This were three groups (Group-01: Fitzpatrick Skin Type 5 & Type 6), Group-02:Age 51-70 years and Group-03:BMI Grade I & II) are independently recruited participants study of 286 subjects. The Accurate 24 BPM accuracy was compared to Welch Allyn DuraShock DS66 Trigger Aneroid.

Primary endpoint

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Fitzpatrick Scale (Type 5 & Type 6) population validation data set were as follows: (1) mean bias for systolic BP: 1.81 ± 4.44 mmHg (2) mean bias of diastolic BP: -0.90 ± 5.13 mmHg (3) PR accuracy: 0.175 beats/min.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Age (51-70 years) population validation data set were as follows: (1) mean bias for systolic BP: 1.53 ± 4.04 mmHg and (2) mean bias of diastolic BP: 2.13 ± 6.50 mmHg.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the BMI (Grade I & II) population validation data set were as follows: (1) mean bias for systolic BP: 1.11 ± 4.55 mmHg and (2) mean bias of diastolic BP: 1.36 ± 4.87 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

5.9 Conclusion

The Accurate 24 BPM is as safe and effective as the predicate devices. The Accurate 24 BPM has the same intended uses and similar indications, technological characteristics, and principles of operation. In addition, the minor technical differences between the Accurate 24 BPM and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Accurate 24 BPM is as safe and as effective as the predicate. Thus, the Accurate 24 BPM is substantially equivalent.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-June 9 2023, Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

Here is the fourth email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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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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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)*
K222658

Device Name
Accurate 24 Non-invasive blood pressure monitor

Indications for Use *(Describe)*
The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

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

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Development Environment Description

Document Number: (b)(4)

Version: (b)(4)

2021/07/05

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) *Date* 2021-07-05

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Document name: Accurate 24 BPM Measurement

Specification Test Report

Document Number: (b)(4)

Presented by
Falcao Chang

Approved By (b)(6)
Kuan Jen, Wang (General Manager)

Date 2023-04-11

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024



K222658
Accurate Meditech Inc.
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Contact Name: Wang Jen

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 K222658 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 K222658 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" issued

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

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on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

(b)(4)

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

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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.

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- 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 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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

Here is the sixth email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

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Duplex Utilization of Radial Artery Imaging

30

Leon Salem, Jorge Rey, Sean P. Roddy, and R. Clement Darling III

Abstract

Radial artery duplex ultrasound is used in different clinical situations. It has been used to document changes in the radial artery in a variety of systemic diseases, such as hypertension, end-stage renal disease, and coronary artery disease. Radial artery duplex is used for mapping of the radial artery prior to harvesting for coronary artery bypass grafting and in conjunction with forearm muscle flaps. This is important in order to assess suitability as a conduit, as well as to minimize the risk of hand ischemia after harvesting. Radial artery duplex has been used to assess suitability for transradial coronary interventions and to evaluate the impact of cannulation of the radial artery. Arterial mapping prior to construction of a radiocephalic arteriovenous fistula has been used in order to identify factors associated with failure. The protocol for radial artery duplex is described.

(b)(4)

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

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Human Factors & Usability Engineering Report

Document Number: (b)(4)
Version: (b)(4)
2022/08/31

Presented by
Stanley Wang / General Manager

Approved By (b)(6) *Date* 2022-08-31

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail: info @accurate-meditech.com

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

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Hi Meaghan,

Thank you for the quick review. We think we can have a full response by Monday.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@fda.hhs.gov

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received: *Here*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) ; k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) ; k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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safe.

Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

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

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(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2567
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: June 20, 2023

Reviewer: Meaghan Erlewein

510(k)# K222658/S003 Subject: Traditional

Applicant: Accurate Meditech Inc.	**Device Trade Name:** Accurate 24 Non-invasive blood pressure monitor
Contact Name: Wang Jen	**Contact Title:** General Manager
Correspondent Firm: Accurate Meditech Inc.	**Phone:** 886 (2) 299-91196 **Email:** stanley@accurate-meditech.com
Received Date: May 15, 2023	**Due Date:** June 21, 2023
Pro Code(s): DXN **Class:** II **Reg #:** 870.1130	**Reg Name:** Noninvasive Blood Pressure Measurement System

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K190792	DQA, DXN, DRG	Bb-613wp	BioBeat Technologies Ltd.

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Digital Signature Concurrence Table (Doc ID: 04500.15.00)	
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.	
Reviewer Sign-Off	

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

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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Combining Local PWV and Quantified Arterial Changes for Calibration-Free Cuffless Blood Pressure Estimation: A Clinical Validation

Cheng-Yan Guo, Chi-Hung Huang, Chia-Chi Chang, Kuan-Jen Wang, and Tung-Li Hsieh, *Member, IEEE*

***Abstract*—This study proposes a novel calibration-free cuffless blood pressure monitor (BPM). Unlike the cuffless BPM that requires timing correction with the traditional BPM, the calibration-free cuffless BPM can directly estimate the arterial blood pressure (BP) based on the hemodynamics mathematical model. Our proposed device integrates a pair of piezoelectric ceramics as pressure sensors to sense the pressure wave in the radial artery. It calculates the local pulse wave velocity (PWV) with our waveform detection algorithm of our proposed one. A photoplethysmogram (PPG) probe is set between the pair of pressure wave sensors. This PPG probe is used to monitor the radial artery's PPG intensity ratio (PIR). We design PPG signal processing algorithms to quantify the PIR. We recruited 129 participants for the BP monitoring experiment. Compared with the reference sphygmomanometer, the error mean ± standard deviations (STDs) systolic BP (SBP) was 2.1 ± 3.4, and the correlation r-value was 0.97. The diastolic BP (DBP) was 0.8 ± 4.2, the correlation r-value was 0.90, and $p < 0.05$ is taken as statistically significant. A new type of wearable continuous calibration-free BPM can replace the situation that requires the use of traditional ambulatory BPM and reduce patient discomfort. Our proposed BP measurement passed all ANSI/AAMI/ISO 81060-2:20181_5.2.4.1.2 data analysis criterion 1 and 2 standard requirements.**



***Index Terms*— Blood pressure monitor (BPM), photoplethysmogram (PPG) intensity ratio, photoplethysmogram, pulse wave velocity (PWV), systolic blood pressure (SBP).**

I. Introduction

A CUFFLESS BPM is a BPM without an occluding cuff [1]. The difference between cuffless BPM and traditional BPM is that it does not need to pressurize the patient's arteries, reducing the discomfort caused by the procedure. Techniques used in this field include measuring physical parameters with electrocardiogram (ECG) and photoplethysmogram (PPG), phonocardiographic sensors, elastic modulus, dimensions, and stiffness of the intervening vessels, and establishing mathematical models to estimate blood pressure (BP) according to the sensor technology of choice. Ambulatory BP monitoring (ABPM) is the current gold standard for determining changes in an individual's BP and for determining hypertension [2]. Clinically, ABPM is valuable for controlling hypertension because it can better assess BP in patients with underlying hypertension affected by the white-coat effect [3]. However, patients wearing ABPM suffer from sleep disturbance as well as pain and skin irritation [4], [5]. Since cuffless BPM has no pressure cuff, it can greatly reduce the side effects and the interference of daily life and rest for patients using a traditional ABPM. Current cuffless BPMs [6] use ECG and PPG sensors to measure the pulse arrival time (PAT), convert it to pulse wave velocity (PWV), and then regress the measured PWV and the BP measured by the reference sphygmomanometer to get the correction coefficient [7]. However, studies have shown that PAT is affected by the pre-ejection period (PEP) [8], [9], meaning that PAT cannot accurately estimate PWV and, thus, BP. Moreover, in the current cuffless BPM correction procedure, the correction frequency needs to

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Cheng-Yan Guo and Kuan-Jen Wang are with Accurate Meditech Inc., New Taipei City 241406, Taiwan (e-mail: r04458006@ntu.edu.tw; stanley@accurate-meditech.com).

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Chia-Chi Chang is with Advanced Micro Devices Inc., Hsinchu 300052, Taiwan (e-mail: tammy.chang@amd.com).

Tung-Li Hsieh is with the Department of Electronic Engineering, National Kaohsiung University of Science and Technology, Sanmin, Kaohsiung City 807618, Taiwan (e-mail: tunglihsieh@gmail.com).

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be determined according to the technical details of different cuffless BPMs [10], and patients still cannot be exempted from the use of a traditional BPM. Even if the regression model is modified to a more complex machine learning model, using various physiological signal characteristics and demographics (e.g., age and sex) as parameters, and matching different hyperparameters to predict BP, it is unclear how much of the attained BP measurement accuracy, especially of the calibration-free device, is due to the actual hemodynamic measurement [11]. The Moens–Korteweg (MK) equation [12] in hemodynamics describes the relationship between PWV and BP, in which the arterial parameters must be considered. The characteristics of arterial hemodynamics differ between individuals, and only considering the correlation between PWV and BP would produce inaccurate BP measurements. To accurately estimate BP, calibration-free cuffless BPMs should not only be able to measure PWV accurately but also be able to monitor arterial distension. Since changes in arterial diameter (ΔD) correlate with pulse pressure (PP) [13], changes in arterial diameter can be quantified using the PPG intensity ratio (PIR) method. Therefore, this study proposes a calibration-free cuffless BPM measurement method using two piezoelectric sensors to measure the local PWV of the wrist radial artery combined with the physiological characteristics of arterial changes measured by the PPG probe. For this, we used a mathematical model based on hemodynamics to correlate PIR with arterial changes. This approach could integrate the sensor into a wearable device, affording more comfort to patients who require a traditional ABPM for long-term BP monitoring.

II. Our Contribution

We propose and implement a calibration-free cuffless BPM measurement method that uses a pair of piezoelectric sensors to measure the patient's pulse transit time (PTT) and convert it to local PWV. Also, we use a PPG sensor to detect the patient's PIR signals and quantify artery parameters using a hemodynamics-based mathematical model. Therefore, we have designed a wearable device that integrates these two sensors to achieve calibration-free cuffless BP monitoring. We verified it with ANSI/AAMI/ISO 81060-2, and our proposed BP measurement passed all ANSI/AAMI/ISO 81060-2:20181_5.2.4.1.2 data analysis criterion 1 and 2 standard requirements. This study provides patients with a solution to replace the traditional ABPM monitoring scenario, reducing patients' adverse reactions when BP is monitored for an extended period.

III. Calibration-Free Method of the Cuffless BPM

Our proposed method uses a pair of piezoelectric sensors and a PPG sensor set between them. These two types of sensors measure the pressure waveform and PIR of the patient's radial artery integrated with a PPG sensor, as shown in Fig. 1. The piezoelectric ceramic is rigid, and applying only a small deflection of the material is required to return a good signal. This makes the sensors very robust and tolerant of overpressure conditions and also means that they respond rapidly to changes in pressure [14]. Using a piezoelectric



Fig. 1. Piezoelectric sensor and PPG sensor are integrated.

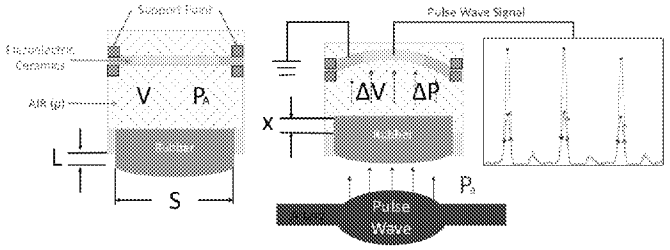


Fig. 2. Mechanical model of the piezoelectric sensor.

sensor, rather than a PPG sensor, to measure PWV avoids the need to consider the different characteristics of the PPG signal and the difference in PWV measured by the derivative method [15]. Therefore, PPG is used to measure the patient's PIR in this study and is related to arterial parameters and PP through a mathematical model. Setting the PPG probe between the two piezoelectric sensors ensures that when both piezoelectric sensors sense the pressure of the pulse wave, the PPG sensor is also above the radial artery and can receive the artery expansion signal.

A. Local PWV Measurement

In previous studies, we developed a piezoelectric sensor and algorithm [16] that can be used for PWV detection. Fig. 2 shows the mechanical model of the piezoelectric sensor. The volume change ΔV is generated when the pulse wave is transmitted via the induction period and skin motion. The internal pressure change ΔP of the sensor is the sum of the pressure before pressurization P_A and the pulse wave pressure P_a. The mass that pushes the rubber to compress the air when the artery expands is S $\times$ L multiplied by the air density. Note that the air density is not constant during the pulsed cycle. According to Newton's law, we can find the force of the piezoelectric ceramic. The piezoelectric signal generated by the piezoelectric ceramic is the pulse wave.

Fig. 3 shows the pulse wave sensor's analog front end (AFE). Our proposed device uses two pulse wave sensors and AFE. The output of the AFE is sampled by the 12-bit analog-to-digital converter (ADC) integrated into the microcontroller unit (MCU) of the ARM Cortex-M4 architecture. The sampling rate is 10 kHz, making the resolution of PTT in 0.1 ms. The parasitic capacitance of the piezoelectric ceramic is 8000 pF (at 120 Hz) [17]. The AFE can amplify the pulse wave signal, measured by the piezoelectric sensor, and filter it. Our filter design uses the second-order Sallen–Key architecture [18]. The cutoff frequencies of high-pass filters (HPFs) and low-pass filters (LPFs) are 0.58 and 10.6 Hz, respectively. The 12-bit ADC inside the MCU samples the pulse wave output

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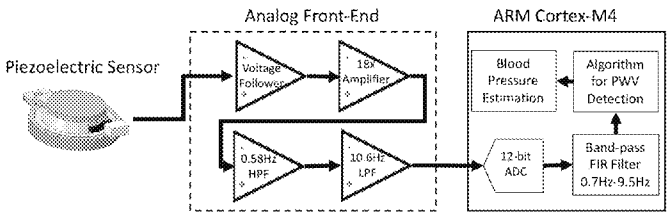


Fig. 3. Pulse wave sensor's AFE.

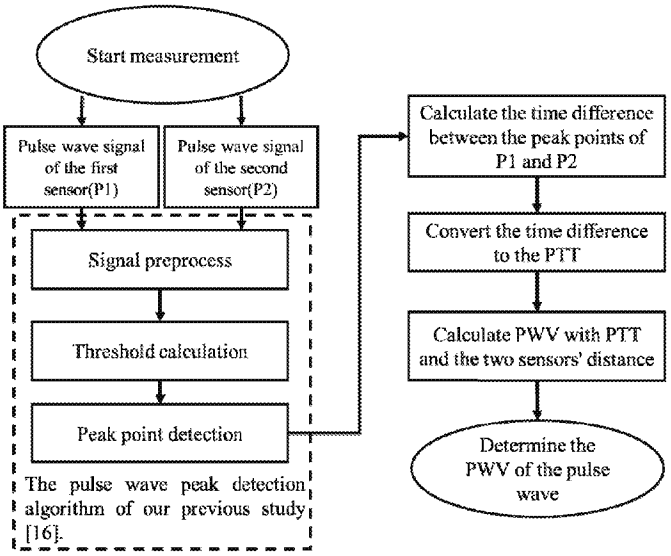


Fig. 4. Flowchart of the algorithm for determining PWV.

by the AFE at a sampling rate of 10 000 Hz. Through the finite impulse response (FIR) digital signal filtering algorithm running on the processor, the two-channel pulse wave sensor of the AFE output signal is filtered. Our design uses a bandpass filter of order 128 and uses the Kaiser window function, with the cutoff frequency set from 0.7 to 9.5 Hz [19], [20]. Based on the dynamic PWV detection algorithm developed in our past research, the PWV of the patient can be well detected. The algorithm can detect the feature points of the pulse wave and calculate the peak-to-peak value of the pulse wave signal at two different positions on the radial artery. As shown in the flowchart of Fig. 4, to determine the PWV between two pulse wave peaks, the time difference between the two pulse wave peaks at different positions needs to be converted to PTT after it can calculate PWV with PTT and two sensors' distance [21].

B. PPG Signal Process and PIR Estimate

When the pulse wave sensor detects the arterial pulse wave and can calculate the PWV, showing that the device is placed on the arterial segment of the human body, the PPG sensor is activated to sense the optical signal of arterial expansion. The PPG sensor is the MAX30101 integrated circuit produced by Analog Devices Inc. (ADI), which is a diffuse reflectance spectroscopy (DRS) sensor with three wavelengths of excitation light [22], [23]. The distance between the light-emitting diode (LED) and the photodiode (PD) is 3 mm. We set the ADC sampling rate of the PD to 100 Hz and the resolution to 18 bits. According to the Beer–Lambert law, the light path is arc-shaped. The photons start from the skin surface, penetrate deep into the tissue, before returning to the PD surface, and

Algorithm 1 I_H and I_L Detection Algorithm for PPG Signal

Inputs: PPG{index, value}, and gradient
is_I_H, is_I_L:= **FALSE**
if value > local_maxima **then**
local_maxima:= PPG{index, value}
end if
if value < local_minimal **then**
local_ minimal:= PPG{index, value}
end if
if is_emission == **TRUE** and x < local_maxima – gradient **then**
is_emission:= **FALSE,** is_I_H:= **TRUE**
falling:= PPG{index, value}
local_minimal:= local_maxima
result:= {is_ I_H, local_maxima}
end if
if is_emission == **FALSE** and x > local_minimal + gradient **then**
is_emission:= **TRUE,** is_ I_L:= **TRUE**
rising:= PPG{index, value}
local_maxima:= local_minimal
result:= {is_ I_L, local_minimal}
end if
if is_ I_H != **TRUE** and is_ I_L != **TRUE then**
result:= {-1, the current PPG signal is not a I_H or I_L }
end if
Outputs: result

are converted to an electron signal [24]. The path depth of photons in tissue depends on the wavelength of light. We chose infrared (IR) light with a wavelength of 880 nm as our PPG signal for estimating arterial changes. IR light can penetrate deeper into the tissue than visible wavelength light and can therefore obtain more tissue optical information [25].

Using PIR to estimate changes in arterial diameter is a feasible method [26]. However, it is necessary to filter the PPG signal to quantify the PIR of arterial changes accurately. Also, we would need to design a feature recognition algorithm based on dynamic thresholds to detect the minimal level and highest level of the ac signal of the PPG. To filter the PPG signal, we use the FIR filter algorithm. First, an HPF filters the PPG signal, which is then filtered a second time by an LPF. We set the cutoff frequency of low-pass filtering to 7.5 Hz and the cutoff frequency of high-pass filtering to 0.75 Hz.

The PPG signal after FIR filtering can use the feature detection algorithm, based on the dynamic threshold, to detect the minimal level I_L and highest level I_H of the PPG signal. We use the window size of half the sampling rate to calculate the dynamic threshold. When the window size is shorter, the response speed of the dynamic threshold is faster, and it is more sensitive to the change rate of the PPG signal. Equation (1) is the calculation method of the dynamic threshold, in which (2) is the formula of covariance (CV), which is used to calculate the previous rate of change of the signal intensity. Before calculating the CV, the average value of the signal needs to be determined by (3). The root mean square (rms) is the amplitude level of the signal, see (4). The gain can be adjusted manually according to the performance of different sensors, and the gain level of the dynamic threshold is set to 1 in this study.

The dynamic threshold of the current PPG signal is determined through (1). This threshold can be input into the

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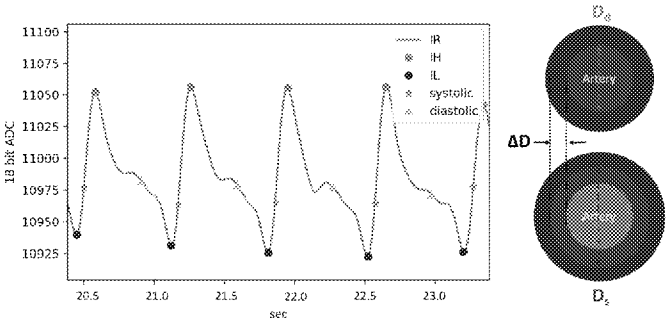


Fig. 5. PPG signals of different amplitudes according to the dynamic threshold, and the labeling of the feature points.

feature detection algorithm, which can dynamically identify the features in the PPG signal. The pseudocode of the feature detection algorithm proposed in this study is Algorithm 1 [27]. This algorithm can detect PPG signals of different amplitudes according to the dynamic threshold and label the feature points, as shown in Fig. 5, including the PPG signal's systole and diastole start points as well as the local maximum I_H and the local minimum I_L of the PPG signal. During the diastole phase, the arterial diameter is at its minimum level D_d, the absorption of light by the blood volume in the artery decreases, and the diffuse light intensity is at its highest level I_H. Conversely, during the systole phase, as the diameter of the artery increases to D_s, the absorption of light due to higher blood volume in the artery increases, causing diffuse light intensity to decrease to the minimum level I_L. ΔD is the change in arterial diameter from diastole to systole during cardiac cycles. It should be noted that the definition of the relationship between the PPG signal and the diameter of the artery must differ according to the design of the amplifier for the PD signal of the PPG sensor, specifically whether it is a noninverting amplifier or an inverting amplifier.

To make the IR light penetrate as deep as possible into the tissue and to improve the signal-to-noise ratio (SNR) of the PPG signal, when measuring arterial changes, the system will detect whether I_H is close to the saturation current 2^{18} measured by the ADC. When it is not close to the saturation current, the system will continue to increase the current of the LED constant current source for the PPG sensor until it reaches the required constant current source. Then, the last unsaturated current parameter will be used as the current setting of the LED constant current source for the PPG sensor

$$\text{gradient} = \text{RMS} \cdot \frac{\text{CV}}{100} \cdot \text{gain} \tag{1}$$

$$\text{CV} = \frac{\left(\sum_{k=0}^{N-1} x_k - \text{mean}\right)^2}{N} \tag{2}$$

$$\text{mean} = \frac{\sum_{k=0}^{N-1} x_k}{N} \tag{3}$$

$$\text{RMS} = \sqrt{\frac{\sum_{k=0}^{N-1} x_k^2}{N}}. \tag{4}$$

C. PIR-Arterial Change Estimation Based on Hemodynamic Model

The feature detection algorithm can accurately determine I_H and I_L of the PPG signal, and the PIR signal of the artery can be estimated. However, to build a correlation model of PIR-arterial diameter and PIR-PP, the arterial parameter ΔD and arterial PP should be considered as hemodynamic parameters, and the mathematical model must be based on hemodynamics.

In a study on the PPG analysis of arteries wrapped under tissue by the Monte Carlo simulation [28], arteries of different sizes had different rates of change for the PPG ac signal, and the amount of photons absorbed depended on blood volume. Blood volume is directly related to arterial size, so larger diameter arteries have higher absorption, which can be quantified and used to determine the arterial size, see (5), by normalizing the ac and dc signals of the PPG signal. The artery is under 1 cm of tissue. There is, therefore, an obvious relationship between the diameter of the artery and the normalized PPG signal. Furthermore, the blood vessel phantom experiment was used to verify that the variation of the artery and the arterial diameter was proportional to the rate of change of the signal, which was consistent with the results of the Monte Carlo simulation. However, in practice, the dynamic removal of the dc signal of the PPG signal is not easy [29], affecting the ratio of the normalized signal and causing a deviation. Therefore, a more accurate PIR method is used to normalize the PPG.

The relationship between arterial diameter change versus I_H and I_L can be expressed as (6) and (7) by the Beer–Lambert law [30]. The arterial expansion and blood volume changes produced by the cardiac cycle allow the DRS sensor to receive an ac signal. The dc signal is a tissue component, including the optical tissue information of the subject's epidermis, muscle, fat, and arterial tissue. $\alpha_{\text{DC}} = \varepsilon \times \text{c}$, where ε is the absorbance coefficient of human tissue and c is the material concentration of tissue and blood. d_{DC} is the dc component of the optical path of photons in human tissue, including the optical properties of refraction and reflection produced by different layers of tissue media. The product of the two contributes to the dc signal source of the tissue's diffuse reflectance spectrum. D_s and D_d are the systolic and diastolic states of the artery with the progression of the cardiac cycle, respectively. Through (8), I_H and I_L can be expressed as a function of the diffuse reflection light signal for arterial expansion, as the ratio of I_H to I_L is the PIR signal of the DRS sensor. Therefore, we can express the systole diameter D_s and the diastole diameter D_d as formula (9) [31], which means that the PIR changes with the artery diameter change of the cardiac cycle. α is a constant related to the optical absorption coefficients in the light path. The subject's arterial expansion volume can be estimated by modeling the correlation function between the normalized PIR signal and the arterial expansion volume ΔD

$$PPG_{\text{norm}} = \frac{\ln(\text{AC}_\lambda)}{\ln(\text{DC}_\lambda)} \tag{5}$$

$$I_L = I_0 \cdot e^{-\alpha_{\text{DC}} \cdot d_{\text{DC}}} \cdot e^{-\alpha \cdot D_s} \tag{6}$$

$$I_H = I_0 \cdot e^{-\alpha_{\text{DC}} \cdot d_{\text{DC}}} \cdot e^{-\alpha \cdot D_d} \tag{7}$$

$$\Delta D = D_s - D_d = \frac{\ln\left(\frac{I_H}{I_L}\right)}{\alpha} \tag{8}$$

$$\text{PIR} = \frac{I_H}{I_L} = e^{-\alpha \cdot \pi \cdot D \cdot (D_s - D_d)}. \tag{9}$$

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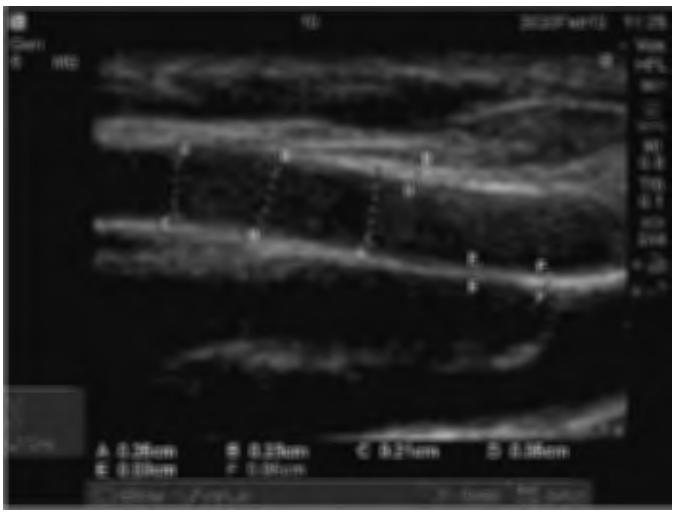


Fig. 6. Labels A, B, and C are artery diameters. Labels D, E, and F are IMT.

The normalized PIR signal was obtained and used to build a PIR-arterial diameter correlation model. We used an ultrasonic imaging device (M-turbo ultrasound system from Sonosite Inc.) to obtain the radial artery's diastolic diameter and record the normalized PIR signal for modeling the PIR-arterial diameter correlation model. In previous studies, the arterial diameter D and the instantaneous diastolic arterial diameter D_d differed by about 10% in each cardiac cycle, so it can be assumed that the two are approximately equivalent [32]. The MK equation of the hemodynamics model assumes an ideal circular and straight cylinder. Therefore, we selected different measurement points on the radial artery segment and averaged the artery diameter and wall thickness of the measurement points as the arterial parameters for building a correlation model to estimate the arterial expansion ΔD and arterial diameter D, as shown in Fig. 6. We used an ultrasound probe to measure and annotate the diameter and wall thickness of the radial artery [33]. We measured the ultrasound probe pressure-free on the surface between 2 and 6 cm above the styloid process [34] and referenced the method used to assess the radial artery in systemic disease to measure the arterial diameter and intima thickness [35] (the method for assessing the radial artery in systemic disease). Previous studies have shown that the arterial change rate is correlated with PP [36]. The PIR-PP correlation model of this study uses the difference between the values of systolic BP (SBP) and diastolic BP (DBP), measured by aneroid sphygmomanometer to reference PP, and is precomputed with the normalized PIR signal.

D. Calibration-Free Cuffless BP Measurement

During a cardiac cycle, the physiological changes of the radial artery can be described as a mathematical model composed of arterial dimensions, stiffness indices, and PTT. The model can quantify the elastic modulus of the artery and describe the compliance of the arterial segment. The hemodynamics theoretical model of the physiological characteristics can be extended and applied to cardiovascular system research [37]. The relationship between arterial pressure P and arterial diameter D can be expressed as (10), where P_d and D_d are the end-diastolic pressure and diameter, respectively, and β constant is the stiffness parameter usually related to the elasticity coefficient of human arteries. Equation (11) shows that the change of arterial pressure difference and arterial diameter are the primary variables that determine stiffness. Therefore, we can calculate the variation of the arterial diameter through the differential equation of the arterial pressure in (12), for the arterial diameter. Since the arterial diameter D and the instantaneous diastolic arterial diameter D_d differ by about 10% in each cardiac cycle, we can replace the arterial diameter term with the arterial cross-sectional area dA, as in (13), where the cross-sectional area A of the artery is calculated as $A = (\pi/4)\ D^2$ [38]. According to the Bramwell–Hill (BH) model [39], pressure pulses in the arteries produce local PWV. The local PWV can be expressed as intra-arterial pressure changes, and the PP is a function of the change in the arterial cross-sectional area, as in the modified BH model of (14), where ρ is the blood density. This study used the density of healthy human whole blood at 1.06 g/mL to calculate the parameter [40]. Equations (13) and (14) can be combined to obtain (15), which determines the value of the arterial local PWV in a cardiac cycle, dependent on the cross-sectional area gradient and the intra-arterial pressure level

$$\ln\left(\frac{P}{P_d}\right) = \beta\frac{D - D_d}{D - d} \tag{10}$$

$$\beta = \frac{\ln\left(\frac{P}{P_d}\right)}{\frac{D-D_d}{D_d}} \tag{11}$$

$$\frac{dP}{dD} = \frac{P\beta}{D_d} \tag{12}$$

$$\frac{dP}{dA} = \frac{2P\beta}{\pi D \cdot D_d} \tag{13}$$

$$\mathrm{PWV}^2 = \frac{A}{\rho}\frac{dP}{dA} \tag{14}$$

$$P = \frac{2 \cdot \rho \cdot \mathrm{PWV}^2 \cdot D_d}{\beta D}. \tag{15}$$

The BH model relates PWV to arterial compliance dA/dP, blood density ρ, and arterial cross-sectional area A, derived from the MK equation [41]. The MK equation is based on hemodynamics, such as with (16), (17), and (19). The MK equation describes the relationship between PWV and BP, where D is the diameter of the radial artery and h is the wall thickness of the radial artery, otherwise called intima-media thickness (IMT), ρ is the average density of whole blood, PTT is the pulse wave time difference measured by the relative distance L between the sensors, E is Young's modulus, P is the pressure, and E_0 and γ are coefficients with values of 1428.7 and 0.031, respectively [42]. Although E_0 and γ depend on the stiffness of the radial artery and vary between individuals [43], this study used mean values from previous clinical studies, assuming that E_0, γ, and ρ are constants, for validation. We combined (16) and (17) to obtain (18), where P in the MK equation approximates mean arterial pressure (MAP) [44]. So far, combining the PIR-arterial diameter correlation model and the PIR-PP correlation model, we can estimate the subject's MAP, PP, ΔD, and arterial diameter D.

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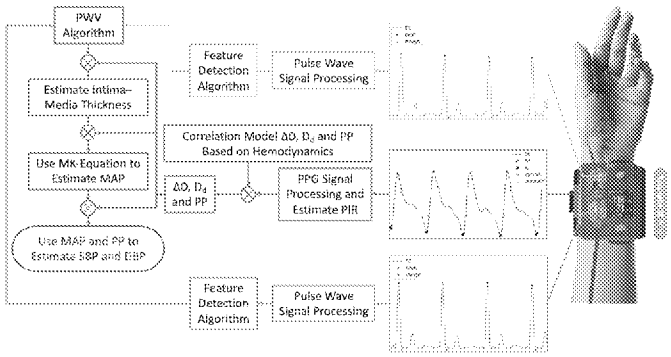


Fig. 7. Calculation flow of the calibration-free cuffless BPM.

Also, we can use the MK equation to enumerate the possible radial artery wall thickness h by assuming a reasonable range for MAP and using the recalculated MAP to track SBP and DBP with PP

$$\mathrm{PWV} = \sqrt{\frac{E_{\mathrm{inc}} \cdot h}{D \cdot \rho}} \tag{16}$$

$$E_{\mathrm{inc}} = E_0 \cdot \exp^{\xi \cdot P} \tag{17}$$

$$P = \frac{\ln\left(\frac{\mathrm{PWV}^2 \cdot \rho \cdot D}{h \cdot E_0}\right)}{\xi} \tag{18}$$

$$\mathrm{PWV} = \frac{L}{\mathrm{PTT}}. \tag{19}$$

Fig. 7 shows the calculation flow of the calibration-free cuffless BPM proposed in this study with the aforementioned theoretical model. First, the sensor detects the participant's pulse wave and PIR signal at the same time. The participant's local PWV can be calculated from the two pulse wave signals through our proposed algorithm, and the PIR can be measured using the DRS sensor. The normalized PIR signal is input into the prebuild PIR-arterial diameter and PIR-PP correlation models and a participant's estimated values of PP, ΔD, and D_d can be obtained. Since the wall thickness h of the participant's radial artery cannot be measured and estimated by the diffuse reflection light sensor, we refer to the known clinical research literature, assuming that the human MAP has a reasonable range under normal conditions [45]. Therefore, the MAP calculated by the MK equation has upper and lower bounds. Through the MK equation, the arterial wall thickness can be increased in 0.01 mm increments according to the arterial characteristics measured for different individuals. The possible range of the participant's arterial wall thickness can be enumerated, and the average value can be taken as the individual wall thickness parameter h. As shown in the enumeration algorithm of Algorithm 2, with h ranging from 0.01 to 1 mm in the MK equation calculation of MAP, if MAP exceeds the reasonable range, the value of the wall thickness must be unreasonable and vice versa. Therefore, the wall thickness value is considered reasonable if the MAP is within the reasonable MAP range. Since the MK equation is a nonlinear function, this enumeration can find a reasonable range of wall thickness according to the parameters of different individuals. This study chose to average this reasonable range as the individual radial artery wall thickness h. Finally, our proposed calibration-free cuffless BPM will extend the MAP and PP calculated by the MK equation to SBP and DBP with the formula of (20) [46]. The coefficient k in this study was set according to the clinical results and here is 0.76

Algorithm 2 Use the MK Equation to Enumerate Arterial Wall Thickness's Upper and Lower Bounds

Inputs: PWV, Diameter, E_0, and ζ
wall_thickness:= 0.01
possible_thickness[0...n]
index:= 0
For wall_thickness < maximum_ wall_thickness
P:= **MK_Equaiton**(PWV, Diameter, E_0,ζ)
if P > MAP_Lower and P < MAP_Upper **then**
possible_thickness[index] = wall_thickness
index:= index + 1
end if
wall_thickness:= wall_thickness + 0.01
end for
result:= (possible_thickness[0] + possible_thickness[index - 1]) / 2
Outputs: result

$$\begin{cases} \mathrm{DBP} = \mathrm{MAP} - k \cdot \mathrm{PP} \\ \mathrm{SBP} = \mathrm{MAP} + (1 - k) \cdot \mathrm{PP}. \end{cases} \tag{20}$$

IV. Clinical Study and Result

This study was approved by the Institutional Review Board (IRB) of the Cathay General Hospital, Taipei, Taiwan, and conducted according to the Declaration of Helsinki ethical principles for medical research on human participants. Each participant signed an informed consent form as defined by the IRB. The study protocol is retrospectively registered with the Taiwan Food and Drug Administration (IRB protocol number: CGH-P108003). In the clinical analysis in this section, our proposed calibration-free cuffless BPM is called Accurate24 BPM, and the sphygmomanometer for reference is called SM. The participants were equipped with Accurate24 BPM on the left wrist, sitting position with the wrist at heart level to remove hydrostatic pressure differences. A sphygmomanometer cuff of appropriate size was positioned on the participant's left upper arm at heart level. Study participants were comfortably seated with their backs and arms supported.

A. Study Protocol and Population

This comparative study followed ANSI/AAMI/ISO 81060-2:20181 [47]. Male and female volunteers totaling 129 subjects were included. The algorithm passed Criterion 2. The distribution of SBP and DBP is shown in Fig. 8(a) and (b), respectively.

BP measurements were taken by trained observers in stations. The clinical study method stated that observers shall be trained in using the proper methodology for performing a resting BP reading with the SM (reference reading) and an Accurate24 BPM device reading (subject under test) lasting at least 60 s, interchanging the reference and subject devices, with three replications of the process.

All data from a subject were excluded if the following conditions hold.

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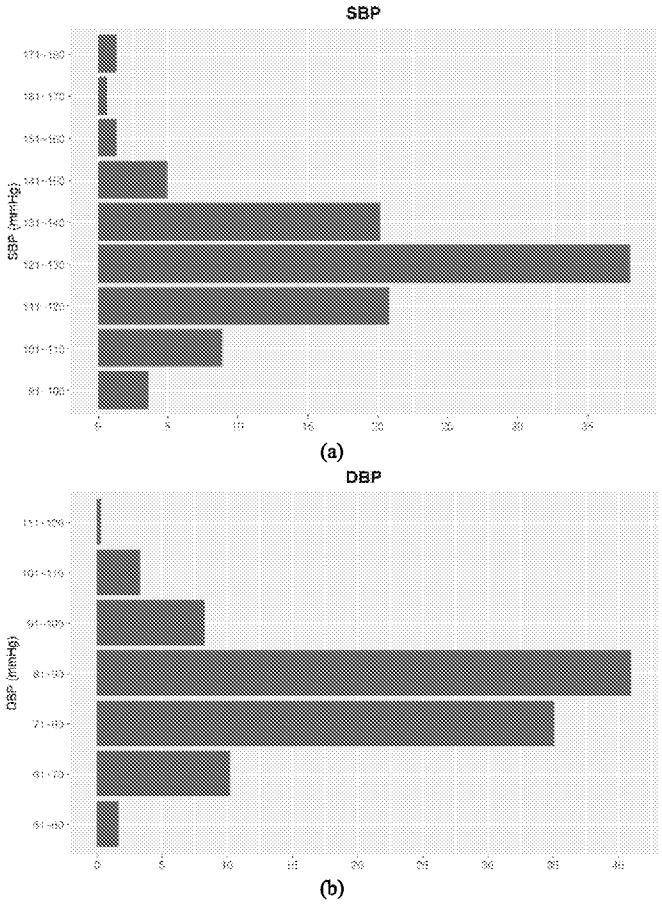


Fig. 8. Distribution of (a) SBP and (b) DBP.

1) Any two reference SBP values differed by more than 12 mmHg (160 kPa).

2) Any two reference DBP values differed by more than 8 mmHg (107 kPa).

B. Statistical Analysis

In this study, two measurement methods were compared: the novel method in this study (the Accurate24 BPM device) and an established one (a standard Korotkoff manometry device). We aimed to determine whether these two methods could be used interchangeably and whether our novel method could replace the established one.

In this study, the collected data for BP measurements were analyzed for mean, maximum, minimum, median, standard deviation (STD), and confidence values (Tables I and II). If the novel measurement technique agreed sufficiently with the established technique, it would be possible to replace it. Agreement between these techniques was analyzed using the Bland–Altman method, which calculates the mean difference between two methods of measurement (the "bias") and looks at the 95% limit of agreement of the mean difference 2STD. It is expected that the 95% limit includes 95% of differences between the two measurement methods. The presentation of the 95% limits of agreement allows for visual judgment of how well two methods of measurement agree. The smaller the range between these two limits, the better the agreement. Linear correlation is a measure of dependence or association between two random variables. The correlation provides a measure of the degree to which these two variables tend to "move together." The Pearson correlation coefficient is bounded between -1 and 1 making it easy to understand the intensity of the linear dependence between two random variables. The closer the correlation coefficient is to 1, the greater the positive linear dependence between the variables, and the closer it is to -1, the greater the negative linear dependence between them. When the correlation equals zero, the variables do not display any of these two tendencies. The Accurate24 BPM device application was compared to a standard Korotkoff manometry device and the differences between their readings were analyzed as explained in the following.

TABLE I
DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE STUDY PARTICIPANTS

Characteristic	Pass requirements
Subject, n	129
Age, n (%)	
≤ 30 years	18 (14.0)
31-40 years	16 (12.4)
41-50 years	60 (46.5)
51-60 years	23 (17.8)
> 60 years	12 (9.3)
Sex, n (%)	
Male	89 (69.0)
Female	40 (31.0)
Recruitment BP (mmHg)	
SBP	
Mean ± SD	125.5±13.0
Median (Range)	125.7 (92,175)
DBP	
Mean ± SD	80.7±8.7
Median (Range)	81 (59,109)

TABLE II
OBSERVER MEASUREMENT IN EACH RECRUITMENT RANGE

SBP (mmHg)		DBP (mmHg)	
BP pairs, n	302	BP pairs, n	302
Overall		Overall	
Mean ± SD	125.1±13.2	Mean ± SD	80.8±9.4
Median (Range)	125 (92,178)	Median (Range)	81 (55,111)
Low (<130), n (%)	207 (68.5)	Low (<80), n (%)	132 (43.7)
Medium (130-160), n (%)	89 (29.5)	Medium (80-100), n (%)	157 (52.0)
High (>160), n (%)	6 (2.0)	High (>100), n (%)	13 (4.3)
Differences (Ref: SM)		Differences (Ref: SM)	
Mean ± SD	2.1±3.4	Mean ± SD	0.8±4.2
Median (Range)	3 (-10,12)	Median (Range)	2 (-12,10)

C. Result

One hundred twenty-nine subjects had valid data sets and were included in the analyses, of which there were 40 females and 89 males. The Pearson correlation and Bland–Altman

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TABLE III
PEARSON CORRELATION AND BLAND–ALTMAN ANALYSIS

	SBP (mmHg)	DBP (mmHg)
Correlation (ref: SM)		
R^2	0.94	0.81
R	0.97*	0.90*
Bland-Altman analysis		
Requirements, (Means±2SD)	(-4.51,8.81)	(-7.43,8.94)
Achieved, n (%)	281 (93.05)	280 (92.72)

*P *value* ≤ 0.05.

TABLE IV
VALIDATION STUDY RESULTS

	Pass requirements	Achieved	
		SBP	DBP
Criterion 1			
BP pairs:302			
Means (*mmHg*)	≤ 5	2.15	0.75
SD (*mmHg*)	≤ 8	3.40	4.18
Results		pass	pass
Criterion 2			
Subject:129			
SD (*mmHg*)	≤ 6.58/6.89	3.21	3.97
Results		pass	pass
Results		pass	

ANSI/AAMI/ISO 81060-2:2018_5.2.4.1.2 Data analysis Criterion 1 & 2

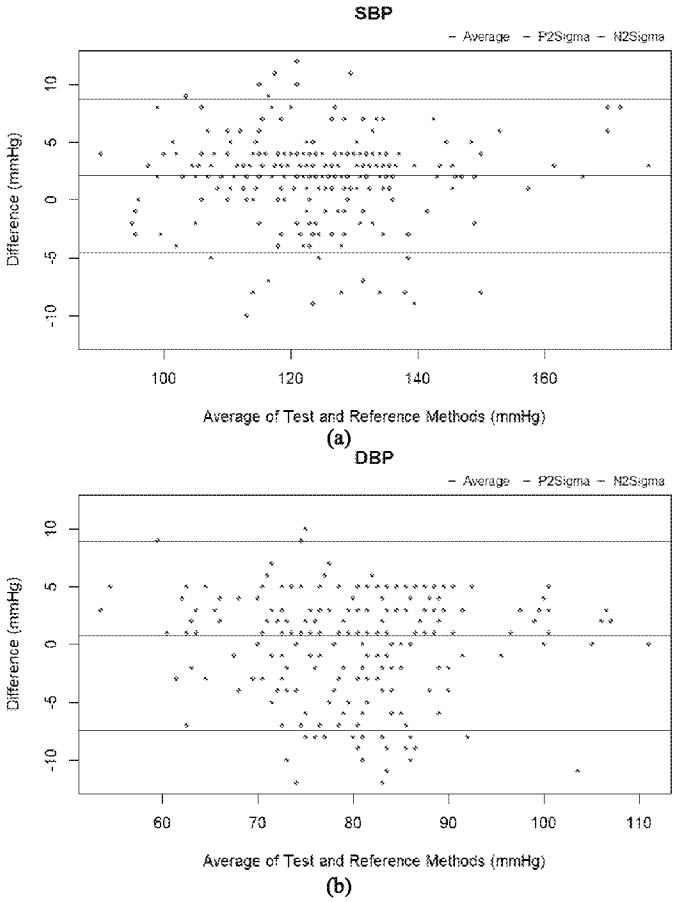


Fig. 9. Bland–Altman plot for (a) SBP and (b) DBP.

analysis between Accurate24 BPM and SM are shown in Table III.

For the SBP analysis, we found that $R^2 = 0.94$, which means that $R = 0.97$, showing that 97% of the data sets are, or are very close to, equal. For the DBP analysis, we found that $R^2 = 0.81$, which means that $R = 0.90$, showing that 90% of the data sets are, or are very close to, equal.

The Mean and SD of the validation study results of criterions 1 and 2 between the reference SM and subject device readings are shown in Table IV.

The ANSI/AAMI/ISO 81060-2:2018 Standard Criterion 1 requires a mean ±SD difference of $\leq 5 \pm 8$ mmHg. The Midmark algorithm clearly passed this criterion. Criterion 2 requires a smaller SD value, using a sliding scale depending on the mean SBP and DBP differences. For SBP, the mean value of 2.15 mmHg gives an upper limit for SD of 6.58, and for the DBP difference of 0.75, the upper limit for SD is 6.89. The algorithm passed criterion 2. The required Bland–Altman plots of SBP and DBP are shown in Fig. 9(a) and (b), respectively.

The Accurate24 BPM device was compared to the gold standard SM device by plotting a visual chart expressing the correlation between their readings in Fig. 10(a) and (b).

Another protocol, from the European Hypertension Society, expresses the data distribution as the percent of readings within 5, 10, and 15 mmHg in comparison to the reference BP values. While the Accurate24 BPM device recorded all values, manometry values were taken periodically as detailed earlier. Thus, we compared the manometer values to the Accurate24 BPM device values recorded at the same time. For Accurate24 BPM measurements according to the international protocol (revision 2010) [48], data are shown in Table V and Fig. 11.

D. Discussion

The data demonstrated that the Accurate24 Noninvasive BP monitor (BPM) for BP measurement passed all ANSI/AAMI/ISO 81060-2:20181_5.2.4.1.2 data analysis criterion 1 and 2 standard requirements. The Accurate24 Noninvasive BPM also surpassed requirements for the European Hypertension Society protocol data analysis for both SBP and DBP. These tests in adults show that the Accurate 24 BPM sensors and applications achieved the required range and were defined as having acceptable error levels by the European international protocol for BP devices, as shown in Table V. For accuracy in ≤5 mmHg, the proportion of Accurate24 BPM in SBP and DBP is 86.8% and 85.8%, respectively, both of which meet the European international protocol (73%). For accuracy in ≤10 mmHg, the proportion of Accurate24 BPM in SBP and DBP is 99.0% and 98.7%, respectively, both of which meet the European international protocol (87%). For accuracy in ≤15 mmHg, the proportion of Accurate24 BPM in SBP and DBP is 100% and 100%, respectively, both of which meet the European international protocol (96%).

V. LIMITATIONS AND FUTURE WORKS

Although the calibration-free cuffless BPM proposed in this study passed the clinical gold standard, according to the

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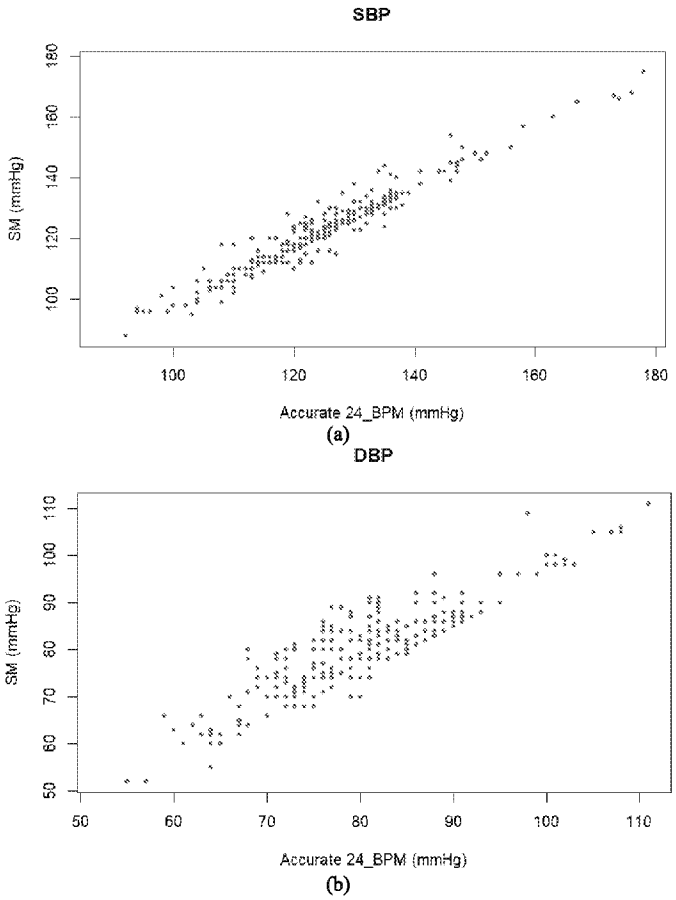


Fig. 10. Scatter plot between Accurate_24 BPM and SM. (a) SBP. (b) DBP.

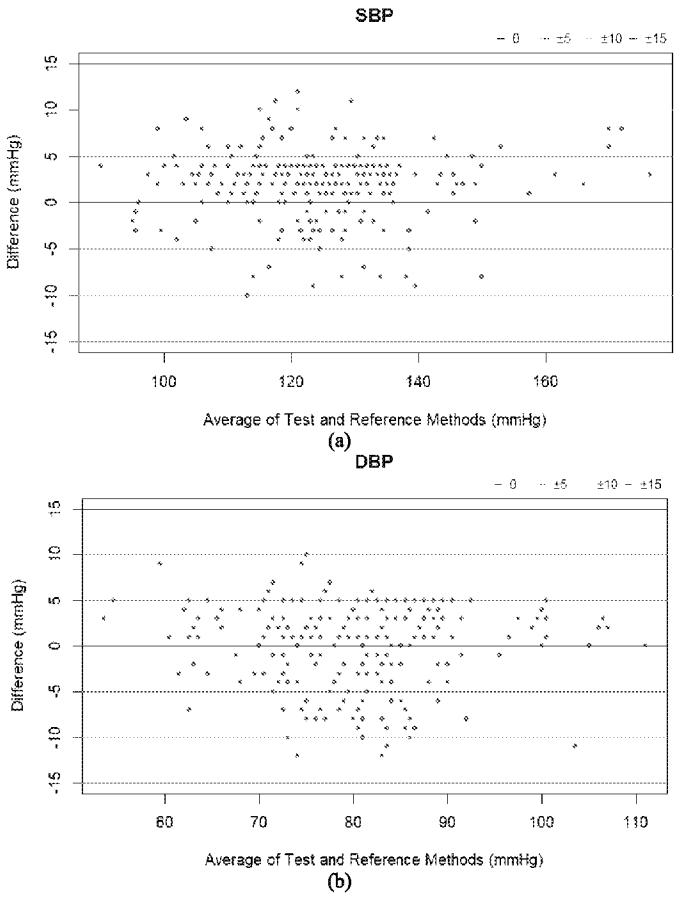


Fig. 11. Accurate24 BPM measurements in relation to the ESH international protocol (revision 2010). (a) SBP. (b) DBP.

TABLE V
VALIDATION STUDY RESULTS RELATING TO THE EHS PROTOCOL IN PERCENTAGE OF DIFFERENCE

Difference	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Required %	73.7%	87.9%	97.0%
Accurate24 BPM			
SBP, n (%)	262 (86.8)	299 (99.0)	302 (100.0)
DBP, n (%)	259 (85.8)	298 (98.7)	302 (100.0)

results, our proposed method still has two points to improve. First, according to the relationship described by the MK equation, the PWV primarily contributes to the result of the MAP calculation. The measurement of the local PWV of the arterial segment is performed over a short distance, resulting in small PTT measurement errors being amplified when converted to local PWV. Therefore, improving the measurement performance of the sensor, such as by increasing the sampling rate and resolution, can effectively reduce the STD value in the clinical results and increasing measurement precision. The application scenarios of beat-to-beat BP estimation will be possible in the future. Second, further research is required for calculating Young's modulus in the MK equation. This coefficient makes the relationship between MAP and PWV nonlinear. Although we calculate the coefficient with data obtained from previous clinical experiments, there are differences in arterial stiffness between individuals in practical applications, which leads to bias in the results of BP estimation. Therefore, finding a feasible technical means to measure the arterial stiffness of subjects noninvasively, and to calculate the nonlinear function of the arterial stiffness for each subject, would reduce the overall BP estimation bias. Normal subjects' arterial blood contains dyshemoglobin, which is a hemoglobin derivative. The two dyshemoglobins that affect tissue oxygenation are methemoglobin (MetHb) and carboxyhemoglobin (COHb), which are usually present in low concentrations in normal subjects in the blood [49]. The main substances that absorb IR light in the blood are oxyhemoglobin and hemoglobin. The absorption ratio of MetHb and COHb is low. However, when the subject is carbon monoxide poisoning or exposed to some chemical, it may increase MetHb and COHb [50]. In this study, using single-wavelength quantitative technology may cause errors, so multiwavelength quantitative technology is a future research direction that can quantify more substances to reduce inaccurate factors.

VI. CONCLUSION

This study proposes a new calibration-free cuffless BPM technique, which uses a pair of high-sensitivity piezoelectric sensors to measure the local PWV, and a DRS sensor to quantify the PIR signal, of the radial artery. With this, we used principles based on hemodynamics and tissue optics to estimate BP. Our proposed calibration-free cuffless BPM has been clinically validated, showing that the technology passed all ANSI/AAMI/ISO 81060-2:20181_5.2.4.1.2 data analysis

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criterion 1 and 2 standard requirements. In the trend of popularization of home medical care in the future, we believe that the sensing technology in this study can be integrated into wearable devices, with measurements based on hemodynamics, making it possible to provide beat-to-beat BP monitoring. This advantage could enable future research on hypertension to shorten the monitoring period from every hour to every minute. The improved performance of BP monitoring technology provides a powerful new tool for research in hypertension.

Acknowledgment

Cheng-Yan Guo, Chi-Hung Huang, Chia-Chi Chang, Tung-Li Hsieh, and Kuan-Jen Wang conceived the presented idea. Chia-Chi Chang and Cheng-Yan Guo developed the theory and performed the computations. Chia-Chi Chang, Tung-Li Hsieh, and Cheng-Yan Guo verified the analytical methods. Chi-Hung Huang and Kuan-Jen Wang encouraged the investigation (a specific aspect) and supervised the findings of this work. All authors discussed the results and contributed to the final manuscript.

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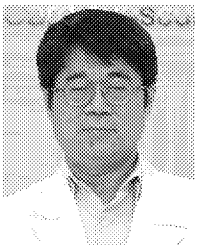
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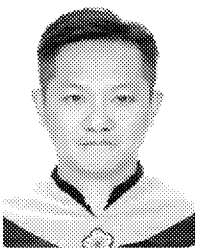


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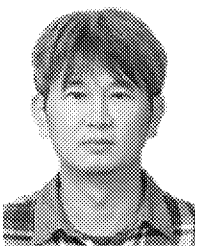
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Comparison of sequentially measured Aloka echo-tracking one-point pulse wave velocity with SphygmoCor carotid–femoral pulse wave velocity

Olga Vriz[1], Caterina Driussi[2], Salvatore La Carrubba[3], Vitantonio Di Bello[4], Concetta Zito[5], Scipione Carerj[5] and Francesco Antonini-Canterin[6]

Abstract

Objectives: Recently, echo-tracking-derived measures of arterial stiffness have been introduced in clinical practice for the assessment of one-point pulse wave velocity. The purpose of this study was to find a relation between carotid–femoral pulse wave velocity and one-point carotid pulse wave velocity, and to find a value of one-point carotid pulse wave velocity that predicts carotid–femoral pulse wave velocity higher than 12 m/s.

Methods: A total of 160 consecutive subjects (112 male/48 female, mean age = 51.5 ± 14.1 years; 96 healthy, 44 hypertensives, 13 with aortic valve disease, and 7 with left ventricular dysfunction) were studied. Carotid–femoral pulse wave velocity was measured with the SphygmoCor system and one-point carotid pulse wave velocity with high-definition echo-tracking system (ProSound Alpha10; Aloka, Tokyo, Japan).

Results: Both carotid–femoral pulse wave velocity and one-point carotid pulse wave velocity correlated significantly with each other ($r = 0.539$, $p < 0.001$) and with age (one-point carotid pulse wave velocity $r = 0.618$, carotid–femoral pulse wave velocity $r = 0.617$, $p < 0.0001$ for both). Median value of carotid–femoral pulse wave velocity (7.2 m/s, 95% confidence interval = 6.2–8.9) was systematically higher than that of one-point carotid pulse wave velocity (5.8 m/s, 95% confidence interval = 5–6.6). The area under the receiver operating characteristic curve was 0.85, identifying the cutoff for one-point pulse wave velocity of 6.65 m/s as the best predictor of carotid–femoral pulse wave velocity more than 12 m/s (sensitivity = 0.818, specificity = 0.819).

Conclusions: One-point carotid pulse wave velocity correlates with carotid–femoral pulse wave velocity, and the cutoff of 6.65 m/s was the best predictor of carotid–femoral pulse wave velocity over 12 m/s.

Keywords

Arterial stiffness, arterial pulse wave velocity, local carotid stiffness, echo-tracking

Introduction

Arterial stiffness has an independent predictive value for cardiovascular events demonstrated in patients with hypertension, diabetes mellitus, and end-stage renal disease, in elderly subjects, and in the general population.[1–5] Recent European guidelines for the management of arterial hypertension and cardiovascular prevention[6,7] recommend measurements of arterial stiffness in hypertensive patients. Pulse wave velocity (PWV) is accepted as the most simple, robust, and reproducible method to determine the regional arterial stiffness, and carotid–femoral PWV is considered the "gold-standard." It has been largely used in epidemiological studies, demonstrating a strong independent predictive value for cardiovascular events. A carotid–femoral PWV higher than 12 m/s is considered an early phenotype of vascular damage.[8] European guidelines[6] recommend also the measurement of carotid intima-media thickness and echocardiographic left ventricular hypertrophy for risk

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stratification, and other local parameters at the carotid level have been proposed as prognostic markers of cardiovascular events.[1,9,10] Therefore, the possibility to collect these data during the same examination using the same ultrasound machine could represent a great cost-saving strategy. However, little information is available about the correlation between the local echo-tracking derived indexes and the carotid–femoral PWV.

The aim of this study was to compare carotid–femoral PWV assessed by SphygmoCor system and one-point carotid PWV obtained by echo-tracking system implemented in a commercially available cardiovascular ultrasound machine (ProSound Alpha10; Aloka, Tokyo, Japan).

Methods

A total of 160 consecutive subjects, who had been referred to the echocardiographic laboratory for cardiovascular risk stratification previously, were examined. Participants with arterial fibrillation and arrhythmias were excluded from the study.

The subjects were introduced in a warm, quiet room and asked to relax for 10–15 min, and then blood pressure (BP) was measured twice with an Omron automated oscillometric device from the right arm at the level of the brachial artery, just before starting the arterial stiffness measurements. Pulse pressure (PP) was calculated as systolic BP − diastolic BP; mean BP was calculated as systolic BP − 1/3 PP.[11]

One-point carotid PWV and the carotid–femoral PWV were measured sequentially by two investigators with a considerable experience in cardiovascular ultrasound.

Carotid local arterial stiffness

Measurements of the local arterial stiffness were obtained at the level of the left common carotid artery, using a high-definition echo-tracking system (implemented in a ProSound Alpha10 echo-machine) that allows assessing local arterial stiffness, deriving the pressure–diameter curve of the artery, and calculating the local PWV from the time delay between the two adjacent distension waveforms. The measurements of stroke changes in diameter and local PP were determined simultaneously.

The relation between arterial pressure, P, and diameter, D, was assumed as $\ln(P/P_0) = \beta(D-D_0)/D_0$, where P_0 and D_0 are the end-diastolic pressure and diameter, and β is a constant called the "stiffness parameter," which is considered to be independent of pressure. Sugawara et al.[12] showed that PWV can be calculated from the stiffness parameter β by the following equation

$$(1/P)(\mathrm{d}P/\mathrm{d}D) = \beta/D_0 \quad (1)$$

The cross-sectional area of the artery (A) was given by $A = \pi D^2/4$. As a consequence, $\mathrm{d}P/\mathrm{d}D = (\pi D/2)(\mathrm{d}P/\mathrm{d}A)$. Substitution of the above equation into equation (1) gives $\mathrm{d}P/\mathrm{d}A = (\beta P/2)/(\pi D D_0/4)$.

Since the change in diameter of the artery during a cardiac cycle is less than 10% under physiological conditions, the reference D_0 may be approximated by the instantaneous diameter D in the above equation. Thus, we can substitute A for $\pi D D_0/4$ in the above equation. Hence

$$\mathrm{d}P/\mathrm{d}A = \beta P/2A \quad (2)$$

According to the general theory of waves in liquid-filled elastic tubes, PWV is given by

$$\mathrm{PWV}^2 = (A/\rho)(\mathrm{d}P/\mathrm{d}A)$$

Substitution of equation (2) into the above equation yields

$$\mathrm{PWV} = (\beta P/2\rho)^{1/2}$$

where ρ is blood density ($\rho = 1050$ kg m^3).

For the evaluation, subjects lay down in the supine position and rested for 10–15 min. The location to be measured was the left common carotid artery at about 2 cm proximal to the bifurcation in order to avoid any influence of the complex flow in the carotid sinus. In the long-axis scanning, optimal images were best achieved by positioning and orienting the probe so that clear and parallel delineation of the intima-media complex at both the anterior and posterior walls could be seen.

The examination was performed using a 7.5 MHz linear probe with the precision of one-sixteenth of the ultrasound wavelength (0.013 mm), and the data were updated at a rate of 1 kHz. Echo-tracking uses the raw radio frequency signals that are based on the video signals. A different ultrasound beam was used for diameter-change and blood velocity measurements.

Figure 1 shows a long-axis view of the common carotid artery (left panel) and ultrasound beam configuration with independent beam steering function. The solid line shows the ultrasound beam direction for velocity measurements, while the dotted line shows the beam for diameter-change measurements. These beams were steered so as to intersect at the center of the range gate. The steering angle of each ultrasound beam could be changed every 5° from −30° to +30°. The echo-tracking gates were manually set at the high echoic line just outside the intima-media complex (near the edge of the adventitia side) where stable tracking was possible. The rate gate for velocity measurements was automatically positioned at the center of the diameter using echo-tracking gates. Flow velocity was corrected for angle between ultrasound beam direction and flow velocity vector. The right section of the figure represents the M-mode for the carotid diameter measurements. During systole, the pressure and diameter-change waveforms were very similar. During diastole, the carotid arterial pressure–diameter relationship showed slight nonlinearity and hysteresis. The maximal and minimal values of a diameter-change waveform were calibrated by the systolic and diastolic relationship.[13] The relationship of pressure–diameter was

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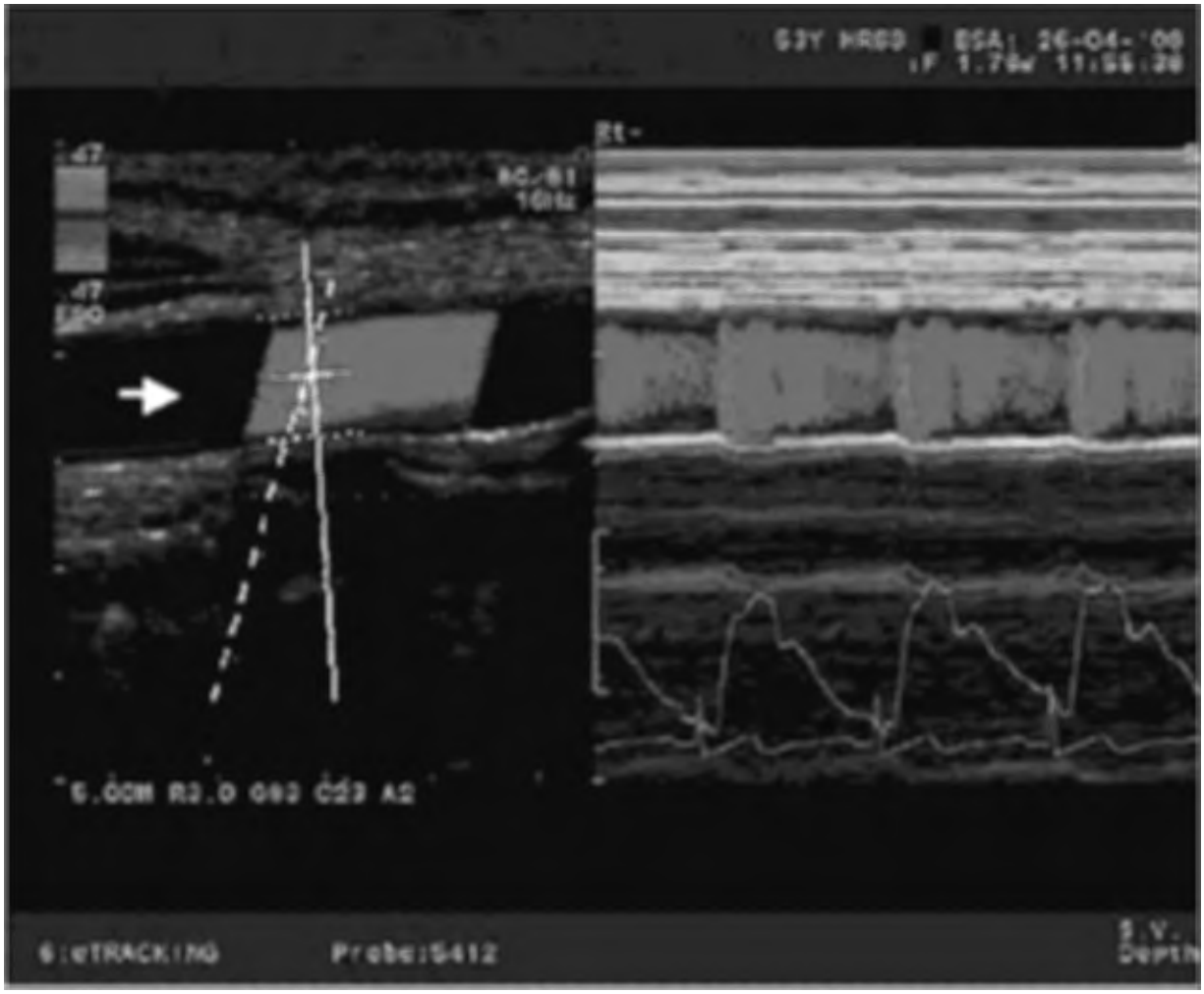


Figure 1. Examination of common carotid artery with simultaneous display of change in diameter using echo-tracking technique. Long-axis view: B-mode (left) and M-mode (right).

thought to be linear.[12] Brachial cuff BP (measured just before starting the carotid study) was entered into the system for the carotid stiffness parameters calculation. A simultaneously recorded electrocardiogram (ECG) was used as a reference to calculate wave transit time.

The anterior and posterior wall positions, velocity, and ECG were fed into a personal computer system and displayed together with calculated diameter change in real time. Three to five beats were averaged to obtain a representative waveform.

Figure 2 shows the output of automatically measured local arterial stiffness represented by PWV. The local PWV was derived from β(PWVβ) as described above.[12]

SphygmoCor

The SphygmoCor (Model SCOR-Px, Software version, 7.01, AtCor Medical Pty Ltd, Sydney, NSW, Australia) uses a single high-fidelity tonometric Millar transducer. To determine the carotid–femoral PWV, the pulse wave was recorded sequentially at the femoral artery and at the carotid artery by the transducer. A simultaneously recorded ECG was used as a reference to calculate wave transit time. Transit time between carotid and femoral pressure waves was calculated using the "foot-to-foot" method. Wave "feet" are identified using intersecting tangent algorithms. Two surface distances were measured by the investigator: between the recording point at the carotid artery and the sternal notch (distance 1) and between the sternal notch and the recording point at the femoral artery (distance 2). The distance traveled by the pulse wave (DPW) and the carotid–femoral PWV were calculated by the SphygmoCor according to the following formulas[14,15]

$$\text{DPW} = \text{distance 2 (m)} - \text{distance 1 (m)}$$

$$\text{carotid–femoral PWV} = \text{DPW (m)}/\text{transit time (s)}$$

Statistical analysis

All statistical analyses were performed with SPSS for Windows version 12.0.1 (SPSS Inc., Chicago, IL, USA).

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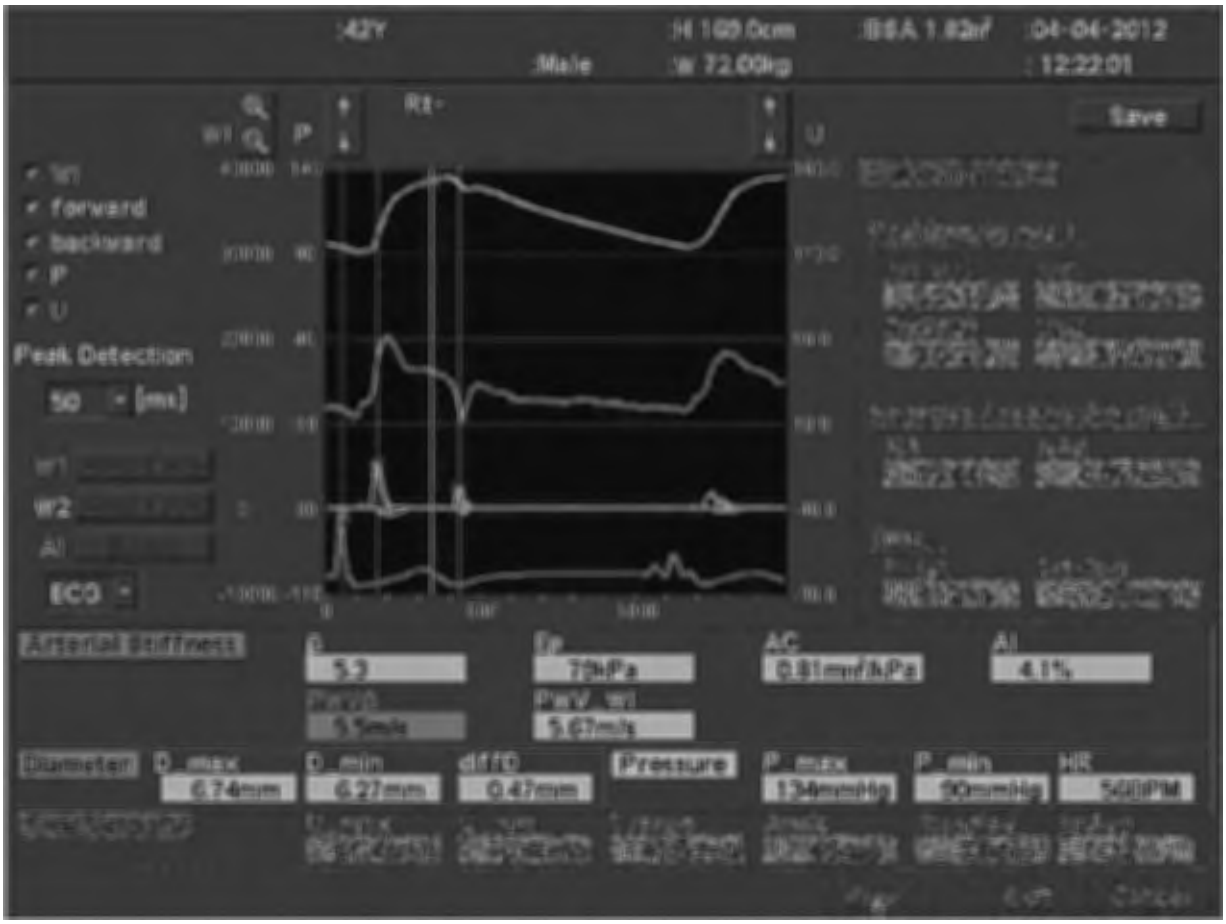


Figure 2. Echo-tracking assessment of parameters of carotid stiffness (top and middle: arterial stiffness) and carotid diameter variations and electrocardiogram (bottom: diameter). Carotid variables are β index and Ep.
PWVβ: local pulse wave velocity; D_max: carotid diameter in systole; D_min: carotid diameter in diastole; HR: heart rate; P_max: systolic blood pressure (BP); P_min: diastolic BP.

Values were presented as mean ± standard deviation (SD) for normal distribution and medians (95% confidence interval (CI)) for non-normally distributed variables. The correlation coefficient was defined as r according to Spearman's test. A receiver operating characteristic (ROC) curve analysis was used to compare the two methods. A backward regression analysis was performed to detect the independent relation between age, body mass index, gender, heart rate, mean BP, carotid–femoral PWV, and one-point PWV. In our laboratory, inter- and intra-observer variability (reproducibility between two observers) was determined using both Pearson's bivariate two-tailed correlations and Bland–Altman analysis.

Table 1. General characteristics of the 160 subjects.

Variables	Mean ± SD
Male/female	112/48
Age (years)	51.5 ± 14.09
Weight (kg)	78.21 ± 13.5
Height (m)	1.73 ± 0.10
SBP (mmHg)	137.6 ± 19.48
DBP (mmHg)	80.66 ± 11.48
HR (bpm)	67.58 ± 13.28
	Median (CI)
Carotid–femoral PWV (m/s)	7.2 (6.2–8.9)
One-point carotid PWV (m/s)	5.8 (5.0–6.6)

SD: standard deviation; SBP: systolic blood pressure; DBP: diastolic blood pressure; HR: heart rate; CI: confidence interval; PWV: pulse wave velocity.

Results

Table 1 displays physiological and hemodynamic characteristics of the 160 subjects: 96 free of overt cardiovascular disease, 44 hypertensives, 13 suffering from aortic valve disease, and 7 with left ventricular dysfunction. The one-point carotid PWV was systematically lower than the carotid–femoral PWV (median = 5.8 m/s, 95% CI = 5–6.6 for one-point carotid PWV and median = 7.2 m/s, 95% CI = 6.2–8.9 for carotid–femoral PWV). Both of them had a good correlation with age (one-point carotid PWV vs age

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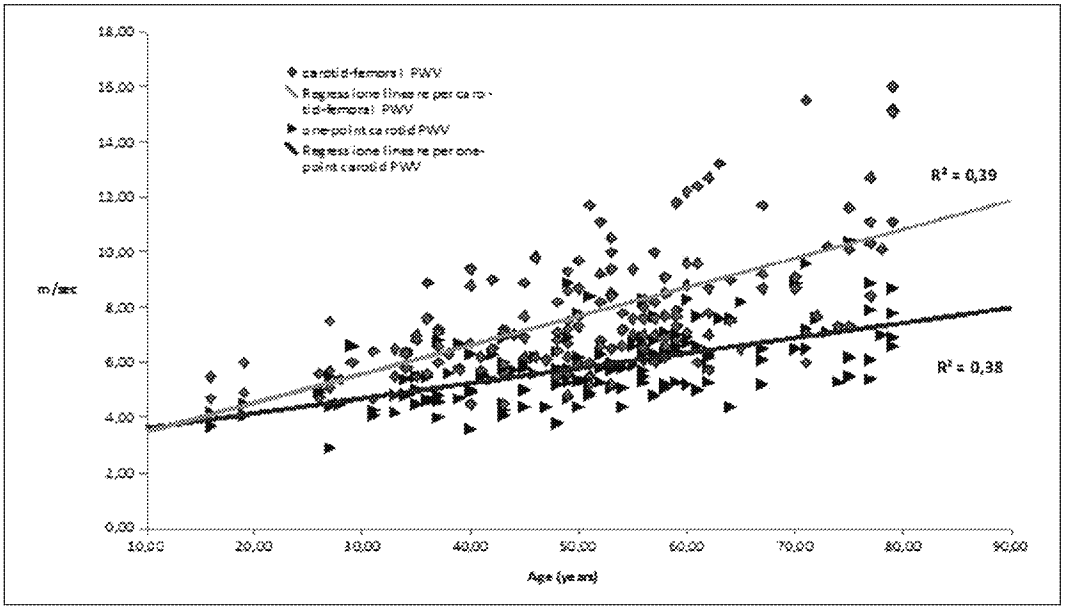


Figure 3. Relationship between carotid–femoral PWV and "one-point" carotid PWV with age.
PWV: pulse wave velocity.

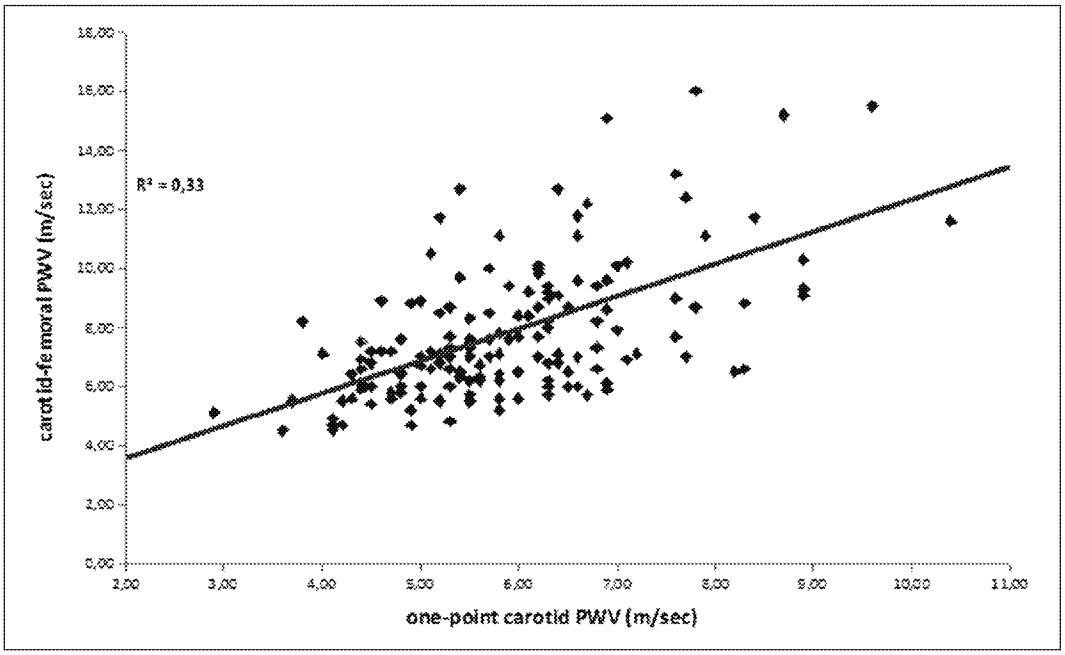


Figure 4. Relationship between carotid–femoral PWV and "one-point" carotid PWV obtained using SphygmoCor and echo-tracking system.
PWV: pulse wave velocity.

$r = 0.618$, carotid–femoral PWV $r = 0.617$, $p < 0.001$ for both) (Figure 3).

A good direct correlation was found between carotid–femoral PWV determined by SphygmoCor and one-point carotid PWV measured by Aloka echo-tracking method ($r = 0.539$, $p < 0.001$) (Figure 4). The area under the ROC curve was 0.85, identifying the cutoff for one-point PWV of 6.65 m/s as the best predictor of carotid–femoral PWV higher than 12 m/s (sensitivity = 0.818, specificity = 0.819) (Figure 5).

The parameters that independently affected one-point PWV were age and mean BP ($R^2 = 0.37$, $p = 0.002$); age was the parameter that affected carotid–femoral PWV ($R^2 = 0.432$, $p = 0.02$).

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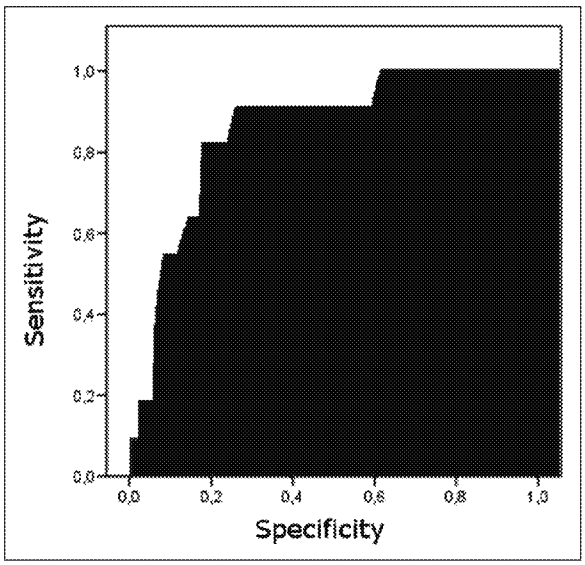


Figure 5. Receiver operating characteristic (ROC) curve analysis of "one-point" carotid PWV of 6.65 m/s as the best predictor of carotid–femoral PWV more than 12 m/s (sensitivity = 0.818, specificity = 0.819). Area under the curve = 0.85.
PWV: pulse wave velocity.

Intra-observer variability was ±3.9% and $r = 0.96$ for carotid–femoral PWV and ±5.5% and $r = 0.93$ for one-point PWV. Interobserver variability was ±3.2% and $r = 0.98$ for carotid–femoral PWV and ±5.9% and $r = 0.95$ for one-point PWV.

Discussion

The PWV is defined as the pulse wave travel speed throughout the aorta. PWV increases as the aorta becomes stiffer, which is a factor that determines the development of cardiovascular complications. This was demonstrated in different populations including patients with hypertension, diabetes mellitus, end-stage renal disease, elderly subjects, and general population.[1–5]

Although carotid–femoral PWV is considered the gold-standard measurement of arterial stiffness and the cutoff of 12 m/s has been identified as the best predictor of cardiovascular events,[8] it may not reflect the exact pathophysiological condition. The distance between the carotid and femoral sites is measured manually and may differ from the true length of the arterial pathway because of anatomic particularities.[16] Furthermore, the aging process on the arterial tree is heterogeneous. The decrease in compliance with age of the arterial wall might be due to a relative increase in collagen fiber which is different in the thoracic aorta from the common carotid artery;[2] measurement of carotid–femoral PWV includes segments of the carotid, iliac, and femoral arteries which are stiffer than the aorta. This could be overcome by using local arterial stiffness indexes to derive the pressure–diameter curve of the artery and to calculate the local PWV from the time elapsed between the two adjacent distension waveforms.[17] With some echo-tracking systems (ProSound Alpha10), it is also possible to determine the local PWV using on-line "one-point" measurements at the same time of echocardiography examination and intima-media thickness determination.[15,17] Moreover, the carotid artery is of special interest because local carotid stiffness has demonstrated a significant predictive value for cardiovascular events.[9]

We compared carotid–femoral PWV to one-point carotid PWV on the basis of the results of their application to a heterogeneous population. The results showed a good correlation between the two methods. The one-point carotid PWV was systematically lower than the carotid–femoral PWV. The elastic properties of arteries vary along the arterial tree, which differs within each region of every artery with more elastic proximal arteries and stiffer distal arteries.[18] Aortic stiffness and carotid stiffness, although providing similar information on the effect of aging on elastic arteries stiffening in normal subjects, seem to be not completely interchangeable predictors in high-risk patients.[1] It has to be considered that in this type of patients, the aorta stiffened more than the carotid artery with age and even more with the addition of other cardiovascular risk factors.[19,20] Our findings are in line with those of the literature; in fact, the relation between carotid–femoral PWV and age was steeper than that for one-point carotid PWV, and also with multiple regression analysis, only age was independently related to carotid–femoral stiffness.

There are few studies reporting on the comparison between different local and regional arterial stiffness. Paini et al.[21] compared aortic PWV with one-point carotid PWV measured with a dedicated echo-tracking device (Wall Track System) in a study cohort including 463 subjects (94 healthy subjects, 243 patients with essential hypertension and with hypertension and type 2 diabetes mellitus). The correlation between the two methods on the overall population was similar to ours. Gaszner et al.[22] compared regional PWV measured by an oscillometric system (arteriograph) in 125 patients with coronary artery disease and 125 healthy subjects and local PWV measured by echo-tracking in a group of patients with coronary artery disease with similar results.

In this study, the parameters of arterial stiffness had good reproducibility and repeatability and they are similar to those recently published.[23] The area under the ROC curve was 0.85, identifying the cutoff for one-point PWV of at 6.65 m/s as the best predictor of carotid–femoral PWV higher than 12 m/s. To our knowledge, there are no other articles reporting a corresponding cutoff number for the one-point carotid PWV.[8]

Moreover, this echo-tracking system embedded in a commercially available cardiovascular ultrasound machine (ProSound Alpha10) allows evaluation of, during the same examination, other two target organ damage parameters: carotid intima-media thickness and left ventricular hypertrophy as recommended by the latest guidelines.[6]

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Limitations of the study

We used brachial BP measurement for the calibration of carotid diameter changes. Brachial pressure usually overestimates central pressure especially in young subjects.[24] Moreover, our study group was rather heterogeneous in order to better evaluate the reproducibility of the method and to find a "one-point" carotid PWV value equivalent to that of the carotid–femoral PWV.

In conclusion, our study shows that one-point PWV, measured at carotid level using echo-tracking technique, is well correlated with traditional carotid–femoral PWV. One-point PWV measured with Aloka (ProSound Alpha10) higher than 6.65 m/s identifies with good sensitivity and specificity subjects with carotid–femoral PWV higher than 12 m/s. Further studies are needed to evaluate the additional clinical significance of these findings in order to use one-point PWV in routine clinical practice for the assessment of vascular function and global cardiovascular risk.

Acknowledgements

We thank Martina Arteni for editing the manuscript.

Declaration of conflicting interests

The authors declare that there is no conflict of interest.

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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510(k) Cover Letter

September 02, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional 510(k) Premarket Notification for the Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (As amended) and as required in 21 CFR § 807 - Subpart E, Accurate Meditech Inc submits this subject Premarket Notification for your review. In accordance with 21 CFR § 807.90(c), this document is submitted in duplicate with this original cover letter, and two additional copies of the cover letter are provided.

(b)(4)

Accurate 24 Non-Invasive blood pressure monitor(Model: Accurate 24 BPM) will be shown to be substantially equivalent to the BioBeat BB-613 WP(**K190792**). The purpose device(Accurate 24 BPM) is a Class II device per 21 CFR 870.1130, ProCode: DXN.

Accurate Meditech Inc considers the intent to market this device as confidential commercial information. Therefore, Accurate Meditech Inc. considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR § 20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

Sincerely,

(b)(6)

Kuan-Jen, Wang
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Hi Megan

Here is the eighth email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

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Sent: Wednesday, May 10, 2023 1:42 AM
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(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
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Douglas Herrington

Principal Consultant

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Annals of Anatomy 238 (2021) 151763

Contents lists available at ScienceDirect

Annals of Anatomy

journal homepage: www.elsevier.com/locate/aanat

RESEARCH ARTICLE

Ultrasound evaluation of the radial artery in young adults — A pilot study

Zygmunt Domagała[a,*], Joanna Grzelak[b], Natalie Pospiech[c], Nicole Hunter[c], Jakub Klekowski[c], Agnieszka Lach[c], Katarzyna Stój[c,d], Bożena Kurc-Darak[a], Mirosław Trzaska[a]

[a] Division of Anatomy Department of Human Morphology and Embryology, Wroclaw Medical University, Poland
[b] Division of Oral Anatomy, Wroclaw Medical University, Poland
[c] Clinical and Dissecting Anatomy Students Scientific Club, Wroclaw Medical University, Poland
[d] Department of Pediatrics, Staten Island University Hospital, Staten Island, NY, USA

ARTICLE INFO

Article history:
Received 31 January 2019
Received in revised form 5 May 2021
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Available online 27 May 2021

Keywords:
Radial artery diameter
Peripheral vascular access
Ultrasonography
BMI
Coronary angiography access

ABSTRACT

The radial artery is a vessel frequently used in various medical procedures which carry a risk of complications. One such method used to minimize the number of complications is a profound knowledge of the artery's diameter, which allows for appropriate selection of an instrument to use for puncture. The purpose of this study is to determine the diameter of the radial artery and its depth from the skin surface in young adults.

Material and methods: 96 volunteers participated in the study. The average age of the volunteers was 20.43 years. All participants underwent a B-mode ultrasonography to measure the distal radial artery's diameter. Certified anthropometric instruments were used to determine the relation between the artery diameter and the selected basic anthropometric parameters.

Results: The mean right arterial diameter for the entire examined population at the level of the styloid process was mean 1.42 (SD 0.26) mm and its distance to the skin was mean 4.00 (SD1.20) mm. Statistical analysis revealed the presence of moderate positive relationship between the diameter of the radial artery and body weight and between the diameter of the radial artery and BMI. A weak correlation between the artery diameter and the width of the wrist was also present.

Conclusion: In the present work, we aimed to determine the dimensions of the distal section of the radial artery in young people free from symptoms of cardiovascular diseases. The obtained initial study results advise selecting instruments for vascular puncture individually, with special attention paid to slender people with slim wrists.

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5. 510(k) Summary

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Accurate Meditech Inc.-June 9 2023, Response

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U.S. FOOD & DRUG ADMINISTRATION

eConsult Cover Sheet

Consult Number: CON2224919

Document Number: K222658/S001

Applicant: Accurate Meditech Inc.

Trade Name: Accurate 24 Non-invasive blood pressure monitor

Consult Type: Analytical

Requestor: Meaghan Erlewein [MEAGHAN.ERLEWEIN]

meaghan.erlewein@fda.hhs.gov

Requestor Home: CDRH\ OHT2\ DHT2A\ THT2A1

Requested Consultant:

Gatekeeper / Consultant: Ahmad Suliman [AHMAD.SULIMAN]

ahmad.suliman@fda.hhs.gov ; 240-402-1799

Consultant Home: CDRH\ OSEL\ DBP

Date Requested: November 2, 2022

Due Date: December 1, 2022

Instructions: Please refer to consult request email sent 11/1/2022. Thank you!

(b)(5)

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Ahmad Suliman
Division of Biomedical Physics
OSEL / CDRH / FDA

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

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Accurate Meditech Inc	PCB DESIGN	ISO Doc NO Doc Version Form Page	(b)(4)

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Cover Letter

K222658
Accurate Meditech Inc.
Contact Name: Kuan-Jen, Wang/General Manager

October 14, 2022

Kimberly Crowley
Lead Reviewer
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

Re: K222658, Response to RTA Requested Additional Information
Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24_BPM

Dear Kimberly,

We, Accurate Meditech Inc, in accordance with the additional information (RTA) request on Sep. 12, 2022, are submitting the supplementary document of the 510(k) submission for K222658, Accurate 24 Non-Invasive blood pressure monitor. Kindly refer to the attachments for the reply to the additional information request, including the answers to the questions and the revised document as per your request.

Please contact Kuan-Jen, Wang/General Manager at +886 2 2999-1596, or via e-mail at stanley@accurate-meditech.com, should you have any questions regarding this 510(k) submission.

Sincerely,

(b)(6)

Kuan-Jen, Wang
Accurate Meditech Inc.
8F-10, No. 12, Ln, 609, Sec. 5, Chongxin Rd.,
Sanchong Dist. New Taipei City
241406 Taiwan

Phone: +886 2 2999-1596
Fax: +886 2 2999-1196
stanley@accurate-meditech.com

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In Vitro Cytotoxicity Test

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

There is no fifth email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGIC HEALTH
Office of Product Evaluation and Quality

Memo: Pre-submission Clinical Review/510(k) Clinical Consult
Date: December 1, 2022
From: Bindi K. Shah, MD
To: Meaghan Erlewein, Lead Reviewer
Stephen Browning, AD Blood Pressure and Hemodynamic Team
Subject: K222658/S001
Accurate Meditech Inc
Accurate 24 Noninvasive Blood Pressure Monitor

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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

Records processed under FOIA Request 2023-10013; Released by CDRH on 07-09-2024

(b)(4)

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

From: (b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

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

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More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

There is no fifth email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

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

From: (b)(6)
Sent: Monday, June 19, 2023 6:33 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Here is our response to your questions along with a revised 510k summary.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, June 16, 2023 8:12 PM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, June 16, 2023 2:18 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Here is our response to your questions along with a revised 510k summary.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, June 16, 2023 1:52 AM
To: (b)(6)
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Dog,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 15, 2023 1:41 PM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, June 14, 2023 1:20 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Monday, June 12, 2023 7:43 PM
To: (b)(6)
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Thank you for the responses (b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Monday, June 12, 2023 5:44 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, June 9, 2023 3:00 AM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 8, 2023 2:31 PM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, June 2, 2023 9:30 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Please find attached our response to the question below.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 26, 2023 11:29 PM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: (b)(6)
Sent: Monday, May 22, 2023 10:24 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Tuesday, May 23, 2023 3:17 AM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Monday, May 22, 2023 7:55 AM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

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

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,
Meaghan

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

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

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Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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Date: December 2, 2022

From: Saryet Kucukemiroglu, Ph.D. (Mathematical Statistician)
CDRH/OCEA/DCEA2/TCEA2C

Subject: Statistical Review of K222658/S001 Accurate 24 Non-invasive blood pressure monitor by Accurate Meditech Inc. (DHP yes, SaMD no, not software only, SaMD AI/ML no, RWE no, data reuse no)

To: Meaghan Erlewein, PhD
CDRH\OHT2\DHT2A\THT2A1

(b)(5)

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If you have any questions, please contact me at 301-796-4671 or email me at saryet.kucukemiroglu@fda.hhs.gov.

Saryet Kucukemiroglu

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

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Development of a piezoelectric polyvinylidene fluoride (PVDF) polymer-based sensor patch for simultaneous heartbeat and respiration monitoring

Yi-Yuan Chiu [a,1], Wan-Ying Lin [b,1], Hsin-Yao Wang [b], Song-Bin Huang [a], Min-Hsien Wu [a,*]

[a] Graduate Institute of Biochemical and Biomedical Engineering, Chang Gung University, Taoyuan 333, Taiwan, ROC
[b] School of Medicine, Chang Gung University, Taoyuan 333, Taiwan, ROC

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Received 4 July 2012
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Sensors
Vital signs
Respirations
Heartbeats

ABSTRACT

This study reports a piezoelectric polyvinylidene fluoride (PVDF) polymer-based sensor patch for simultaneous heartbeat and respiration detections. The principle is based on the piezoelectric sensing mechanism to detect the pulsatile vibrations, and periodical deformations on the chest wall of human body during heartbeats and respirations, respectively. In this study, the sensor patch with a structurally curved PVDF film was designed, and fabricated. The role of the curved structure design to enhance detection signals, and the capability of the sensor to faithfully detect the heartbeats and respirations were experimentally evaluated. Results revealed that the design of curved structure of PVDF film was capable of increasing detection signal by 151% for the respiration measurements compared with its flat counterpart. Moreover, the sensor was proved to be able to generate the heartbeat and respiration signals which were in concordance with those based on a commercial electrocardiogram (ECG), and respiratory effort transducer, respectively. Finally, the heart rate and respiratory rate measured through the sensor patch were proved to have no statistical significance compared with the reference data obtained from the ECG, and respiratory effort transducer-based detections, respectively. As a whole, this study has developed a PVDF-based sensor patch which was capable of monitoring the heartbeats and respirations with high fidelity. Other distinctive features include its small size, light weight, ease of use, low cost, and portability. All these make it a promising sensing device to monitor heartbeats and respirations either in medical centers, or home care units.

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Verification Report of Accurate 24 BPM

Document Number: (b)(4)

Version: (b)(4)

2021/08/03

Presented by

(b)(4)

Approved By (b)(6) *Date* 2021-08-03

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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(b)(4)

Test Report

(b)(4)

(b)(4)

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

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Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

From: (b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6) k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

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

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From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: User Manual

Document Number: (b)(4)
Version: (b)(4)
2023/01/31

Presented by
Catherine Chi/Product Manager

Approved By (b)(6) *Date* 2023-02-03

***Kuan Jen, Wang* (General Manager)**

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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Reversion History

(b)(4)

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

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Accurate 24 BPM User Manual

Revision:1.5
January 2023

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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

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1. Introduction

Thank you for choosing the Accurate 24 Non-invasive Blood Pressure Monitor.

This blood pressure monitor uses the pulse transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and heart rate of adults in a non-invasive manner.

Accurate Meditech shall not take corresponding responsibility for any abnormality or any person or machine damage caused by the irregular use, maintenance, and reposition without the guidance of the instruction, and shall not provide free maintenance for such failures.

This manual is only applicable to Accurate 24 Non-invasive Blood Pressure Monitor (hereinafter referred to as "Device")

2. Intend Use

Accurate 24 Non-Invasive blood pressure monitor is a small, lightweight, wrist-worn device intended for spot-checking and displaying blood pressure (Systolic and Diastolic) and pulse rate. So that the users may have a better understanding of their long-term health trending.
The Accurate 24 Non-invasive BPM is intended for spot-checking adult patients in hospitals, clinics, long-term care, and home use and can obtain results. The measurement results store in the device locally.

3. Indication for Use

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.
The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally.
The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

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4. Safety Announcements

Please read the instruction for use and Safety Announcements in this user manual before operating the unit.

Please follow this user manual thoroughly for your safety.

Please keep it for future reference.

For specific information about your blood pressure, CONSULT YOUR PHYSICIAN.

4.1 Warning

The patient or the operator may die or be seriously injured when the device's operated mistakenly.

- DO NOT use the device in these places full of flammable gas and explosion.
- Allergic reactions may occur in very few other users. If it happens, please stop using the device immediately.
- DO NOT use this device in areas containing high frequency (HF) surgical devices, magnetic resonance imaging (MRI) devices, computerized tomography (CT) scanners, or in oxygen-rich environments.
- DO NOT apply the holder if the wrist has a wound or is undergoing medical treatment, as this can cause further injury.
- This device should not be used adjacent to or stacked with another device.
- DO NOT use any other cables or accessories not approved by the manufacturer in this manual to avoid negative influence on electromagnetic compatibility.
- DO NOT use this device on infants, toddlers, children, or persons who cannot express themselves.
- Patients suffering from cardiovascular diseases perform the measurements as instructed by their physician. Under no circumstances should you change the dosage of any medication prescribed to you by your physician.
- Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.
- The patient is an intended operator.
- DO NOT use when the device is under repair or maintenance.
- Please be noticed that small parts being inhaled or swallowed.
- The device needs to avoid the effects of lint, dust, light (including sunlight), etc.
- DO NOT use the device if there is any known allergy to TPU coated nylon fabric, plastic and rubber.

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- DO NOT use with patients with significant deformity, swelling, irritation, degenerative changes or edema of the wrist.
- DO NOT use the wrist monitor on patients that have restricted blood flow e.g. tourniquet, pressure cuff or IV line.
- DO NOT use with patients with tremors or convulsions.
- DO NOT use on the peripheral vascular disease affected hands.
- Do not use while charging.
- Before use, ensure that there is no visible damage to the device or accessories.
- Store the products where they are inaccessible to small children.
- Remove the product from your wrist if they are worn out or if you are not going to use the instrument for any length of time. This prevents any harm/damage because of leakage.
- The device is not a substitute for medical consultation and treatment. Always consult your doctor if you are experiencing any pain or are suffering from an illness.
- Make sure that no water gets into the device. Do not restart the device until it is completely dry. When storing the device, make sure that no heavy objects are placed on top of it.
- If the device is mechanically damaged it must not be used and must be disposed.

4.2 Caution

The Damage may happen to people or devices when the device is employed incorrectly.

- Please keep and use the device within the regular range of temperature, humidity, and atmospheric pressure; if not, it would lead to damage to the device and inaccurate measurement results.
- DO NOT use in a location where there is moisture or risk of water splashing the device. This may damage the device.
- The device is limited to one user at the same time.
- Please be away from the device with strong electromagnetic interference, such as Mobile telephones, microwave ovens, etc. when using it.
- DO NOT disassemble or attempt to repair the device or components. this may cause an inaccurate reading.
- DO NOT use the device for any purpose other than measuring blood pressure.
- DO NOT use the device in a moving vehicle such as in a car or on an airplane.
- DO NOT drop, or subject this monitor to strong shocks or vibrations.

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

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4.3 Note

Important tips on the operation and use

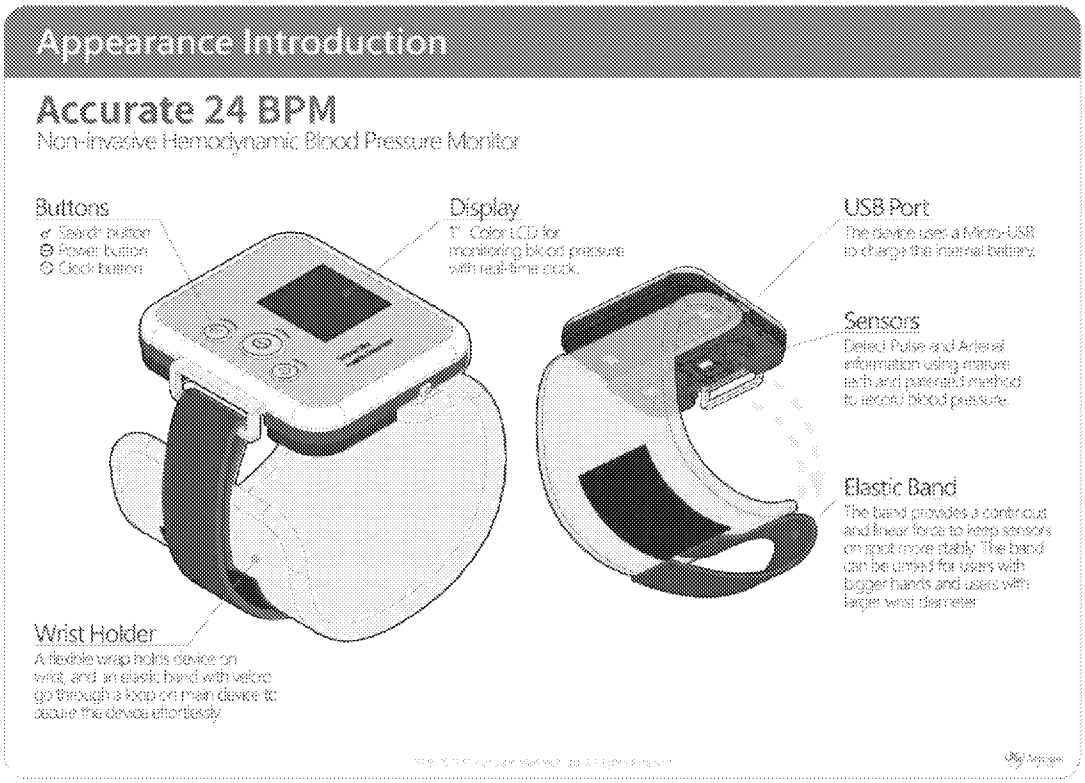
- For patients with arrhythmia, premature heartbeats, atrial fibrillation, arteriosclerosis, hypoperfusion, diabetes, nephropathy, a weak pulse, pregnant patients, or patients with significant fluctuations in their heart rate, it may be difficult to measure the blood pressure exactly. Please consult a qualified physician to interpret your blood pressure measurements.
- The device is a non-Invasive Wrist Blood Pressure Monitor and clinically investigated according to the requirements of ISO 81060-2:2018 (4.1 Clinical investigation method of the a.1: a non-invasive auscultatory reference sphygmomanometer at the upper arm.)
- If those who are equipped with a heart pacemaker, a stent, and beyond the measurement ranges of the device, the accuracy of the output results will be affected.
- Check the battery power after each use. When the battery is less than 1 cell, you must charge the battery, and ensure sufficient storage of electricity.
- Please stop using the device if there is any indication of malfunction.

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

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5. Know Your Device

5.1 Appearance introduction



[Figure 5-1]

Content	Description
Display	Show graphic user interface and measurement related content
Power button	Press to turn on / off the device (Auto measurement starts at power on when the Time and Date are set)
Search button	Press to check History Record
Clock button	Press to change or check settings include Time and Date
Micro USB port	Connect a USB power source to charge the device
Wrist holder	Wrist circumference 13.5 cm to 21.5 cm
Elastic band	To secure the device on wrist

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

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5.2 Monitor Display



[Figure 5-2]

5.3 Battery Display

Our device contains a lithium battery that can be used multiple times, please use our attached USB charging cable to charge it. The information of battery status is shown on the screens fixedly. These battery symbols tell you the current battery status.

Symbols	Description
	The Electricity = 100%
	The Electricity ≤ 80%
	The Electricity ≤ 60%
	The Electricity ≤ 20%
	The Electricity ≤ 5%

[Figure 5-3]

1. When the  and  symbol appears on the display, it is recommended you charge it.
2. When the  symbol appears on the display, "**Battery Low** " will appears on the screen.
3. When the battery is charging, the screen will appear  Please refer to chapter 6.6 for instruction on how to recharge.

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

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Caution:

For safety reason, the device will enter recharging mode and unable to operate once a power input is detected. The device will function again once the power input is removed and manually restarted.

5.4 Before Taking a Measurement

To help ensure an accurate reading, follow these directions:

1. Avoid bathing, drinking alcohol or caffeine, smoking, exercising, and eating for 30 minutes before taking a measurement.
2. Rest for at least 5 minutes before taking the measurement.
3. Stress raises blood pressure. Avoid taking measurements during stressful times.
4. Measurements should be taken in a quiet place.
5. Remove tight-fitting clothing from your arm.
6. Keep a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a while. Try to measure your blood pressure at the same time each day for consistency.

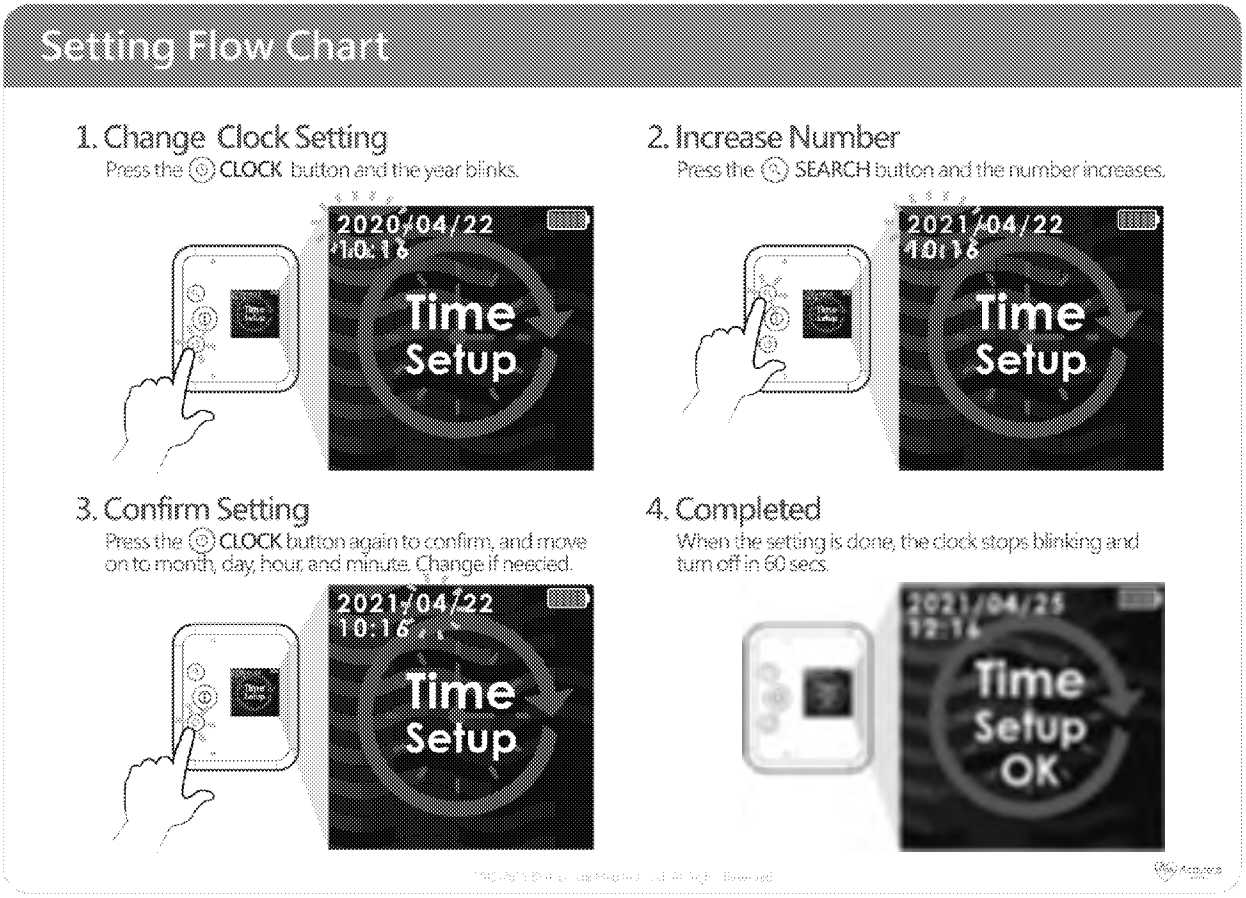
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6. Using the Device

6.1 Date and time set procedure

1. To adjust the date and time, press the "CLOCK" button.
2. The display will show a blinking number representing the YEAR. Change the YEAR by pressing the "SEARCH" button. Each press will increase the number by one in a cycling manner. Press the "CLOCK" button to confirm the entry. The screen will then show a blinking number representing the MONTH.
3. Change the MONTH, DAY, HOUR, and MINUTE as described in Step 2 above, using the "SEARCH" button to change the numbers and the "CLOCK" button to confirm the entries.



▲ Repeat the process to set MONTH, DAY, HOUR, and MINUTE. [Figure 6-1]

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

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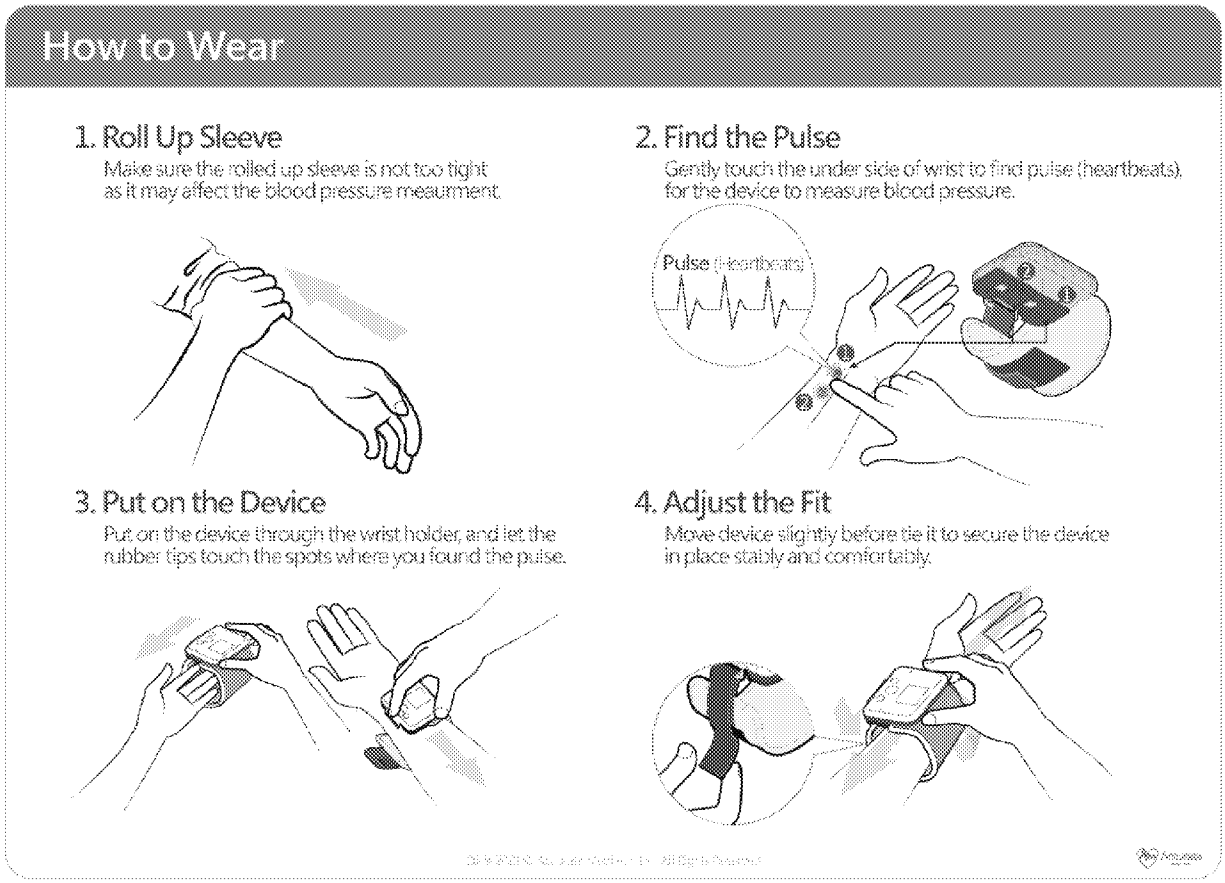
6.2 Applying the Wrist holder

Note

- The following steps are for applying the Wrist holder to your left wrist. When you measure your right wrist, apply the Wrist holder using the same steps as on your left wrist.
- The blood pressure can differ between the right wrist and the left wrist, and the measured blood pressure values can be different. Accurate recommends always use the same wrist for measurement. If the values between both wrists differ substantially, please check with your physician as to which wrist to use for your measurements.

Caution

- Remove tight-fitting, thick clothing and any accessories from your wrist while taking measurements.

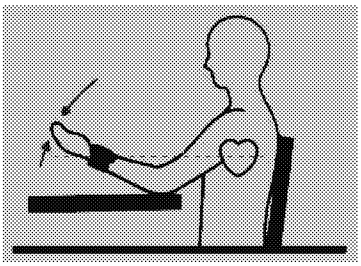


[Figure 6-2]

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

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6.3 How to Sit Correctly



To take a measurement, you need to be relaxed and comfortably seated, at a comfortable room temperature.

- Sit in a chair with your legs uncrossed and your feet flat on the floor.
- Sit upright with your back straight.
- Sit with your back and arm being supported.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.
- Your device must be approximately the same height as your heart.

Note:

- When the device is about at the same height as the heart, the device will prompt the light function. If the device is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.
- If you are unable to make any seat or table adjustments, please make sure that the height of the device is positioned as close to heart-level as possible and ignore the prompt lights.

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

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6.4 Taking a Measurement

Caution

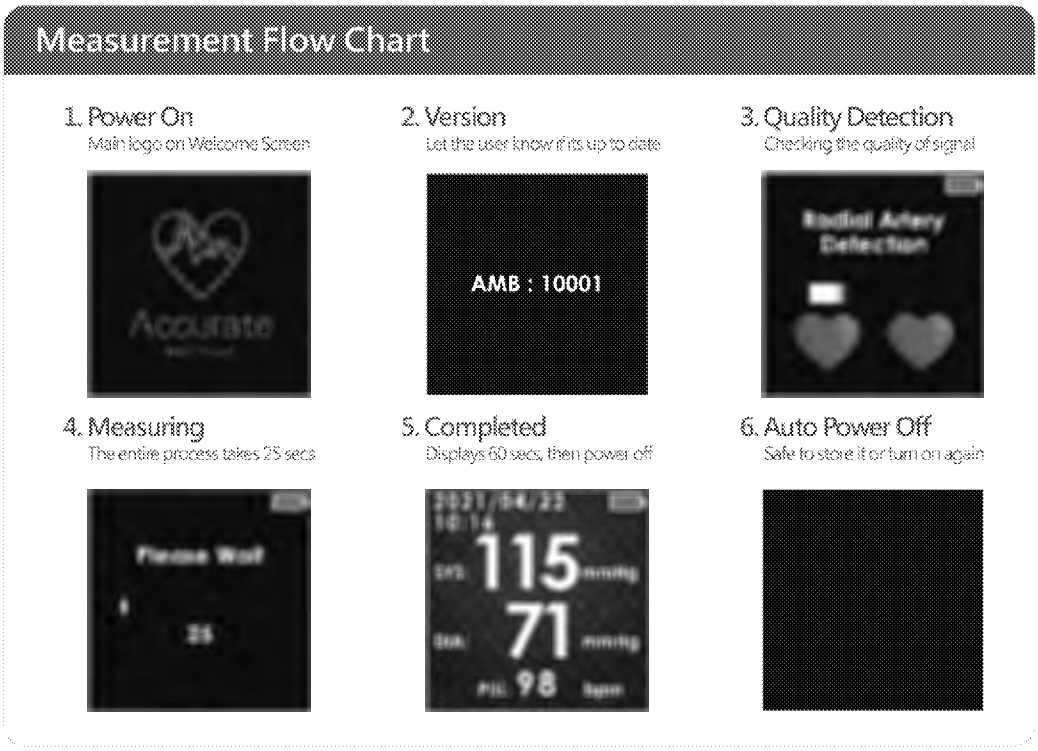
- DO NOT use this monitor with another medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and /or cause an inaccurate reading.
- Remain still and do not talk while taking measurements.

---

1. Press the “POWER” button.
2. Check the positioning indicator.
   Your device has a built-in positioning sensor that is used as an aid in determining if the device is at the correct height. When your device is at the correct position relative to your heart, blue indicator light will be displayed on the right side of the screen. Due to difference in individual size and physique, this feature may not be helpful in all cases, and you may wish to disable this feature. If you feel the position of the wrist according to positioning indicator's guidance does NOT match your heart level and follow your judgement.
3. Duration of Measurement is about 25 seconds
4. When the measurement is completed, systolic pressure, diastolic pressure, and pulse will be shown simultaneously on the screen. The measurement is then automatically stored in memory.

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▲ The automatic measurement [Figure 6-3]

Note

- This monitor automatically turns off approximately 1 minute after the last operation. You may also press the "POWER" button to turn the unit off.
- To interrupt measurement, you may press the "POWER" button to turn the unit off.
- This spot-checking device provides only one blood pressure measurement during a single recording session.

6.5 Viewing the Readings Stored in Memory

Your device automatically stores up to 480 readings. If the maximum number of 480 data records has been reached, the oldest data record will be deleted and the new data record will be saved in the first slot.

1. Press the "SEARCH" button.



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The identifying number of current saved User

2. Press the "SEARCH" and "CLOCK" buttons. repeatedly to scroll through the previous readings stored in the memory.

6.6 Recharge the Battery

Caution

For safety reason, the device will enter recharging mode and unable to operate once a power input is detected. The device will function again once the power input is removed and manually restarted.

Steps

- Find the included USB cable in the box.
- Insert the micro-USB (smaller end) into the device.
- Insert the USB-A (larger end) into a power adaptor.
- If an extension cord is used, please make sure it is plugged in securely.
- The display will show  once power input detected.
- Unplug the cable from the device once  is shown.
- The device will show current time for 3 seconds then turn off.

7. Troubleshooting

If any abnormality arises during use, please check the following points.

Display Problem	Possible Cause	Solution
E001	Piezo sensor 1(upper sensor) failure	Contact your local distributor representative.
E002	Piezo sensor 2 (lower sensor) failure	
E003	Pressure sensor 1(upper sensor) failure	
E004	Pressure sensor 2(upper sensor) failure	
E005	Optical sensor 1(upper sensor) failure	
E006	Optical sensor 2(upper sensor) failure	
E007	G sensor failure	
E008	Battery fault	
E009	Data acquire failure	Re-apply the Wrist holder, then take

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E010	Signal noise too large	another measurement.
E011	Measurement failure	
W001	Detect movement	Repeat measurement. Remain still and do not talk during measurement. Refer to section 6.4
W002	The Wrist holder is too tight	Refer to section 6.2
W003	The signal is saturation	Re-apply the Wrist holder, then take another measurement.
Battery Low	Low Battery Alarm	Please charging the Battery.
No power. Nothing appears on the display of the monitor.	The battery is completely depleted.	Contact your local distributor representative.
	Broken Button	
	Broken Battery	
Any other problems occur.	Press the "POWER" button to turn the device off, then press it again to take a measurement. If the problem persists, contact a local distributor representative.	

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8. Maintenance

To protect your device damage, please follow the directions below:

- Changes or modifications not approved by the manufacturer will void the user warranty.

Caution

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

8.1 Storage

keep your monitor in the storage case when not in use.

- Store your monitor in a clean, safe location.
- Do not submerge the device or any of the components in water.
- Do not operate the device in extreme temperatures, humidity, or direct sunshine.
- Do not violently shake the unit or drop it on the floor.

8.2 Cleaning

- Do not use an alcohol-based cleaning solution or solvent to clean the device.
- Use a soft dry cloth or a soft cloth moistened with neutral soap to clean your monitor and Wrist holder, and then wipe them with a dry cloth.
- Do not wash or immerse your device and Wrist holder in water.
- Turn off the "POWER" button before cleaning the device.

8.3 Battery

- This device adopts a built-in battery, which cannot be arbitrarily removed from it.
- Do not charge the battery using other power devices, so as not to damage the battery.
- The aging battery cannot be thrown away in the fire, to avoid the explosion.
- Do not use the battery to supply power for other electronic devices.
- Destruction of the battery should comply with local laws and regulations.
- In order to extend the useful life of the battery, please use the battery properly and preservation. The device should be changed regularly for

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maintenance though it is not used for a long time. Generally, it should be charged once a month and 1 hour each time.

- Please contact with local distributor representative directly if the battery is already broken.
- This device is equipped with a built-in battery. Regardless of whether the boot for use, as long as alternating current (AC) is connected with the device, the process of charging is working. When the battery is full, please disconnect the AC because the charging time should not exceed 12 hours.
- Please use the power adapter configuration provided by a qualified power adapter by IEC 60601-1, Using an un-qualified power adapter will cause damage to the device, any unauthorized modification or repair is not accepted.

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9. Specifications

Product description	Automatic Wrist Blood Pressure Monitor
Model	Accurate 24 BPM
Display	PMOLED digital display
Pressure range	0 to 299 mmHg
Blood pressure measurement range	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg
Pulse measurement range	40 to 250 beats/min.
Accuracy	Mean difference ≤ ±5 mmHg Standard deviation ≤±8 mmHg Pulse: ±5% of display reading
Measurement method	Pulse transit time with the hemodynamic method
IP classification	IP 22
Rating	DC 5V 1A max
Power source	250 mAh
Battery life	150 measurements with full charge battery
Durable period	3 years
Operation conditions	5 °C to 40 °C / 10 to 95% RH / 70.0 kPa～106.0 kPa
Storge/Transport conditions	-20°C to 55°C / 10 to 95% RH / 70.0 kPa～106.0 kPa
Weight	Approximately 100g
Dimensions	70mm x 60mm x 14mm (NOT including the Wrist holder)
Measurable wrist circumference	13 cm to 21.5 cm
Memory	Stored up to 480 readings
Contents	Device/Micro USB cable/User manual
Protection against electric shock	Internally powered ME equipment
Wrist holder material	TPU coated nylon fabric
Applied part	Type BF

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10. Guidance and Manufacturer's Declaration

- Comply with IEC 60601-1:2012 "Medical electrical equipment -Part 1: General requirements for safety".
- Comply with 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".
- Comply with 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".
- Comply with IEC 80601-2-30:2018" Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers".

Symbol Description	
	Type BF (Body Floating)
	Follow the Instruction
	Water Proof Level
	Manufacturer
	Production Date
	Serial Number
	Expiration Date
	Lot Number
	Waste Electrical and Electronic Device (WEEE) Directive

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	DO NOT use if the packaging is damaged
	DO NOT use the device in an MR environment.
	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

Manufacturer 	Accurate Meditech Inc. 12, Ln. 609, Sec. 5, Chongxin Rd., Rm.10, 8F., Sanchong Dist., New Taipei City 241406, Taiwan www.accurate-meditech.com +886-2-2999-1596

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

For conformity with the requirements for EMC (Electro Magnetic Compatibility), with the aim to prevent unsafe situations, the EN60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interference as well as maximum levels of electromagnetic emissions for medical devices. Medical devices manufactured by Accurate Meditech Inc. conform to this EN60601-1-2 standard for both immunity and emissions. Reference to the applicable standard can be found in the instruction manual of the product.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by Accurate Meditech Inc., may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- During use (or measurement), portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by Accurate Meditech Inc. Otherwise, degradation of the performance of the device could result.

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- *Refer to further guidance below for individual products regarding the EMC environment in which the device should be used.*

Correct Disposal of This Product (WEEE) 

- In order to avoid the pollution and infecting others, other device and environment, the device should be cleaned before the disposal of device and according to local regulation (regulations on disposal of electronic and electrical components and device) it can be disposed.If there is no related regulation, please dispose of it in accordance with the rules of the disposal ofwaste in the local hospital.
- Do not throw away battery randomly and knock it down, and then contact with the local supplier.This product must be recycled and processed in accordance with local law.
- Please do not treat obsolete electrical or electronic device as unclassified municipal waste. Collected separately, the device can be safely, properly reused, treated, and recycled.

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FCC Caution

This device complies with part 15 of the FCC Rules. Operation is subject to the followingtwo conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note:

This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates uses and can radiate radio frequency energy and, if not installed and used following the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this device does cause harmful interference to radio or television reception, which can be determined by turning the device off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the device and receiver.
- Connect the device into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the device.
- This device complies with FCC radiation exposure limits set forth for an uncontrolled environment and can be used without any restrictions.

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Manufacturer's declaration-electromagnetic emissions		
The Accurate 24 BPM is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Accurate 24 BPM should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
RF emissions CISPR 11	Group 1	The Accurate 24 BPM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Accurate 24 BPM is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Not applicable	

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Manufacturer's declaration-electromagnetic immunity			
The Accurate 24 BPM is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Accurate 24 BPM should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air±2 kV, ±4 kV, ±8 kV,±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/output lines	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical home and professional healthcare environment.
Surge IEC 61000-4-5	± 0.5kV, ±1kV line(s) to line(s) ± 0.5kV, ±1kV, ± 2kV line(s) to earth	± 0.5kV, ±1kV line(s) to line(s) Not applicable	The mains power quality should be that of a typical home and professional healthcare environment.
Voltage Dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Voltage interruptions: 0 % U_T; 250/300 cycle	Voltage dips: 0 % U_T; 0,5 cycle 0 % U_T; 1 cycle 70 % U_T; 30 cycles Voltage interruptions: 0 % U_T; 300 cycles	The mains power quality should be that of a typical home and professional healthcare environment. If the user of the Accurate 24 BPM requires continued operation during power mains interruptions, it is recommended that the Accurate 24 BPM be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	The Accurate 24 BPM power frequency magnetic fields should be at levels characteristic of a typical location in a typical home and professional healthcare environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

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Manufacturer's declaration-electromagnetic immunity			
The Accurate 24 BPM is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Accurate 24 BPM should assure that it is used in san the and environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment-guidance (for home and professional healthcare environment)**
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	**Portable and mobile RF communications equipment should be used no closer to any part of the** Accurate 24 BPM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	$d = 1,2\sqrt{P}$ 80MHz to 800 MHz $d = 2,3\sqrt{P}$ 800MHz to 2,7 GHz 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 meter meters Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and, people.			

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The recommended separation distance between portable and mobile RF communications equipment and the Accurate 24 BPM

The Accurate 24 BPM is intended for use in an electromagnetic environment (for home and professional healthcare) in which radiated RF disturbances are controlled. The customer or the user of the Accurate 24 BPM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Accurate 24 BPM as recommended below, according to the maximum output power of the communications equipment.

The rated maximum output power of the transmitter W	**Separation distance** (m) **according to the frequency of the transmitter**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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Manufacturer's declaration-electromagnetic immunity
Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The Accurate 24 BPM is intended for use in the electromagnetic environment (for home and professional healthcare) specified below. The customer or the user of the Accurate 24 BPM should assure that it is used in such an environment.

Test frequency (MHz)	**Band** [a] (MHz)	**Service** [a]	**Modulation** [b]	**Maximum power** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)	**Compliance LEVEL** (V/m) (for home and professional healthcare)
385	380 –390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9	9
5 500							
5 785							

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
c) 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 the worst case.

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2567
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: December 9, 2022

Reviewer: Meaghan Erlewein

510(k)# K222658/S001 Subject: Traditional

Applicant: Accurate Meditech Inc.	**Device Trade Name:** Accurate 24 Non-invasive blood pressure monitor
Contact Name: Wang Jen	**Contact Title:** General Manager
Correspondent Firm: Accurate Meditech Inc.	**Phone:** 886 (2) 299-91196 **Email:** stanley@accurate-meditech.com
Received Date: October 17, 2022	**Due Date:** January 15, 2023
Pro Code(s): DXN **Class:** II **Reg #:** 870.1130	**Reg Name:** Noninvasive Blood Pressure Measurement System

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K190792	DQA, DXN, DRG	Bb-613wp	BioBeat Technologies Ltd.

(b)(5)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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(b)(5)

Digital Signature Concurrence Table (Doc ID: 04500.15.00)	
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.	
Reviewer Sign-Off	Meaghan Erlewein -S Date: 2022.12.09 13:54:05 -05'00'

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Lithium Batteries - Component

(b)(4)

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Skin Sensitization Study in Guinea Pigs (Maximization Test)

(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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K222658
Accurate Meditech Inc.
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Contact Name: Wang Jen

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 K222658 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 K222658 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" issued

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

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on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

(b)(4)

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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.

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- 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 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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: (b)(6)
Sent: Monday, June 12, 2023 5:44 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, June 9, 2023 3:00 AM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 8, 2023 2:31 PM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Records processed under FOIA Request 2023-10915, Released by CDRH on 07-09-2024

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, June 2, 2023 9:30 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Please find attached our response to the question below.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 26, 2023 11:29 PM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Monday, May 22, 2023 10:24 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Tuesday, May 23, 2023 3:17 AM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Monday, May 22, 2023 7:55 AM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6); k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

5. 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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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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 2023-10915; Released by CDRH on 07-09-2024

Hi Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Tuesday, May 23, 2023 3:17 AM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Monday, May 22, 2023 7:55 AM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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 Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@fda.hhs.gov

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received: *Here*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6); k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON (b)(6)
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Douglas Herrington
Principal Consultant

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Cc: (b)(6); k222658@docs.fda.gov
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Thanks,
Meaghan

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Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Douglas Herrington
Principal Consultant

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To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
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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 2023-10915, Released by CDRH on 07-09-2024

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(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 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2015; Released by CDRH on 07-09-2024

Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K222658 Date Received by DCC:

Lead Reviewer: Meaghan Erlewein

Center: CDRH Office: OHT 2 Division: DHT2A

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ○ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* ~~If the product does not appear to be a device or such a combination product, mark "No."~~	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☒	☐
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

Records processed under FOIA Request 2024-6063 released by CDRH on 07-09-2024

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Records processed under FOIA Request 2023-10915, Released by CDRH on 07-09-2024

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (*https://www.fda.gov/media/86323/download*).*	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☒		☐	☒	
a) Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☐	☐	☒		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☒	☐	☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☒		☐		
i) For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that is was not subject to the regulations under 21 CFR 56.104 or 56.105). **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812.	☐	☐	☒		
ii) For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.	☒	☐	☐		
Comments:	(b)(4)				
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☒	
Comments:	(b)(4)				
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling).	☐	☐	☒	☐	

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

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☐ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☒ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☐	☒	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☒	
Comments:	(b)(4)				
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☒	
Comments:	(b)(4)				
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					

Questions? Contact FDA/CDRH/OSEL/DCD at CDRH-PMA-Templates@fda.hhs.gov or 301-796-6126

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☒ Does require electrical safety evaluation					
☐ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

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36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	

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a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Records Processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Digital Signature Concurrence Table

Reviewer Sign-Off	Meaghan Erlewein -S	Digitally signed by Meaghan Erlewein -S Date: 2022.10.28 10:13:25 -04'00'
Management Sign-Off (digital signature optional)*		

* Management review of checklist and concurrence with with decision required.

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-May 2023 Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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(b)(4)

Report Number: (b)(4)

Skin Irritation Test of Reusable Blood Pressure Cuff Using ISO 10993-10:2010 Test Method 0.9% Sodium Chloride Injection Extract

(b)(4)

(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)

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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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

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(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

October 14, 2022

K222658 RTA Checklist Response

(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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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

510(k) Cover Letter

FDA/CDRH/DCC
MAY 15 2023
RECEIVED

K222658 | S003

May 08, 2023

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

Re: This refuse-to-accept (RTA) for K222658 response is being submitted for the Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

(b)(4)

We have contacted Douglas Herrington, the principal consultant of Herrington Consulting LLC. to act as our official correspondent. He should be contacted directly for any questions, comments or issues arising from review of this submission.

Sponsor & Manufacturing Address:

Accurate Meditech Inc
8F-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.
Sanchong District
New Taipei City 241406
Taiwan (R.O.C.)
Phone: +886.937.987.729
Fax: +886.2.2999.1196

Official Contact Name

Douglas Herrington
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New Taipei City 252, Taiwan (R.O.C.)
Telephone: 1.248.369.5564
Fax: 1.877.881.4412
E-mail: **(b)(6)**

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Sincerely,

(b)(6)

Signature

Kuan-Jen, Wang

CEO, Accurate Meditech Inc.

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Architecture Design Chart

Document Number: (b)(4)

Version: (b)(4)

2021/07/05

Presented by
Falcao/Firmware Manager

Approved By (b)(6) *Date* 2021-07-05

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Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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Accurate Meditech Inc.-May 29 2023, Response

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Skin Sensitization Study in Guinea Pigs (Maximization Test)

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Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1-2
Medical Electrical Equipment
PART 1-2: General Requirements for Basic Safety and Essential Performance
Collateral Standard: Electromagnetic Compatibility

Report Reference Number. .....:	(b)(4)
Approved by(+signature)	
Date of issue:	
Total number of pages:	99
Name of Testing Laboratory preparing the Report.....:	(b)(4)
Applicant's name .....:	Accurate Meditech Inc.
Address .....:	8F-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406, Taiwan
Test specification:	
Standard.....:	IEC 60601-1-2:2014 (Fourth Edition) EN 60601-1-2:2015
Test procedure .....:	Test Scheme
Non-standard test method .....:	N/A
Test Report Form No. .....:	(b)(4)
Test Report Form(s) Originator ....:	
Master TRF.....:	

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sensors

MDPI

Article

Piezoelectric Sensor for the Monitoring of Arterial Pulse Wave: Detection of Arrhythmia Occurring in PAC/PVC Patients

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Abstract: Previous studies have found that the non-invasive blood pressure measurement method based on the oscillometric method is inaccurate when an arrhythmia occurs. Therefore, we propose a high-sensitivity pulse sensor that can measure the hemodynamic characteristics of the pulse wave and then estimate the blood pressure. When an arrhythmia occurs, the hemodynamics of the pulse wave are abnormal and change the morphology of the pulse wave. Our proposed sensor can measure the occurrence of ectopic beats from the radial artery, and the detection algorithm can reduce the error of blood pressure estimation caused by the distortion of ectopic beats that occurs when the pulse wave is measured. In this study, we tested patients with premature atrial contraction (PAC) or premature ventricular contraction (PVC) and analyzed the morphology of the pulse waves when the sensor detected the ectopic beats. We discuss the advantages of using the Moens–Korteweg equation to estimate the blood pressure of patients with arrhythmia, which is different from the oscillometric method. Our research provides a possible arrhythmia detection method for wearable devices and can accurately estimate blood pressure in a non-invasive way during an arrhythmia.

Keywords: piezoelectric; Moens–Korteweg equation; PAC; PVC

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1. Introduction

In previous studies, arrhythmia has affected the accuracy of blood pressure measured by an oscillometric-based electronic sphygmomanometer [1]. The blood pressure measurement function is attached to a wearable device with non-invasive blood pressure measurement technology. It is necessary to overcome the inaccuracy of the oscillometric method in estimating blood pressure when an arrhythmia occurs. Electronic sphygmomanometers currently on the market, such as the Microlife B3 AFIB, can also detect atrial fibrillation (AF) belonging to arrhythmia [2]. When an arrhythmia occurs, the strength of the pulse wave of the peripheral artery changes [3,4], and the arrhythmia can be detected by monitoring the R–R interval of each pulse wave signal in the envelope curve [5]. The current electronic sphygmomanometer can detect an arrhythmia, but the blood pressure measurement result is inaccurate because the arrhythmia causes the hemodynamics of the artery to change [6]. The pulse wave amplitude attenuates, causing distortion, so the corresponding systolic and diastolic pressure points cannot be accurately estimated from an envelope curve measured with the oscillometric method.

The piezoelectric sensor we propose can avoid the distortion of the pulse wave measured by the oscillometric method when an arrhythmia occurs and detect and filter out arrhythmia through a dynamic threshold algorithm. Two piezoelectric sensors are arranged to measure the pulse wave velocity (PWV) of the radial artery, and the blood pressure is estimated by the Moens–Korteweg (MK) equation based on the hemodynamics [7]. This enables the wearable device to measure the blood pressure of patients. PAC) and premature

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ventricular contraction (PVC) are the most common types of ectopic beats that can mimic the irregular beat pattern typical of AF [8,9]. Therefore, this study aims to detect the pulse wave of PAC/PVC patients and assess the influence of PAC/PVC on PWV.

Currently, several research methods for measuring the PWV of local arteries include the direct use of two pressure cuffs to pressurize between the upper arm and the wrist to obtain the PWV of the two-point pulse wave [10]. However, the size of such a device is too large to be suitable for a wearable device. Two or more photoplethysmography (PPG) probes can also measure the pulse wave of the local artery [11]. However, the diffuse reflectance spectrum (DRS) pulse wave reflects the change of hemoglobin and oxygenated hemoglobin in the artery, and a correction of the regression model needs to be applied based on blood flow because that change is not a mechanical wave. Multiple sets of bio-impedance-based sensors can also be deployed. When the artery expands due to pulse waves, the bio-impedance will change. PWV can be obtained by measuring the bio-impedance changes at two points in the local artery. A bio-impedance sensor needs two parts: AC signal output and signal receiver [12,13]. The position where the AC signal is applied on human tissue is not easy to determine. Due to the limited length of wearable devices, the distance between measurement points is prone to errors. The measurement method based on a motion sensor, with the placement of dual accelerometer probes over the artery [14], measures the pulse wave by the local artery. In the application scenario of wearable devices, the accelerometer needs to eliminate the interference caused by the user's movement.

Therefore, to accurately measure the PWV of the local artery, the sensor needs to have good rigidity. The relative position of the two pulse waves remains unchanged at any time. It is sensitive to vibration signals and can sense when an arrhythmia occurs. The piezoelectric film is a sensor made of polyvinylidene fluoride (PVDF). It has thinness and flexibility and can integrate into wearable devices [15]. The cost of piezoelectric film is usually in the tens of dollars. We have considered the balance between cost and measurement performance. The pulse wave sensor designed in this research is a piezoelectric ceramic based on a buzzer, with the advantages of being easy to get and low cost. The manufacturing process of plastic parts encapsulating piezoelectric ceramics can be completed using a 3D printer without the need for a micro-electro-mechanical systems (MEMS) process [16], making it easy to produce a pulse wave sensor that can detect the occurrence of arrhythmia.

Our Contribution

The contribution of this research is the design of a small, low-cost, and highly sensitive pulse wave sensor that can measure the pulse wave signal when an arrhythmia occurs. In addition, we designed an algorithm based on the dynamic threshold to detect the pulse wave of the PVC/PAC waveform. Our method avoids the measurement error caused by the pulse wave distortion due to arrhythmia and also uses the MK equation based on hemodynamics to estimate blood pressure. Finally, we verified that subjects with arrhythmia with PAC/PVC could accurately estimate their individual blood pressure.

2. Materials and Designs

Piezoelectric ceramics can sense tiny mechanical waves. Pressure waves are a kind of mechanical wave that can deform piezoelectric ceramics. When the pressure generated by the pulse wave transmitted by the radial artery deforms the piezoelectric ceramics, the piezoelectric ceramics can convert the pulse wave into a voltage signal. This chapter explains the cavity structure of the small piezoelectric sensor we designed. This cavity structure enables the piezoelectric sensor to be integrated into the wearable device. The pressure of the pulse wave is sensed when the device is close to the radial artery. Air pressure will be concentrated on piezoelectric ceramics, ensuring that the received pulse wave signal has a better signal-to-noise ratio.

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2.1. Mechanical Design

Figure 1 shows the cavity structure of the pulse wave sensor proposed in this study. The piezoelectric ceramic is fixed between the top and bottom covers, and the joint between the covers is filled with a sealing gel to eliminate any gap around the piezoelectric ceramics and dissipate the pressure of the pulse wave. In addition, the piezoelectric sensor has a rubber cap on its side to measure the pulse wave. The rubber cap allows the piezoelectric sensor to adsorb on the human skin easily, increasing the signal-to-noise ratio (SNR) of the pulse wave signal. To prevent damage to the piezoelectric ceramics, a layer of film between the piezoelectric ceramics and the measuring surface is required. This film is composed of high-density fibers, which can prevent the permeation of sweat while also allowing pulse waves to penetrate. The piezoelectric ceramic we use is the same material as the piezoelectric ceramic used in the buzzer, making the sensor we designed easy to manufacture. The synthetic materials of this type of piezoelectric ceramic are zinc oxide (ZnO), lithium niobate ($LiNbO_3$), lithium tantalite ($LiTaO_3$), and barium titanate ($BaTiO_3$).

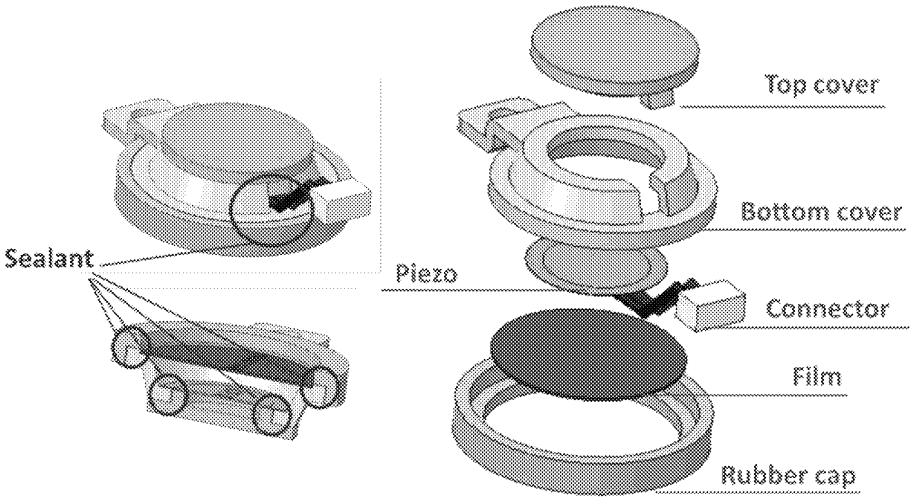


Figure 1. The cavity structure of the pulse wave sensor.

Figure 2 illustrates the change of the piezoelectric sensor when the pulse wave transmits in the radial artery. The volume change ΔV when the pulse wave transmits to the sensing period and the skin movement is calculated per Equation (1). Equation (2) indicates that the internal pressure change ΔP of the pressurized sensor is the sum of the pressure P_A before being pressurized and the pulse wave pressure P_a. Therefore, the proportional relationship between the pressure changes of P_A and ΔP is determined in Equation (3), which involves the ratio of specific heats γ, which is about 1.4 for air [17]. The mass m is then SL times the density of air ρ, as per Equation (4), moved by the difference in pressure between the artery and piezoelectric ceramic. Newton's law of acceleration is Equation (5). We can find the relationship between the force F and the action force of the piezoelectric ceramic with Equation (6).

$$\Delta V = V - S \cdot L \tag{1}$$

$$\Delta P = P_A + P_a \tag{2}$$

$$\frac{P_a}{P_A} = -\gamma \frac{\Delta V}{V} = -\gamma \frac{S \cdot L}{V} \tag{3}$$

$$m = S \cdot L \cdot \rho \tag{4}$$

$$\frac{F}{m} = \frac{d^2x}{dt^2} \tag{5}$$

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$$\frac{d^2x}{dt^2} = \frac{P_a \cdot S}{S \cdot L \cdot \rho} = -\frac{\gamma \cdot S \cdot P_A}{\rho \cdot V \cdot L} \cdot L \tag{6}$$

where V is the piezoelectric sensor's volume before the pulse wave is pressurized, S is the section area, and L is the displacement length of the skin movement of the pulse.

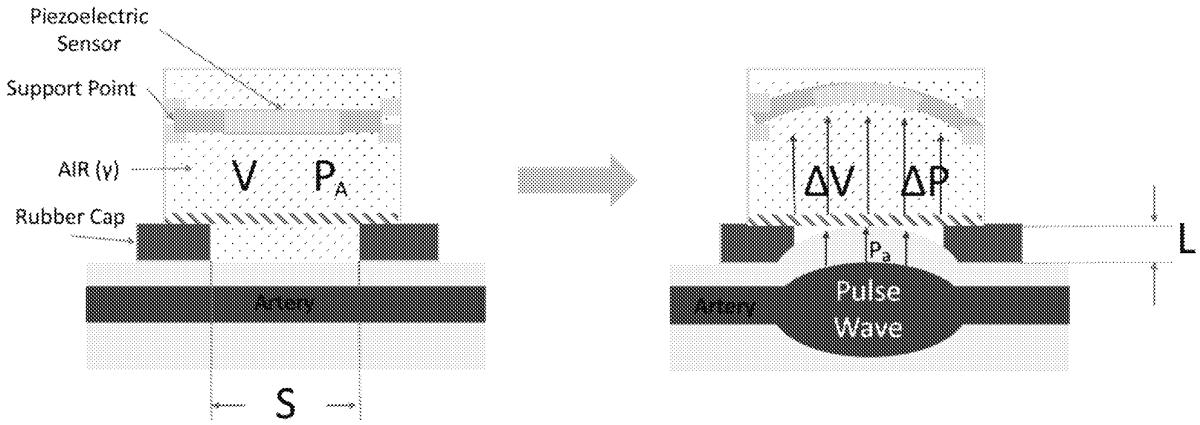


Figure 2. Change of the piezoelectric sensor in cavity housing when the pulse wave transmits in the radial artery.

Figure 3 shows the position where the pulse wave sensor is placed on the wearable device. This study uses two sensors to measure the subject's pulse wave and pulse transit time (PTT) [18]; then, the distance between the two sensors divided by the PTT can be converted to a PWV. The wearable device with the dual-piezoelectric sensor can detect and filter out the pulse wave when an arrhythmia occurs. The MK equation is applied based on hemodynamics to determine the blood pressure with this PWV. This approach avoids the issue of blood pressure measurement errors in patients with arrhythmia using the oscillometric method.

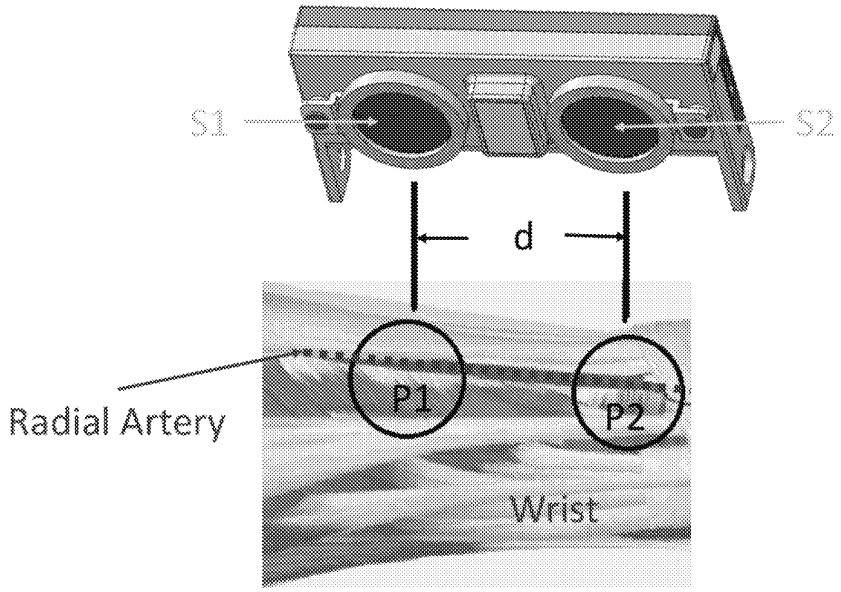


Figure 3. Position where the pulse wave sensor is placed on the wearable device.

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2.2. Analog Front End Design

The voltage signal generated by piezoelectric ceramics is on the millivolt scale. In this study, the analog front end (AFE) is designed to amplify the voltage signal of piezoelectric ceramics and use filters to improve the SNR. Figure 4 shows the processing of piezoelectric signals from piezoelectric ceramics by various amplifiers of the AFE. Figure 5a shows the voltage follower (VF), which is the infinite input impedance, providing the complete input of the piezoelectric ceramic signal on the mV level. If we connect the piezoelectric sensor to the external load, we get a high-pass filter. The cut-off frequency of the high-pass filter is the point in the circuit with a 3dB drop in magnitude. Therefore, we need to add an external load resistor to ensure the quality of the piezo signal. To determine the corresponding load resistor $R1$ in Equation (7), we need to measure the parasitic capacitance C_p of the piezoelectric ceramics [19], and f is the cut-off frequency of 1 Hz of heartbeats with rates around 60 beats per second. Table 1 shows the piezoelectric sensor specifications, and the C_p of the piezoelectric ceramics is 8000 pF. It can be calculated that the most suitable load resistor is about 20 M ohms.

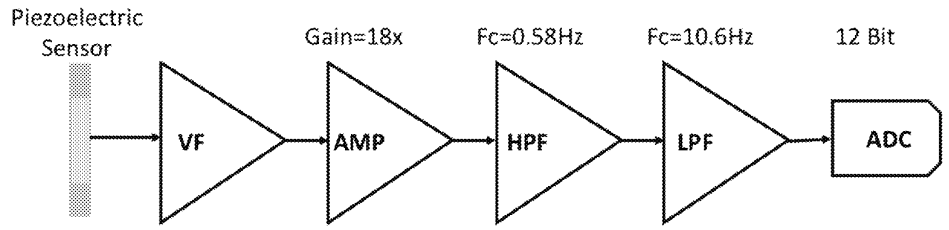


Figure 4. Processing of piezoelectric signals from piezoelectric ceramics by various amplifiers of the AFE.

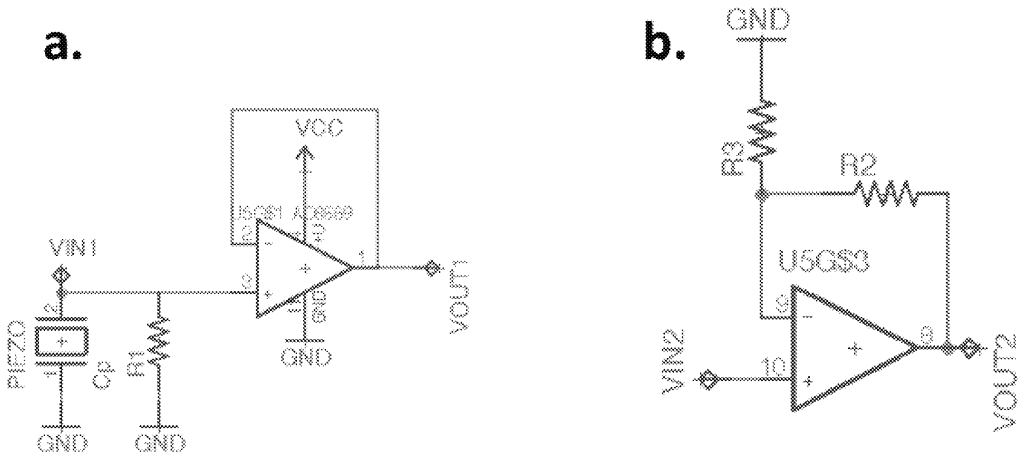


Figure 5. (**a**) VF and (**b**) signal amplifier and gain adjust.

Table 1. Piezoelectric sensor specifications.

Specification	Detail
Capacitance (pF, at 120 Hz)	8000 ± 30%
Plate material	Brass
Plate material (mm)	Φ10 × 0.05
Ceramic size (mm)	Φ7 × 0.07
Weight (g)	0.2
Price (USD)	0.35

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Figure 5b is a signal amplifier, and the gain is adjusted by selecting $R2$ and $R3$ through Equation (8). The signal passes through the signal amplifier, and the voltage signal of the pulse wave is amplified to hundreds of millivolts. When the voltage signal of the pulse wave is amplified, the noise will also be amplified. Figure 6a is the second-order Sallen–Key high-pass filter (HPF); Equation (9) is its transform function calculation formula, and the cut-off frequency is determined by Equation (10). The cut-off frequency of the HPF set in this study is 0.58 Hz; $R4$ and $R5$ are equal, and $C4$ and $C5$ are also designed with the same value. After the signal passes through the HPF, the DC component can be filtered out.

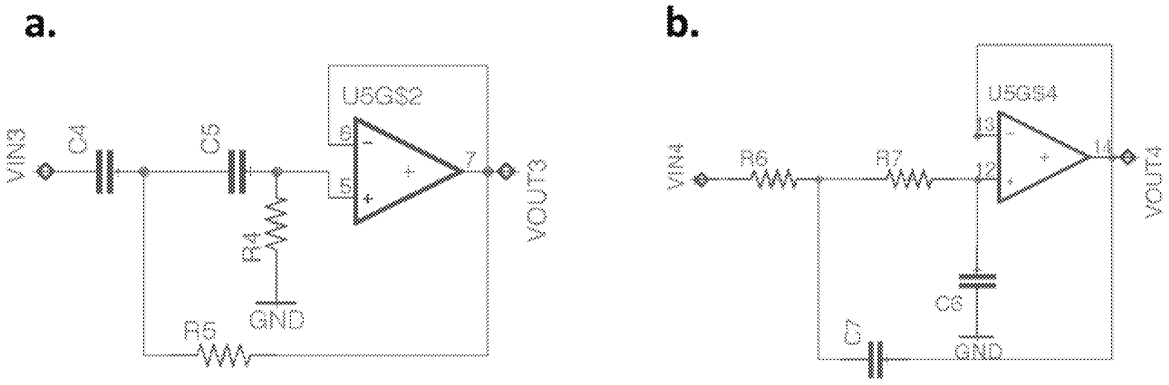


Figure 6. (**a**) Second-order Sallen–Key HPF and (**b**) second-order Sallen–Key LPF.

Figure 6b is the second-order Sallen–Key low-pass filters (LPF) [20]; Equation (11) is its transform function calculation formula, and the cut-off frequency is determined by Equation (12). In this study, the cut-off frequency of the LPF is 10.6 Hz; $R6$ and $R7$ are equal, as are $C6$ and $C7$, which can attenuate the interference caused by the supply mains frequency and other disturbances.

$$R1 = \frac{1}{(2 \cdot \pi \cdot f \cdot C_p)} \tag{7}$$

$$Vout = Vin \cdot \frac{R2}{R3} \tag{8}$$

$$\frac{Vout(s)}{Vin(s)} = \frac{s^2}{s^2 + s\left(\frac{1}{R4 \cdot C4} + \frac{1}{R4 \cdot C5}\right) + \frac{1}{R4 \cdot C4 \cdot R5 \cdot C5}} \tag{9}$$

$$fc_{HPF} = \frac{1}{2\pi\sqrt{R4 \cdot C4 \cdot R5 \cdot C5}} \tag{10}$$

$$\frac{Vout(s)}{Vin(s)} = \frac{\frac{1}{R6 \cdot C6 \cdot R7 \cdot C7}}{s^2 + s\left(\frac{1}{R7 \cdot C6} + \frac{1}{R6 \cdot C6}\right) + \frac{1}{R6 \cdot C6 \cdot R7 \cdot C7}} \tag{11}$$

$$fc_{LPF} = \frac{1}{2\pi\sqrt{R6 \cdot C6 \cdot R7 \cdot C7}} \tag{12}$$

3. Piezoelectric Sensor Signal Processing

A 12-bit analog-to-digital converter (ADC) samples the output voltage of the AFE at a rate of 5 kHz. The pulse wave signal measured by the sensor converts the mechanical wave to a digital signal. This conversion process introduces high-frequency noise. Therefore, this research designs a finite impulse response (FIR) band-pass filter for the pulse wave signal sampled by the ADC. To detect the position of the pulse wave, we designed an algorithm that uses the amplitude of the sensor signal to adjust the gradient dynamically. The dynamic gradient adjustment can better adapt to individuals with different pulse

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strengths, and a dynamic gradient detection algorithm can find the position of normal sinus rhythm and arrhythmia.

3.1. Digital Filter Design

In this study, FIR is used to filter the signal after ADC samplings [21]. As shown in Equation (13), the pulse wave signal x sampled by ADC and the filter coefficient b_k are convolutional, obtaining the filtered pulse wave signal y. As in Equation (14), the filter coefficient needs to calculate the frequency response and window function coefficients according to different FIR filter types and convolution kernel size. We use a band-pass filter (Equation (15)) and set the cut-off frequencies f_{c1} and f_{c2} to 0.7 Hz and 9.5 Hz, respectively. This range covers the pulse wave signal composition, where ω_{c1} and ω_{c2} are the cut-off frequencies of the band-pass filters, and f_{c1} and f_{c2} are the transition frequencies, which need to be divided by the ADC sampling rate of 5 kHz (Equation (16)). The term w is the window function of the Kaiser window [22], as defined in Equation (17), and N is the window size, chosen as 128 in this study. The variable I_0 is the modified Bessel function of the second kind, as defined in Equation (18), where β can adjust the frequency domain's main lobe and sidelobe levels.

$$y[n] = \sum_{k=0}^{N-1} b_k \cdot x[n-k] \tag{13}$$

$$b[n] = w[n] \cdot h_d[n], 0 \le n \le N-1 \tag{14}$$

$$h_d[n] = \begin{cases} \frac{\sin(\omega_{c2}(n-N))}{\pi(n-N)} - \frac{\sin(\omega_{c1}(n-N))}{\pi(n-N)}, n \neq N \\ \frac{\omega_{c2}-\omega_{c1}}{\pi}, n = \frac{N}{2} \end{cases} \tag{15}$$

$$\omega_{c1} = \frac{f_{c1}}{5000}, \omega_{c2} = \frac{f_{c2}}{5000} \tag{16}$$

$$w[n] = w_0\left(\frac{L}{N}(n - \frac{N}{2})\right) = \frac{I_0[\beta\sqrt{1-(\frac{2n}{N}-1)^2}]}{I_0[\beta]}, 0 \le n \le N \tag{17}$$

$$I_0 = \sum_{i=1}^{n}\left(\frac{(\beta/2)^i}{i!}\right)^2 \tag{18}$$

3.2. Adaptive Threshold and Peak Detection

The pulse wave amplitudes of different subjects can vary. Therefore, the threshold of the detected pulse wave signal must be dynamically adjusted. The response speed of the dynamic threshold is dependent on the calculated size. In this study, we use half of the sampling rate as the calculated size for the dynamic threshold.

Equation (19) is the calculation method of the dynamic threshold, and Equation (20) is the formula for covariance (CV), which is used to calculate the rate of change of the past signal strength. Before calculating the CV, the mean value of the signal amplitude is determined per Equation (21). The root mean square (RMS) is the amplitude level of the signal per Equation (22). The *gain* can adjust the level of the dynamic threshold, and we chose one in this study. When the SNR is lower, the waveform of the pulse wave has a smaller CV for the overall signal. Increasing the gain can reduce the false positive of peak detection.

$$\text{gradient} = \text{RMS} \cdot \frac{CV}{100} \cdot gain \tag{19}$$

$$CV = \frac{\left(\sum_{k=0}^{N-1} x_k - mean\right)^2}{N} \tag{20}$$

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$$mean = \frac{\sum_{k=0}^{N-1} x_k}{N} \tag{21}$$

$$RMS = \sqrt{\frac{\sum_{k=0}^{N-1} x_k^2}{N}} \tag{22}$$

Figure 7 shows the pseudocode [23] of the peak detection algorithm proposed in this study. The *gradient* is the dynamic threshold calculated by Equation (19), the index is the order of sampling points, and *value* is the current signal amplitude. When the signal amplitude starts to rise, the pulse wave is transmitted to the sensor. When the current amplitude is greater than the previous value, the local maxima are updated; the signal amplitude is less than the local maximum minus the gradient, and the previous local maximum is the peak of the pulse wave. The local minimum is updated when the signal amplitude decreases and the current amplitude is smaller than the previous value. When the signal amplitude is greater than the local minimum plus the gradient, the local minimum is the trough of the pulse wave. This algorithm only needs to update the gradient and record local maxima and minima for real-time pulse wave detection. It is suitable for running on wearable devices with limited memory and performance.

Figure 8 shows the result of the algorithm used in this study. The four pulse wave signals in the figure include three normal sinus rhythms and one arrhythmia. The yellow star indicates that the pulse wave is rising when the signal strength is greater than the last minimal plus gradient. The red circle is the peak of the pulse wave. The green triangle is when the signal amplitude is less than the last maxima minus the gradient, indicating the pulse wave is falling. The black circle is the trough of the pulse wave.

When the peak position of each pulse wave can be determined, we can count the peak-to-peak time difference of a set of measurement sequences. The algorithm identifies the pulse waves whose time difference is much larger or smaller than the average value, effectively detecting the pulse when an arrhythmia occurs. Placing pulse wave sensors at two points in the artery can measure two pulse waves that are the same but with a phase shift. After the peaks of the two pulse waves are detected, the phase shift time difference between the two is calculated as the PTT. The PTT can be converted into a PWV through the known distance of two points of the sensor.

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```
function PeakDetection(index, value, gradient) return local-maxima or local-minimal
 {
        is_peak, is_trough := FALSE

        if(value > local_maxima)
                local_maxima := (index, value)
        if(value < local_minimal)
                local_ minimal:= (index, value)

        if is_emission == TRUE and x < local_maxima – gradient
                is_emission := FALSE
                is_peak := TRUE
                local_minimal := local_maxima
                return is_peak, local_maxima

        if is_emission == FALSE and x > local_minimal + gradient
                is_emission := TRUE
                is_trough := TRUE
                local_maxima := local_minimal
                return is_trough, local_minimal
 }
```

Algorithm

function *PeakDetection*(index, *value*, *gradient*) return local-maxima or local-minimal

```
1:      is_peak, is_trough := FALSE

2:      if(value > local_maxima)
3:              local_maxima := (index, value)
4:      if(value < local_minimal)
5:              local_ minimal:= (index, value)

6:      if is_emission == TRUE and x < local_maxima – gradient
7:              is_emission := FALSE
8:              is_peak := TRUE
9:              local_minimal := local_maxima
10:             return is_peak, local_maxima

11:     if is_emission == FALSE and x > local_minimal + gradient
12:             is_emission := TRUE
13:             is_trough := TRUE
14:             local_maxima := local_minimal
15:             return is_trough, local_minimal
```

Figure 7. Pseudocode of the peak detection algorithm.

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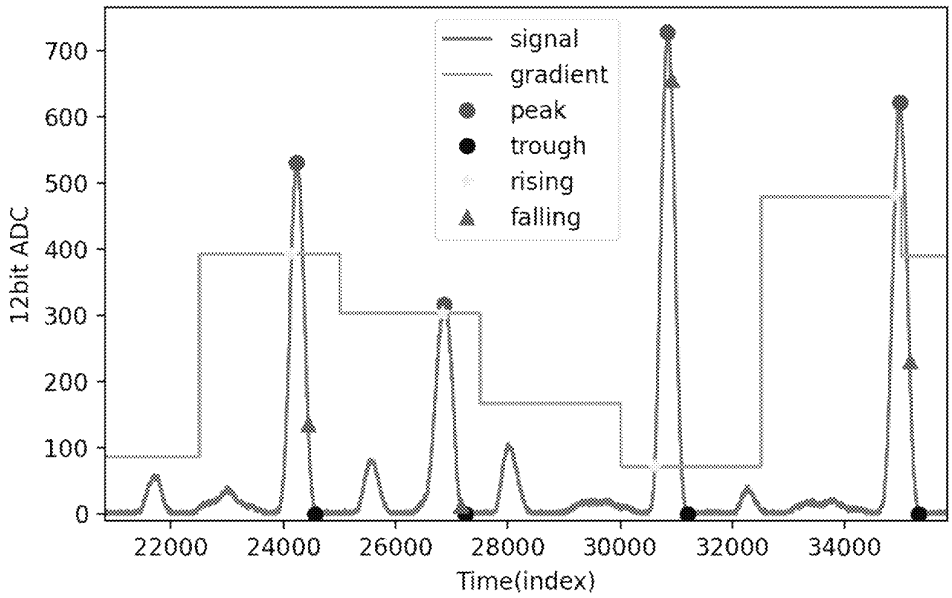


Figure 8. Result of the algorithm used in this study.

4. Result and Analysis

4.1. Experiment Equipment and Setup

Figure 9a shows the pulse wave measurement device that integrates two piezoelectric sensors. The distance between the two sensors is 2.5 cm. The device was placed on the subject's wrist and transmitted the pulse wave signal to USB data acquisition software (Figure 9b), which sampled the piezoelectric sensor signal at a rate of 5 kHz and ran the pulse wave detection algorithm proposed in Section 3 in real time to detect the position of the normal sinus rhythm and the arrhythmia. Furthermore, the data from the acquisition software were stored in the file for analysis.

To verify that the piezoelectric sensor could receive the pulse wave when an arrhythmia occurs, the subject's ECG signal was recorded simultaneously as a reference. Figure 9c is the ECG measurement device (ADI AD8232 IC [24]) and limb lead (MLII). The chip is an AFE circuit designed for ECG measurement. The AD8232 could sense the ECG signal of the human body, and sample the ECG signal at 360 Hz through a 12-bit ADC, and transmit it to the ECG signal acquisition software (Figure 9d) through a USB. The ECG signal acquisition software recorded the subject's signal as a reference for verifying the occurrence of arrhythmia by the piezoelectric sensor. This study performed pulse wave and ECG measurements simultaneously, and the recording time was one minute.

Figure 10a,b shows blood pressure measurement devices and wrist cuffs based on the oscillometric method. The Wheatstone bridge pressure sensor in this study (MPS-3117-006GC) is the type of sensor used by typical electronic blood pressure monitors. The pressure curve of the device was calibrated with the mercury manometer. Our electronic sphygmomanometer air pump, with a range of 40 to 180 mmHg, pressurized the wrist cuff at an increased speed of 4 mmHg per second in closed-loop control and was connected to the data acquisition software (Figure 10c) through a USB. At a sample rate of 1 kHz, the subject's envelope waveform was recorded. A subject with arrhythmia measured by the oscillometric method would have distortion [25].

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Figure 9. (**a**) Pulse wave measurement device. (**b**) USB data acquisition system. (**c**) ECG measurement device and limb lead. (**d**) ECG signal acquisition software.

To avoid the issues with the oscillometric method measuring arrhythmia in subjects—the distorted waveform and the blood pressure estimation error—we used a pulse wave measuring device that integrates two piezoelectric sensors. The PWV of the subject could be measured, and the MK equation based on hemodynamics estimated blood pressure. Since the MK equation requires the subject's arterial diameter and tube wall thickness, an ultrasound imaging device was used in this study to sample the radial artery image of the subject's wrist. Figure 11 shows the ultrasound imaging device Sonostar U-Probe-L6C transducer, which has 196 elements. We sampled the subject's radial artery and took the average artery diameter and wall thickness [26] to verify the MK equation. The Korotkoff sound is the gold standard [27] for non-invasive blood pressure measurement. The subject wore a cuff on the arm with a stethoscope placed between the cuff and arm. The researcher then pressurized the cuff and listened for the brachial artery pulse sound through the stethoscope. After no pulse sound was heard, the researcher would leak air at 2 mmHg per second. The pressure point of the first pulse heard during the decrease of the cuff pressure is the systolic blood pressure (SBP), and the last pulse is the pressure point of the diastolic blood pressure (DBP). Figure 12a shows the Welch Allyn 5098-27 DS66 aneroid sphygmomanometer used in this study, and Figure 12b shows the cuff and the subject.

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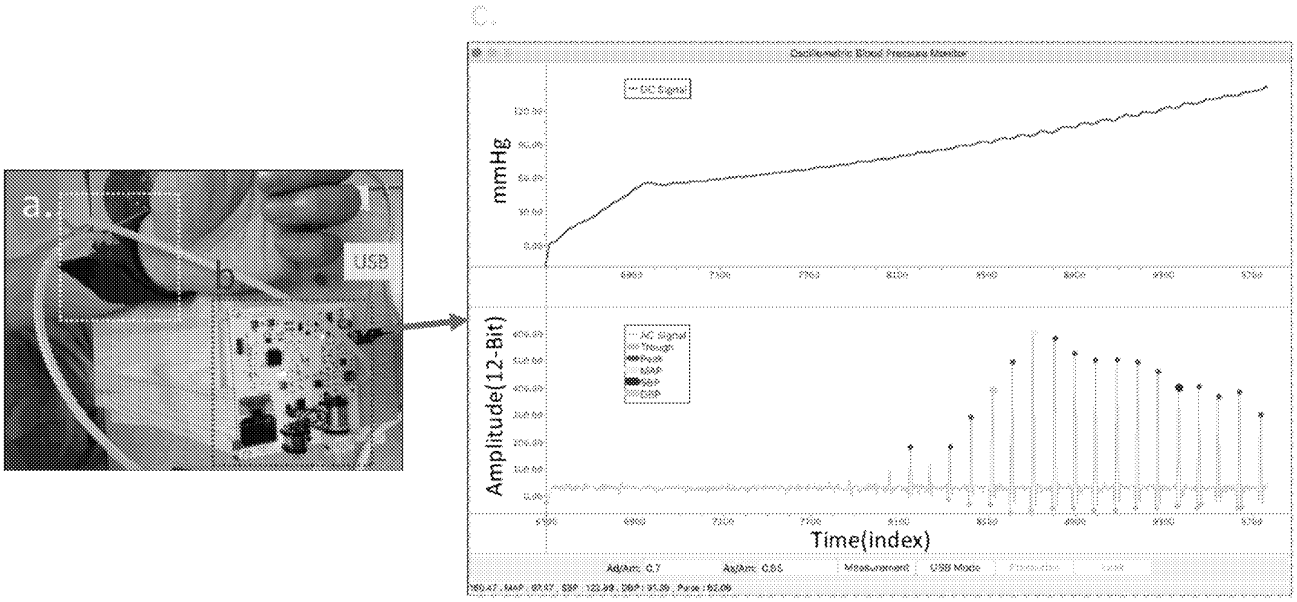


Figure 10. Blood pressure measurement device: (**a**) wrist cuffs based on the principle of the oscillometric method, (**b**) Wheatstone bridge pressure sensor, (**c**) electronic sphygmomanometer air pump.

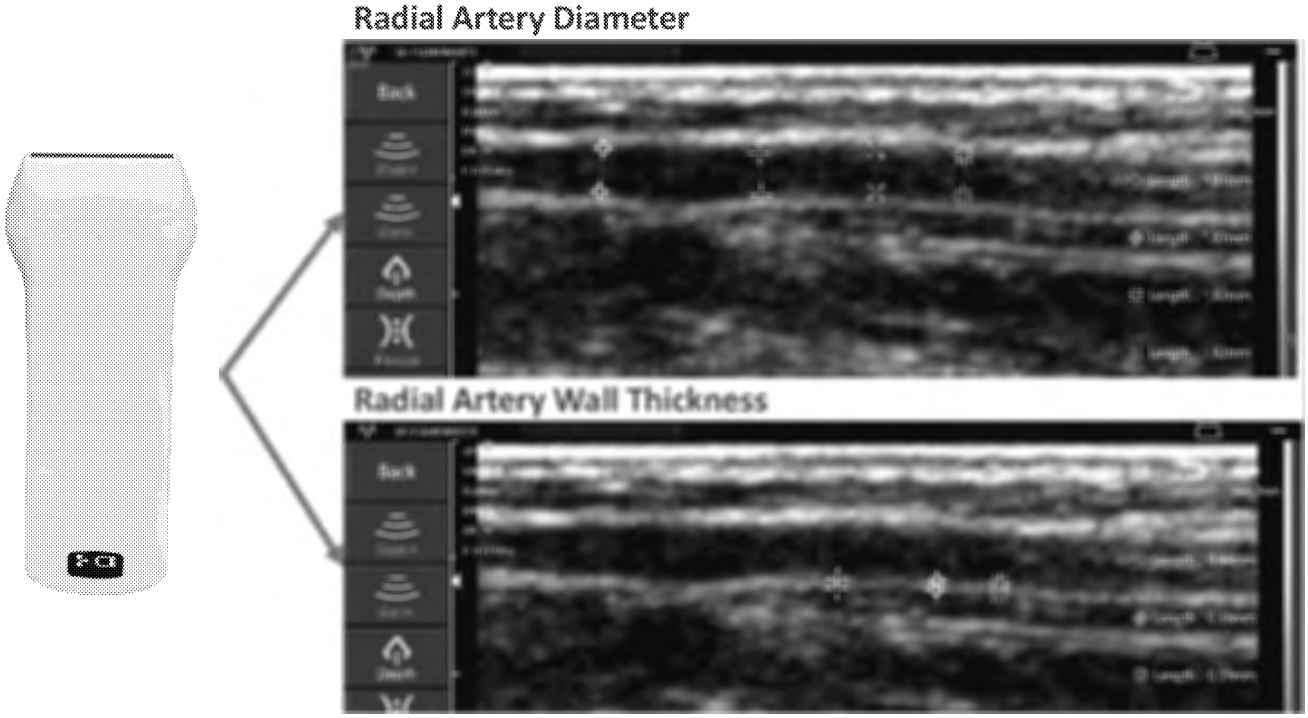


Figure 11. Ultrasound imaging device Sonostar U-Probe-L6C transducer.

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Figure 12. (**a**) Welch Allyn 5098-27 DS66 aneroid sphygmomanometer; (**b**) subject wearing the cuff with a stethoscope between the cuff and the arm, and the researcher pressurizing the cuff.

4.2. Protocol

This study acquired the pulse wave signals of arrhythmia from patients with PAC/PVC. The experimental protocol is shown in Figure 13 and described in the following. The subject needs to first rest for 5 min before the test. Then, the researcher secures the subject's wrist to prevent movement. The ECG limb lead II and pulse wave measurement device are attached to the subject's wrist, and the ECG and pulse wave signal are acquired for one minute. The signal sequence is obtained three times in total, with the subject resting for one minute after each interval. The researcher then sets up the blood pressure measurement device and cuff on the subject's wrist. The cuff position is the same as that of the pulse wave measurement device. The blood pressure measurement device acquires the envelope waveform ranging from 40 to 180 mmHg. Finally, the researcher uses an aneroid sphygmomanometer to sample the reference blood pressure of the subject, and an ultrasound imaging device to sample the subject's radial artery images.

4.3. Pulse Wave Signal Analysis of Atrial Fibrillation

Figure 14 shows the ECG and pulse wave signal sequence of a PAC patient. When another area of the atrium depolarizes before the sinus node and thus triggers a premature heartbeat [28], the ECG signal indicates that PAC occurs, making irregular changes in the heart rhythm. The pulse wave signal during a PAC can be detected by the algorithm proposed in this research to detect the irregular position of the pulse wave.

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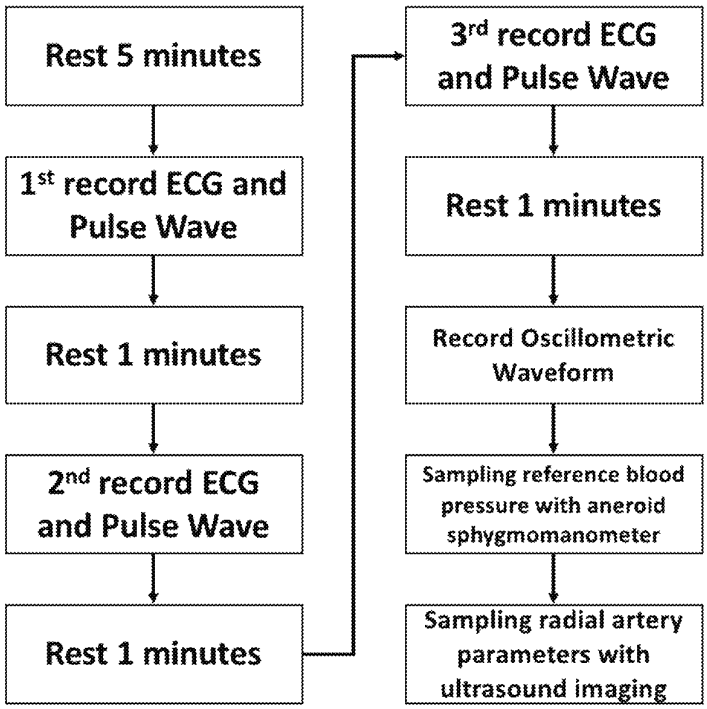


Figure 13. Experimental protocol.

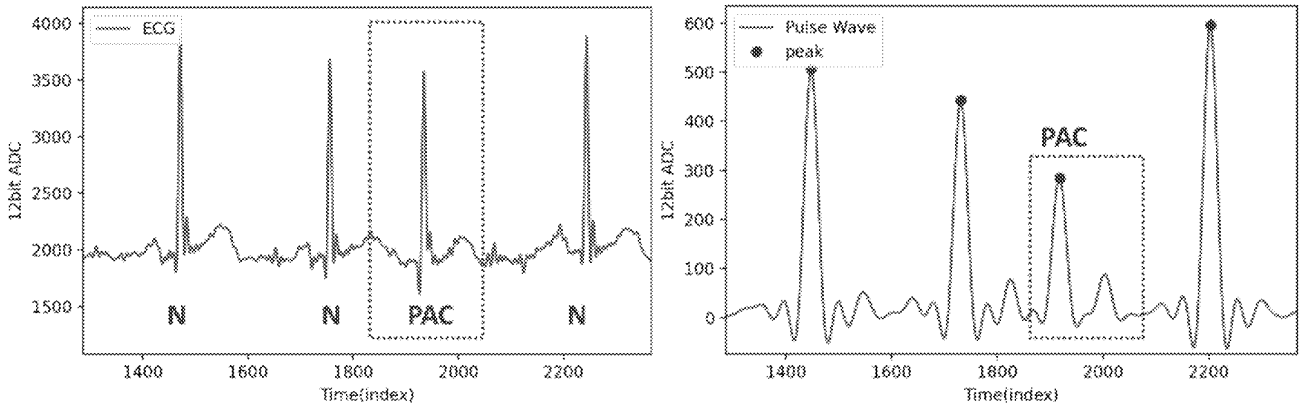


Figure 14. ECG and pulse wave signal sequence of a PAC patient.

Figure 15 shows the ECG and pulse wave signal sequence of a PVC patient. The characteristic of PVC in the ECG signal is that the QRS complex is long and deformed [29]. The pulse wave signal responds to the pressure of the heart when the heart ejects changes when PVC occurs—the hemodynamics in the arteries change, and the amplitude of the first peak of the pulse wave signal is significantly attenuated to close to the second peak. The algorithm proposed in this study can dynamically adjust the threshold to detect the position of the first peak.

Figure 16 shows the oscillometric envelope waveform of a PAC/PVC patient. When a pressurized electronic sphygmomanometer is used to measure the blood pressure of an arrhythmia patient during an arrhythmia, the pulse in the envelope waveform disappears, and the envelope waveform distorts. The oscillometric method uses the pulse with the maxima amplitude as a reference, then finds the pressure point of a specific ratio from the amplitude of each pulse during the measurement, as the subject's SBP and DBP. Figure 16

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clearly shows the issue of the oscillometric method measuring arrhythmia patients being unable to estimate blood pressure.

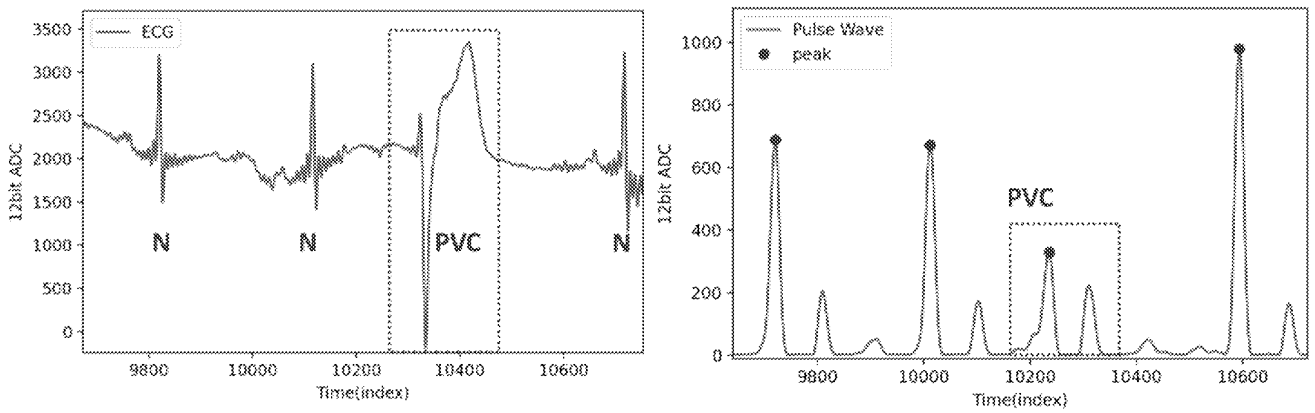


Figure 15. ECG and pulse wave signal sequence of a PVC patient.

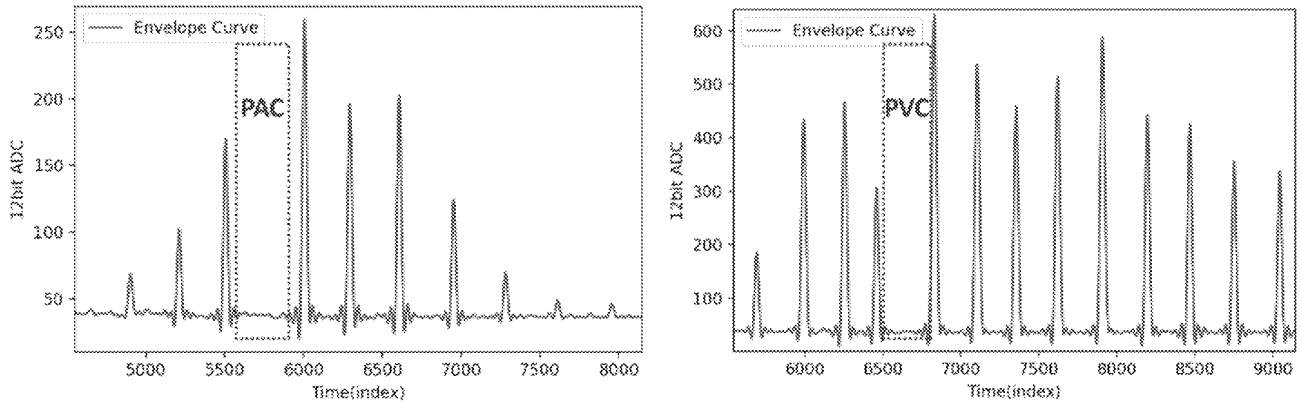


Figure 16. The oscillometric envelope waveform of a PAC/PVC patient.

4.4. Results

In this study, we refer to the QRS complex position to label the location of the pulse wave signal. The pulse wave signal has a first peak and a second peak. We use the local maxima of the first peak of the pulse wave as the reference point to label. For the local maxima labeling point of each pulse wave, the position of the error within the three points detected by the algorithm is a true positive (TP). If the position detected by the algorithm is out of the range of three points, or if it is not detected, it is a false negative (FN). This study's pulse wave sampling rate was 5 kHz, so the error of three points is approximately 0.6 ms. Table 2 shows the analysis results of the pulse wave signals of PAC patients. The total beat (TB) of the normal pulse wave was 187, of which TP was 186 and FN was 1; the sensitivity (Se) and the accuracy (Ac) were 99.4%, and the pulse wave when PAC occurred had a TB of 19, TP of 17, FN of 2, Se of 89.4%, and Ac of 89.4%. Figure 17 compares the PWVs of PAC patients, including the pulse waves of PACs and the statistical distribution of PWV with the PAC removed (normal pulse waves). The range of values significantly reduced without PAC, so the accuracy of PWV can be improved if the pulse wave of PAC can be detected and filtered.

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Table 2. Results of analyzing the pulse wave signal of PAC patients.

Pulse Wave Statistic	TB	TP	FN	Se (%)	Ac (%)
Normal	187	186	1	99.4	99.4
Abnormal	19	17	2	89.4	89.4

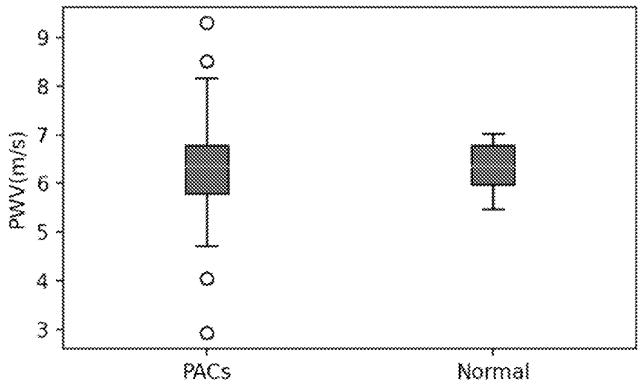


Figure 17. PWVs of PACs compared to the statistical distribution of PWV with the PAC removed (normal pulse wave).

Table 3 lists the results of analyzing the pulse wave signals of PVC patients. The TB of the normal pulse wave was 195, while TP was 195, FN was 0, Se was 100.0%, and Ac was 100.0%. The pulse wave when PVC occurred had a TB of 14, TP of 12, FN of 2, Se of 85.7%, and Ac of 85.7%. We used the same signal analysis as the previous section. The amplitude of the first peak of the pulse wave when PVC occurred was significantly attenuated when too close to the second peak. The algorithm detection is more complex than with the pulse wave signal when PAC occurs. Figure 18 compares the PWVs of patients with PVC, including the pulse waves of PVCs, the statistical distribution, and the normal pulse wave after removing the PVC. The results are similar to Figure 17. The range when PVC was included was more extensive than the statistical distribution of PWV with PVC filtered out.

Table 3. Results of analyzing the pulse wave signals of PVC patients.

Pulse Wave Statistic	TB	TP	FN	Se (%)	Ac (%)
Normal	195	195	0	100	100
Abnormal	14	12	2	85.7	85.7

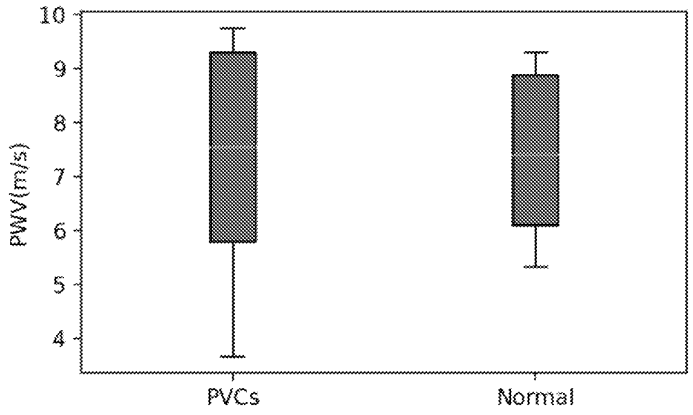


Figure 18. PWVs of PVC and the statistical distribution of the PWV of the normal pulse wave after removing the PVC.

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Equation (23) is the MK equation, where E_{inc} is Young's modulus, D is the diameter of the radial artery (m), h is the wall thickness of the radial artery (m), and ρ is the whole blood density of 1061 kg/m^3 [30]. Equation (24) illustrates the relationship between PWV and pressure P (mmHg), where E_{inc} is Young's modulus, and E_0 and γ are used as coefficients in this study, and are 1428.7 and 0.031, respectively [31]. The Young's modulus of the previous article is from pressure-volume curves of the aorta in animal experiments [32]. In the relationship between PWV and P of the MK equation, previous studies have shown that P is approximately the mean arterial pressure (MAP) because the systolic period is 1/3 and the diastolic period is 2/3 [33]. Therefore, MAP is approximately equal to 1/3 of SBP plus 2/3 of DBP. For comparison, we convert the SBP and DBP measured by the aneroid sphygmomanometer into MAP through Equation (25).

$$PWV = \sqrt{\frac{E_{inc} \cdot h}{D \cdot \rho}} \tag{23}$$

$$E_{inc} = E_0 \cdot \exp^{\xi \cdot P} \tag{24}$$

$$MAP = \frac{SBP + (2 \cdot DBP)}{3} \tag{25}$$

Table 4 shows the physiological parameters of the PAC/PVC subjects. We used the MK equation to estimate the MAP of each PWV and then averaged the MAPs. The PWVs of the pulse wave signals when an arrhythmia occurred are not excluded. The mean difference of the MAP estimate by the MK equation and the aneroid sphygmomanometer was greater than the mean difference of MAP that filters the pulse wave signal during an arrhythmia. This is because when an arrhythmia occurs, the hemodynamics of the radial artery change, making the pulse wave unstable and causing an error in the calculation of PWV. Therefore, estimating blood pressure by PWV with the MK equation can avoid the issue of the oscillometric method. Electing pulse wave signals when an arrhythmia occurs and filtering out arrhythmia can further improve its accuracy.

Table 4. Physiological parameters of the PAC/PVC subjects.

Subject Characteristics	Patient with PACs	Patient with PVCs
Artery diameter (mm)	1.75	2.35
Artery wall thickness (mm)	0.39	0.47
Mean $PWV_{Arrhythmia}$ (m/s)	6.15	6.77
Mean PWV_{Normal} (m/s)	6.34	7.14
$SBP_{Reference}$ (mmHg)	112	126
$DBP_{Reference}$ (mmHg)	74	86
$MAP_{Reference}$ (mmHg)	86.54	99.2
Mean $MAP_{Arrhythmia}$ (mmHg)	81.78	91.5
Mean MAP_{Normal} (mmHg)	83.7	94.8
$MD_{Reference-Arrhythmia}$ (mmHg)	4.76	7.7
$MD_{Reference-Normal}$ (mmHg)	2.84	4.4

5. Conclusions and Future Work

The piezoelectric sensor proposed in this study measured the pulse wave signal when a subject's arrhythmia occurred. We verified that the piezoelectric ceramic with a cavity structure and our AFE design could measure the occurrence of PAC/PVCs. The pulse wave detection algorithm was verified based on the dynamic threshold of our proposed technique, which can recognize ectopic beats. We used a piezoelectric sensor to collect the pulse wave signals of patients with arrhythmia, showing that the algorithm detects the pulse wave's position when the PAC/PVC in the arrhythmia occurs. Our experimental results prove that our proposed pulse wave detection method has an accuracy of 99.4% for PAC patients' normal pulse wave signal and 89.4% for the pulse wave when PAC occurs. The normal pulse wave signal for PVC patients has an accuracy rate of 100%, and

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the pulse wave when PVC occurs has an accuracy rate of 85.7%. We compare the mean difference between the MAP of the pulse wave when the arrhythmia occurs and the aneroid sphygmomanometer. For PAC patients, the MAP result of the pulse wave without PAC is 4.76 mmHg, and the MAP with the pulse wave when PAC occurs is 2.84 mmHg. For PVC patients, the MAP result of the pulse wave without PVC is 7.7 mmHg, and the MAP that filters out the pulse wave when PAC occurs is 4.4 mmHg. Therefore, for PAC/PVCs patients, filtering out the pulse wave when an arrhythmia occurs can effectively reduce the error with the aneroid sphygmomanometer and significantly improve the accuracy of non-invasive blood pressure measurement for arrhythmia patients. This approach also avoids the oscillometric method's inaccuracy caused by the distortion of the envelope curve during an arrhythmia. Future research can use this method to obtain more pulse waves of different types of arrhythmia patients through experiments. The method we propose provides non-invasive blood pressure measurement technology during an arrhythmia that improves the accuracy of the wearable device for patients with arrhythmia. **Author**

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Hi Megan,

Here is the ninth email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: Mukibi, Sherifah * [Sherifah.Mukibi@fda.hhs.gov]
Sent: 5/9/2023 6:00:27 PM
To: (b)(6)
Subject: Corrected K222658/A001 Acknowledgment Notification
Attachments: Acknowledgment Letter-K222658_A001.pdf

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

Acknowledgment Letter

5/9/2023

Douglas Herrington, Official Correspondent
Herrington Consulting LLC
No 64, Haijing 3rd St
Sanzhi District
New Taipei City 252
TAIWAN

Dear Douglas Herrington:

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: K222658/A001
Received: 05/09/2023
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

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.

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

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Sincerely yours,

Center for Devices and Radiological Health

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Douglas Herrington

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(b)(4)

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Doug

Douglas Herrington

Herrington Consulting LLC

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Principal Consultant

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(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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Principal Consultant

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Cover Letter

FDA/CDRH/DCC
OCT 17 2022
RECEIVED

K222658
Accurate Meditech Inc.
Contact Name: Kuan-Jen, Wang/General Manager

k222658/S001

October 14, 2022

Kimberly Crowley
Lead Reviewer
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

Re: K222658, Response to RTA Requested Additional Information
Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24_BPM

Dear Kimberly,

We, Accurate Meditech Inc, in accordance with the additional information (RTA) request on Sep. 12, 2022, are submitting the supplementary document of the 510(k) submission for K222658, Accurate 24 Non-Invasive blood pressure monitor. Kindly refer to the attachments for the reply to the additional information request, including the answers to the questions and the revised document as per your request.

Please contact Kuan-Jen, Wang/General Manager at +886 2 2999-1596, or via e-mail at stanley@accurate-meditech.com, should you have any questions regarding this 510(k) submission.

Sincerely,

(b)(6)

Kuan-Jen, Wang
Accurate Meditech Inc.
8F-10, No. 12, Ln, 609, Sec. 5, Chongxin Rd.,
Sanchong Dist. New Taipei City
241406 Taiwan

Phone: +886 2 2999-1596
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Mobile Networks and Applications (2022) 27:728–738
https://doi.org/10.1007/s11036-019-01323-6

Detection and Removal of Motion Artifacts in PPG Signals

David Pollreisz[1] · Nima TaheriNejad[1]

Published online: 8 August 2019
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Abstract
With the rise of wearable devices, which integrate myriad of health-care and fitness procedures into daily life, a reliable method for measuring various bio-signals in a daily setup is more desired than ever. Many of these physiological parameters, such as Heart rate (HR) and Respiratory Rate (RR), are extracted indirectly and using other signals such as Photoplethysmograph (PPG). Part of the reason is that in some cases, such as RR measurements, the devices which directly measure them are cumbersome to wear and thus, rather impractical. On the other hand, signals, such as PPG from which the RR can be extracted, are not very clean. This poses a challenge on reliable extraction of these metrics. The most important problem is that they are corrupted by motion artifacts. In this paper, we review the state of the art algorithms which are used to detect and filter motion artifacts in PPG signals and compare them in terms of their performance. The insight provided by this paper can help the scientists and engineers to obtain a better understanding of the field and be able to use the most suitable technique for their work, or come up with innovative solutions based on existing ones.

Keywords Motion artifact · PPG · Wearable devices · Health-care systems

1 Introduction

The face of health-care systems across the globe is changing thanks to Wearable Health-care Systems (WHS) and Internet of Things (IoT), and their benefits such as cost effectiveness and the extended information they provide [1–6]. Their applications ranges from daily well-being purposes to emotion recognition [7, 8], Early Warning Score (EWS) [4, 9, 10], and detection of epileptic seizures [11]. Moreover, typical medical devices in the health-care domain that are present in a hospital are expensive and need trained practitioners to operate them. In contrast, wearable devices can be operated by general public, cost little, and can be deployed to perform their job inside and outside hospitals [4, 6]. This can reduce hospitalization and play an important role for the aging population. [4, 6, 10, 12].

However, one of the main challenges that WHSs face is that of accuracy and noise [4, 10, 13]. This is an important factor since many of these devices have limited number of sensors and many of the extracted information are indirectly obtained through those sensors. Thus, their inaccuracy can propagate through the system and lead to false diagnoses. One of these fundamental and widely-used sensors is the Photoplethysmograph (PPG) because it is easy to use, cheap and can help in extracting many health-care parameters of interest. PPG measures the blood pulse wave from which the heart rate, its variations and even the respiratory rate can be extracted. Through physiological mechanisms respiration modulates the blood volume pulse in three different ways: Amplitude Modulation (AM), Baseline Wanderer (BW) and Frequency Modulation (FM) [14]. From these features respiratory rate can be extracted.

The largest problem with the proper extraction of these health parameters is that the PPG signals are often measured during various kinds of movement and therefore are corrupted with motion noise. This noise can appear in the form of unruly signals of large amplitudes in the PPG signals. It is also reflected in the frequency domain and overlaps with the frequency range of breath or heart rate [15]. Luckily, another fundamental sensor which is often integrated in wearable devices is an accelerometer which helps in detection and removal of this noise. With the accelerometer (or similar reference signals) it is possible to measure movement and link it to the part of the respiratory signal which is corrupted with motion artifacts [16, 17]. With a reference signal (such as the acceleration) it is easier to remove the motion noise. This is particularly important when the noise lays in the same frequency band as the signal

✉ Nima TaheriNejad
nima.taherinejad@tuwien.ac.at

[1] Technische Universität Wien, Vienna, Austria

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of interest [16]. Therefore, traditional filtering methods may not work well since they cannot distinguish between the sought after signal and the movement noise.

Nevertheless, there are some possibilities to alleviate this issue (contamination of the signal due to motion artifacts) even if no acceleration signal is available. Mainly, thanks to the fact that if there is no noise, some statistical values are almost the same over time. Thus, it is possible to calculate values such as skewness and kurtosis [18], set them as thresholds and compare them to the upcoming periods and consequently mark parts of the PPG signal as corrupt. The disadvantage of these methods is that it only marks the faulty parts and cuts them out entirely. To overcome this problem it is possible to generate a syntethic reference signal out of the corrupted PPG signal [19] with the use of Empirical Mode Decomposition (EMD).

In this paper, we review the state of the art regarding all aforementioned methods as well as their advantages and disadvantages. This should provide designers with a good insight into design challenges and possible solutions in their specific applications. The rest of the paper is structured as follows: The methods for detection or reduction of motion artifacts which do not use acceleration data are presented in Section 2. Methods using synthetic reference signals are reviewed in Section 3 and those which measure the acceleration signal using a dedicated sensor are presented in Section 4. Afterwards the result of all different methods are summarized and compared in the Section 5. Finally, Section 6 concludes the paper.

2 No acceleration data

If there is no accelerometer or other reference signals available, the motion artifacts can mainly be marked and cut out - but not filtered out. In this section, we review three different methods for this purpose.

2.1 A statistical approach

The simplest approach does not use any extra sensors for acceleration or try to reproduce it. As proposed in [18], they use only statistical parameters of the PPG signal to detect and cut out signal parts contaminated with Movement Artifacts (MAs). As seen in Fig. 1, the first step of the algorithm is to filter the corrupted signal using a band-pass filter with the passing band of 0.5 to 6Hz, which is the main frequency band of interest for heart rate.

Afterwards it is segmented based on the signal period and from the segmented signal the standard deviation, skewness, and kurtosis is calculated using Eqs. 1, 2, and 3, respectively, where $\bar{x}$ is the mean value. If there is no movement during the recording, the statistical values such as kurtosis, skewness, and standard deviation for each cycle are almost equal. These values are then calculated and set as thresholds for the comparison algorithm.

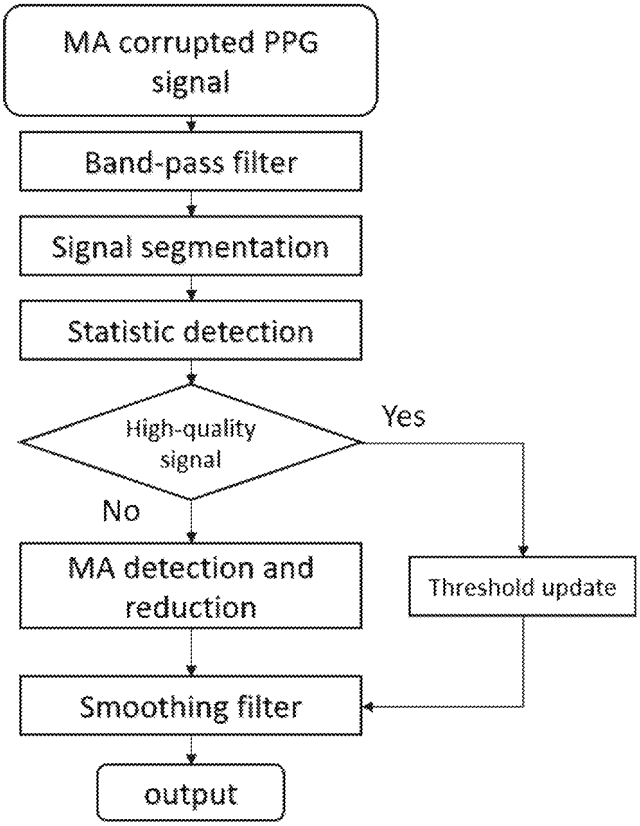


Fig. 1 Flowchart of MA removal algorithm with no acceleration data [18]

$$\text{std} = \sqrt{\frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^2} \tag{1}$$

$$\text{skewness} = \frac{\frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^3}{std^3} \tag{2}$$

$$\text{kurtosis} = \frac{\frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^4}{std^4} \tag{3}$$

If there are movement, the amplitude of the PPG signal changes greatly and consequently the statistical parameters rise above the formerly set thresholds and the signal is marked as corrupt. The corrupted signal is then cut out of the original signal and only the clean signal is left.

The method was tested with 10 healthy subjects who had to perform four different tasks: (i) no movement, (ii) finger movement, (iii) wrist movement, and (iv) elbow movement. They recorded the PPG signal with a TI's AFE4400-SPO2EVM sensor, which is a chest strap. According to a set threshold, a part of the signal is marked as corrupted with movement and cut out as seen in Fig. 2. They compare their

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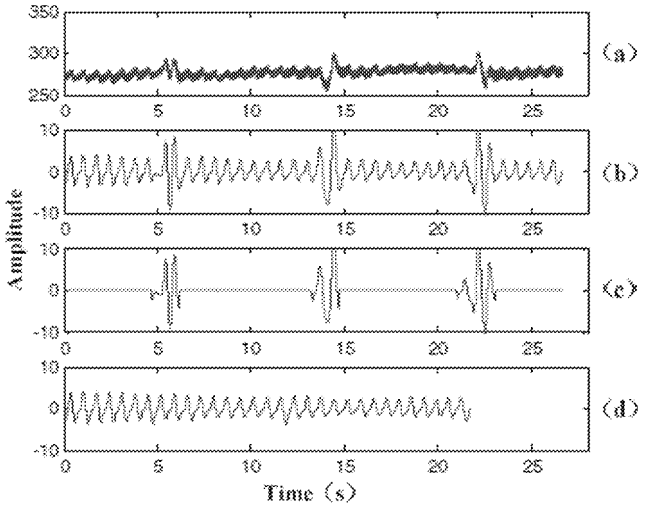


Fig. 2 **a** Original PPG signal, **b** PPG after pre-processing, **c** detected movement, **d** cut-out algorithm applied [18]

results with an Independent Component Analysis (ICA)-Least Mean Square (LMS) algorithm. The corrupted PPG signal had a mean Standard Deviation (STD) error of 7.16 ± 0.36 Beat Per Minute (BPM) for elbow movement, 6.12 ± 0.65 BPM for wrist movement and 11.02 ± 0.56 BPM for finger movement. The ICA-LMS method had an error of 6.39± 1.46 BPM for elbow movement, 6.41 ± 1.38 for wrist movements and 10.6 ± 1.67 for finger movement. Therefore, the statistical method had a mean error of 6.58 ± 1.32 BPM for elbow movement, 6.22 ± 0.8 for wrist movement and 10.77 ± 1.09 for finger movement. Overall, for all three motions, the proposed algorithm had a mean error of 7.85 BPM, compared to the original 8.1 BPM of the corrupted signal.

2.2 Variable frequency complex demodulation

Here we describe another method which does not use a reference signal but an algorithm based on Variable Frequency Complex Demodulation (VFCDM) [20]. This detection method looks at dominant peak amplitudes and dominant frequency components. Each 30 seconds of the PPG signal was first band-pass filtered to 0.5Hz - 10Hz using a 6th order zero-phase Butterworth filter, detrended, and then normalized by the maximum. On this signal a peak detection method is used to mark all the peaks of the PPG signal. If there is a gap between the finger and the camera (their PPG sensor) this induces motion artifacts. Such motion artifacts are marked in the 30 second windows of the PPG signal with the pre-processing filtering and peak detection. Afterwards, to detect artifacts the VFCDM method is used to differentiate spectral characteristics of the noise from the clean PPG signal. The first step involves obtaining the initial time-frequency spectrum using fixed frequency complex demodulation. For the next step, the complex demodulation is calculated by using the center frequencies of the previously obtained time-frequency spectrum. In a clean signal, the dominant frequency for the heart rate is nearly continuously present and between 0.5 - 3.5 Hz but in a corrupted signal the dominant frequency can shift due to the noise and thus, lead to a wrong Heart rate (HR) detection. Out of these differences a threshold system was developed to mark signals as moderately corrupted and corrupted. After the signal is marked as corrupted it can be deleted as in the method before.

For this work 200 subjects took part of the experiments to test the algorithm and 521 recordings were made, each one minute long. The used signal was recorded using an iPhone camera and the PPG signal was extracted based on the average of 50x50 pixels of the green band. Out of these signals three features were extracted: root mean square of successive differences, Shannon entropy and sample entropy. These features are then used in a linear Support Vector Machine (SVM) classifier to detect irregular heart rhythms. The SVM was trained with 82 clean signals and tested with 898 segments (30 seconds each). Without the noise detection algorithm out of 449 recordings 156 were misclassified and with the noise detection only 29 were false positives.

2.3 Discrete wavelet transform

In the Discrete Wavelet Transform (DWT) method, it is tried to identify the heart rate out of the PPG signal [21] without any reference signal, even if it is corrupted with motion artifacts. This is a method that uses a few measurements of noise to generate an estimate of unknown states. First, as seen in Fig. 3, the data is pre-processed. In this step, the DC components are separated from the AC component and with a wavelet transformation the PPG signal is first decomposed and afterwards the components in the bandwidth of 0.39 - 12.5 Hz are reconstructed.

In the next step, the following features are extracted: standard deviation of peak-to-peak amplitudes as in Eq. 1, standard deviation of peak-to-peak intervals, the kurtosis as calculated in Eq. 3, and Mean Absolute Deviation (MAD) of peak-to-peak amplitudes as in

$$MAD_n = \sum_{i=1}^{N} \frac{|A_{n,i}, -\bar{A}_n|}{N} \tag{4}$$

where A_n is the peak-to-peak amplitude and N is the number of peak-to-peak intervals in the signal.

An SVM is then used to classify the data sets after training and a 10-fold cross-validation. To remove motion artifacts Kalman filter is used. The filter observes a series

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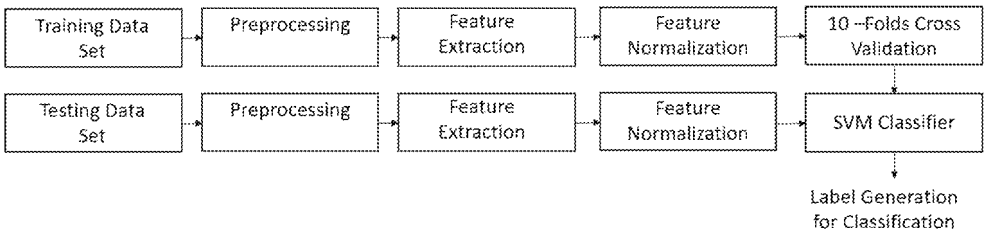


Fig. 3 The Flowchart of the DWT algorithm with one path for training and the other to test it [21]

of corrupted signals to generate an estimate of the unknown state. First the controlled process x, is calculated by

$$x_k = Ax_{k-1} + Bu_{k-1} + w_{k-1}, \tag{5}$$

and a measurement, z, is described by

$$z_k = Hx_k + v_k, \tag{6}$$

where w_k and v_k are random variables that represent the process and measurement noise. The matrix A is the state transition matrix and the matrix B is the optional input model for the control u_k. Matrix H relates to the measurement z_k, as shown in Eq. 6.

To test their algorithm, eleven subjects took part in the measurements and they had to perform two different motions; (i) keep their hand still for one minute, and (ii) wave their hand. This was done to identify and remove motion artifacts from two PPG sensors that were attached to the left and right index finger. During their analysis, they found out, that for their tests a window length of seven seconds had the best results. With their method, they could reduce the absolute bias from 13.97 BPM to 6.87 BPM.

3 Synthetic reference data

3.1 EMD technique

Another possible solution without an accelerometer signal is to generate a reference signal from the corrupted PPG signal using Complex Empirical Mode Decomposition (CEMD) technique [19]. To generate the reference noise signal the following steps have to be done. First, all the local minima and maxima of the originals signal ($x(t) = d(t) = S(n) + N(n)$) need to be found. The next step is to envelope all the maxima ($umax$) and all the minima ($umin$). After all the envelope signals are generated, the mean value, $m(t)$, is calculated:

$$m(t) = \frac{umax + umin}{2}. \tag{7}$$

The value of the mean is then subtracted from the original signal: $h(t) = x(t) - m(t)$. The new signal $h(t)$ is decomposed into Intrinsic Mode Function (IMF) by sifting process until $h(t)$ meets the IMF conditions. The next step is to identify the quasi-residue function $r(t) = x(t) - c$. This loop has to be repeated until $r(t)$ has only one extrema. Afterwards, the spectrum of each IMF based on the predefined frequency range has to be computed. The last step to generate the reference noise signal is identifying the desired signal portion range and eliminating IMF corresponding to the desired frequency components of the PPG.

For the "adaptive step-size LMS algorithm" block, seen in Fig. 4, an estimate of the gradient to search the minimum error on the surface is used. The error of each step is reduced by updating the step size parameter. To implement the adaptive filter the following steps as seen in Eq. 8 to Eq. 12 are used.

$$y(n) = w^T(n)u(n) \tag{8}$$

$$e(n) = d(n) - y(n) \tag{9}$$

$$w(n+1) = w(n) + \mu e(n)u(n) \tag{10}$$

$$\mu(n+1) = \mu(n) + \rho e(n)\gamma^H(n)u(n) \tag{11}$$

$$\gamma(n) = \frac{\mathrm{d}}{\mathrm{d}\mu(n)}(w(n)) \tag{12}$$

where $u(n)$ is the generated reference signal, $y(n)$ the filter output, $w(n)$ the filter coefficients, $e(n)$ the error, $d(n)$ the PPG signal (which would be the desired output if there is no noise), μ the step size, γ^H the gradient vector and ρ controls the step size parameter.

Figure 5 is an example of the results of the algorithm designed in [19]. The test subjects had to perform three different movements with their finger: (i) horizontal motion, (ii) vertical motion, and (iii) bending. For the measurement

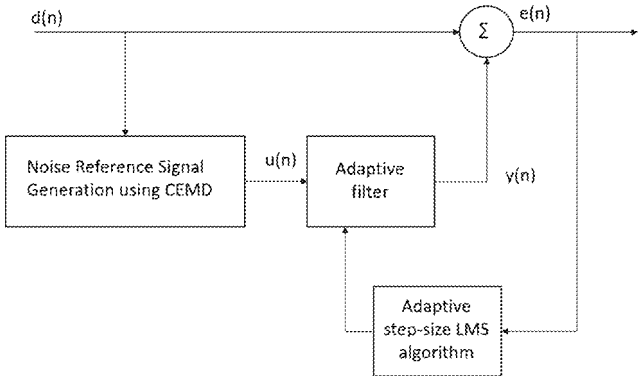


Fig. 4 Adaptive filter using CEMD technique to generate the reference signal out of the PPG signal [19]

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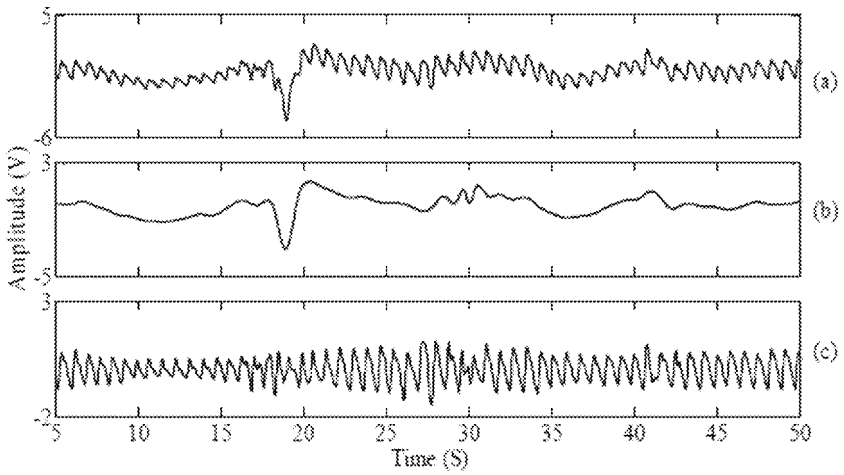


Fig. 5 **a** Original signal, **b** generated movement signal, **c** original signal minus the movement noise [19]

of the PPG signal a clip-on type PPG sensor with an Ni-DAQ Pad-6015 data acquisition system was used. To compare the original corrupted signal with the signal without noise, the peak to peak values of the PPG signal are compared. For corrupted PPG signal with horizontal motion the mean error is 0.426 ± 0.087 BPM, with vertical movement 0.514 ± 0.107, and for bending motion 0.459 ± 0.067. In comparison, the proposed algorithm had an error of 0.379 ± 0.036 BPM for horizontal movement, 0.435 ± 0.059 for vertical movement, and 0.363 ± 0.131 for bending motion. Overall, the mean error of the proposed algorithm is 0.392 BPM compared to 0.466 BPM of the (originally) corrupted signals.

3.2 Dual PPG sensor

A similar approach that uses synthesized reference signal was shown in [22]. A second PPG sensor is used to generate the movement signal. The second PPG sensor is positioned a few millimeters[1] away from the skin, as seen in Fig. 6a, so it only measures when the subject is in motion. In Fig. 6b one can see typical outputs of both sensors, first few seconds without motion and afterwards with motion.

This algorithm starts by band-pass filtering both of the recorded signals between 0.8 to 5 Hz with a Hanning window of 128 points and a sampling rate of 10 samples per second. Afterwards, an adaptive filter, as seen in Fig. 7, is applied. The $u(n)$ input on Fig. 7 measures the movement and the $d(n)$ is the PPG signal from the sensor which is fully in touch with skin. The adaptive filter tries to bring the difference between $u(n)$ and $d(n)$ down to zero. To do that a Normalized Least Mean Square (NLMS) and Recursive Least Square (RLS) algorithm are applied and two parameters, namely the number of taps, K, and the forgetting factor, λ, are optimized. The output is sliced into windows and fast Fourier transformed.

In [22], only 10 data sets were used to test the algorithm. For their experiments the subjects had to walk, jump, and run. Two PPG sensors, as seen in Fig. 6, that were used were Hamamatsu S9706. They put them on the hip to measure the PPG signal and the movement as well. Since they had only 10 data sets a cross-validation was performed to alleviate this problem. They first selected the n-th data set for validation and use the rest as a training set. Afterwards, the parameters were chosen for the training set and on the chosen validation set the error, E_n, was calculated. These two steps were repeated for all data sets and at the end the average error was calculated. To find the optimal parameter values, the authors swept the K values from 5 to 50, and β from 0.01 to 0.9. With the optimal parameters, the algorithm can reduce root mean square error by 62% for the walking, 83% for the running, and 79% for the jumping. That is, a Root Mean Square Error (RMSE) of 6.5 BPM after reduction and 28.26 BPM RMSE before reduction.

4 Measured acceleration data

4.1 LMS filtering

One of the methods based on acceleration sensors to remove motion artifacts is presented by [16]. The flow diagram of the proposed algorithm is shown in Fig. 8. First, the raw PPG signal is band-pass filtered with a 4th order Butterworth Infinite Impulse Response (IIR) filter in the range of 0.3–5 Hz. For the motion data filtering block a Singular Value Decomposition (SVD) is used which generates a motion artifact reference for the adaptive filter. In the third block of the algorithm, the in-band removal takes place. There, they use a modified LMS adaptive filter, where the coefficients, $h(n)$, are updated based on the least

[1] We could not find what is the exact number for this gap.

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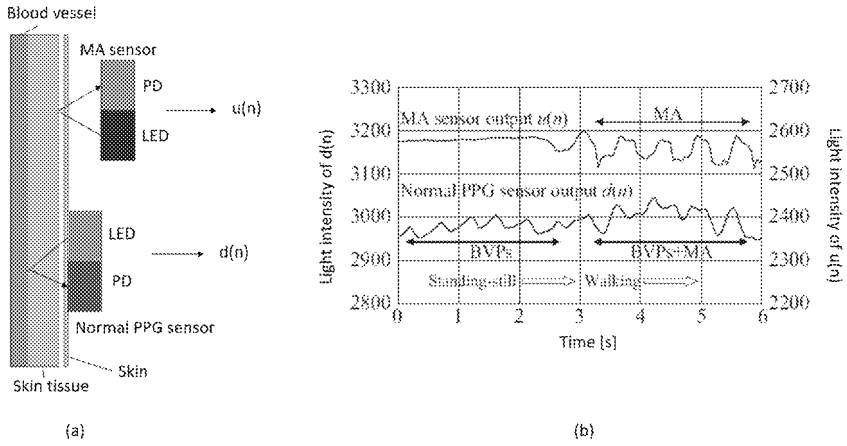


Fig. 6 **a** Application of the two PPG sensors on the skin, where the second sensor is a few millimeter away. **b** The typical output of a two PPG setup [22]

mean error, $e(n)$. An identical filter is placed in the reference signal path to adjust the weights. This adjustment is called X-LMS. In Eqs. 13–16 the X-LMS calculations are shown,

$$y_c(n) = w^T(n) * u(n) : \text{Output generation} \quad (13)$$

$$e(n) = d(n) - y_C(n) : \text{Error calculation} \quad (14)$$

$$u_{C^*}(n) = \sum_{i=0}^{I-1} c_i^* * u(n-i-M+1) \quad (15)$$

$$w(n+1) = w(n) + \mu * u_{C^*}(n)e(n) : \text{Weight updates} \quad (16)$$

where $u(n)$, $d(n)$ and $e(n)$ are input, desired output and error, respectively. $w(n)$ are the weights of the estimated filter and μ the step size. c_i^* represents the coefficients of estimated filter for compensation, and $u_{C^*}(n)$ is the reference signal as one can see in Fig. 9. In the last part, the peak tracking takes place with some adaptive threshold levels. This is done with the Slope Sum Method (SSM), where they use a window size of 2-3 seconds to detect onset and offset of each peak.

For the experiments in [16], 12 different subjects took part and they had to do different exercises such as running up to 12-15km/h. A dual channel PPG alongside a three-axis accelerometer sensor was used to record the data from the wrist with a sampling rate of 125Hz. With the X-LMS method they had an error of 1.37 BPM.

4.2 RLS filtering

A similar approach is proposed by [17]. Instead of X-LMS they use a DC Remover and an RLS adaptive filter. The first step of the algorithm, as shown in Fig. 10, is the DC removal. This IIR filter removes the offset of the PPG signal and thus the RLS adaptive filter has a faster convergence speed compared to an LMS algorithm. The output of the DC remover is the AC component of the PPG signal. The following, Eqs. 17–19, describe the DC remover.

$$w(t) = x(t) + a * w(t-1) \quad (17)$$

$$y(t) = w(t) - w(t-1) \quad (18)$$

$$\frac{Y(Z)}{X(Z)} = \frac{1 - Z^{-1}}{1 - a * Z^{-1}} \quad (19)$$

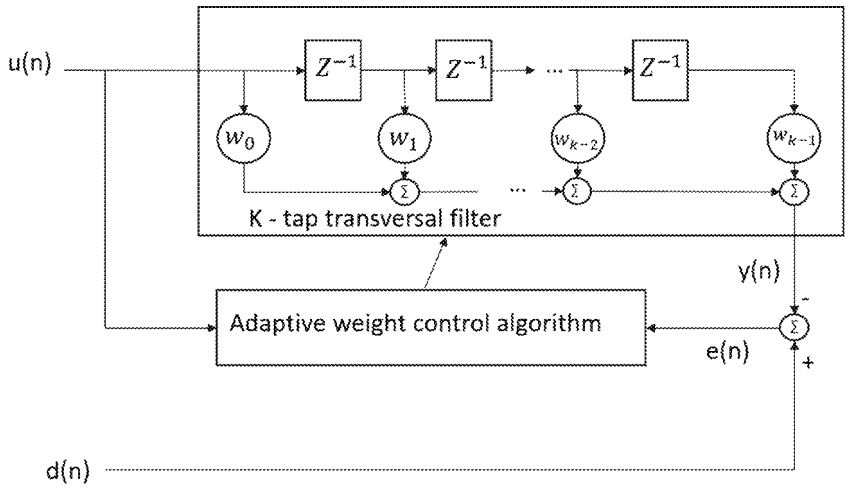


Fig. 7 Adaptive filtering using a second PPG sensor, located a few millimeters afar from the skin of the subject [22]

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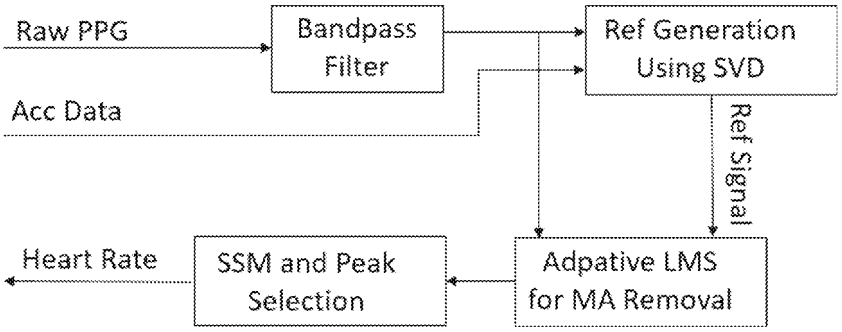


Fig. 8 Flow diagram of the algorithm that uses SVD and LMS adaptive filter to remove motion artifacts [16]

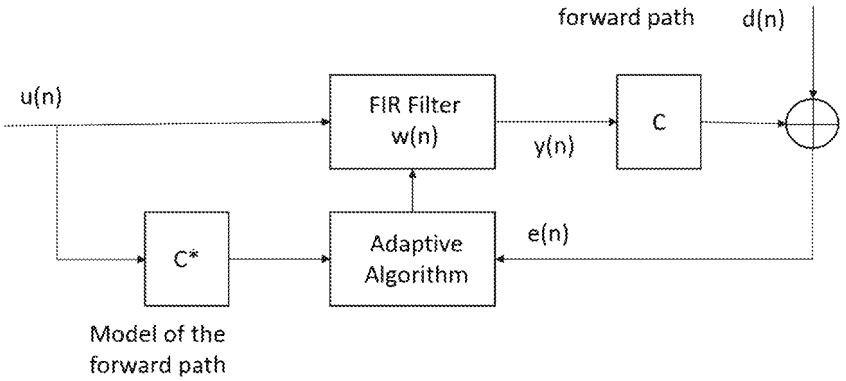


Fig. 9 The flowchart of the LMS adaptive filter [16]

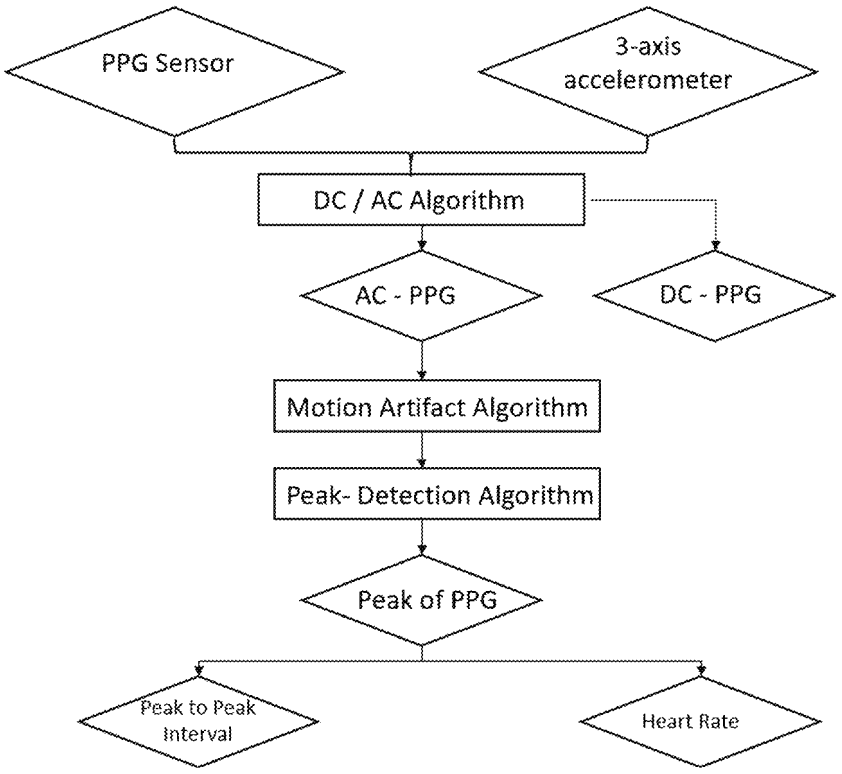


Fig. 10 Flow chart of a motion artifact removal algorithm that uses a 3-axis accelerometer to remove the movement artifacts [17]

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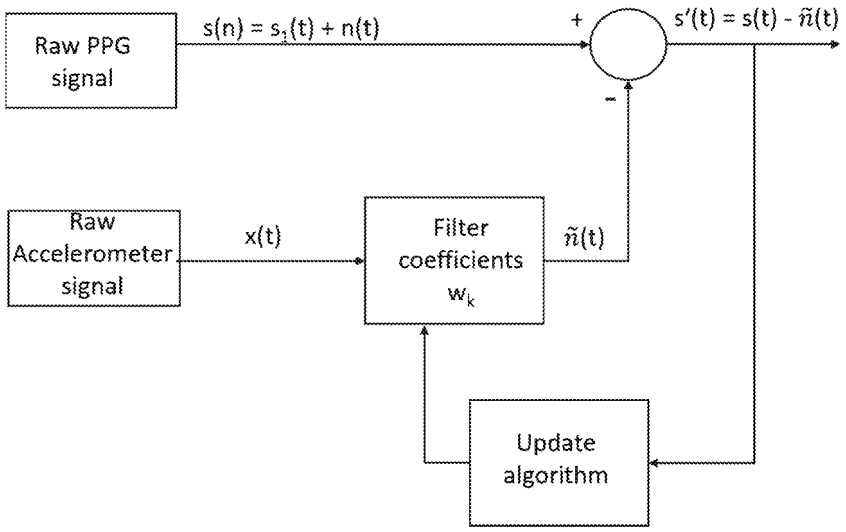


Fig. 11 Flow chart of the algorithm which uses an X-LMS adaptive filter [17]

In these equations, $w(t)$ is the value of the operation process which records the DC drift, and a controls the filter cut-off frequency. When a becomes closer to 1, the slope of the filter response becomes sharper and only the frequencies that disturb the signal are damped, however, when it is 1, the filter effect will be lost. After the signal is removed of its DC values the RLS adaptive filter comes into play.

In Fig. 11, one can see that $s(t)$ is the primary input, x_t is the reference input of the accelerometer sensor, $s_1(t)$ is the noise-free PPG signal and $n(t)$ is the motion noise. Equation 20 shows the formula for calculating the estimated motion noise, where ω_K^T represents the coefficients of the filter, Θ is the matrix of these coefficients, ϕ is the matrix of the accelerometer data, $\hat{n}(t)$ is the estimated motion noise, and t is the sampling time.

$$\hat{n}(t) = \sum_{k=0}^{t} \omega_K^T * x_K = \Theta^T * \phi_t \tag{20}$$

To test their algorithm, in [17], the authors used two different databases. The first one is Multi-parameter Intelligent Monitoring for Intensive Care (MIMIC) and a second set of signals that were measured from 10 subjects, where subjects did small movements such as scratching themselves or shaking slightly. In Fig. 12, we can see the spectrum of a PPG signal after the algorithm removed the motion noise. From the database of the 10 subjects the results of the Bland Altman plot provides a range limit of -4.29 to 4.26 for the difference of the heart rate and the ground truth, with a STD of 3.91 BPM.

4.3 Hankel matrix filtering

The authors of [23] try to overpass previous techniques with Motion Artifact Removal (MAR) and Adaptive Tracking (AT). In [23] they use datasets from subjects who were running. The flow chart of the proposed algorithm can be seen in Fig. 13.

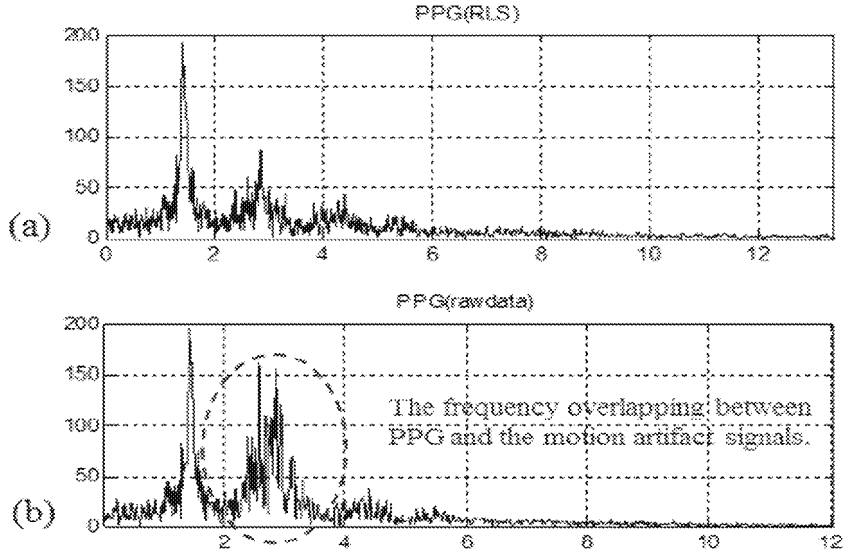


Fig. 12 **a** Cleaned PPG signal, **b** raw PPG signal [18]

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In the first step, the pre-processing, the signals are windowed, filtered and a Hankel data matrix is constructed. The model for the acceleration data is shown in Eq. 21, where X, Y, Z are the three axes of the accelerometer signal and N, and L represent the observations of the three axes accelerometer. H can be decomposed by the SVD and its eigenvalues are calculated by

$$H = [XYZ] \in \mathbb{R}^{Nx3L} \tag{21}$$

The same is done with the PPG signal (g) whose model is shown in Eq. 22, in which e is the heart rate and m is the movement artifact.

$$g = m + e, g \in \mathbb{R}^{N} \tag{22}$$

The corresponding Hankel data matrix of Eq. 22 can be decomposed using SVD. The result of the decomposed process are two orthonormal subsets. When compared with the artifact component, it shows that the artifact and the heart rate signal belong to two orthonormal sub-spaces.

The next step is to find the spectral peaks of the vectors. This is easily done using the calculation in Eq. 22 since the cardiac frequency is the dominant frequency in the matrix. To minimize the error, when motion comes into play, a rough estimation of the joint probability density function of the heart rate versus the motion artifact frequency is performed. This probability function is used to separate the fundamental harmonics of the heart rate from the motion artifact.

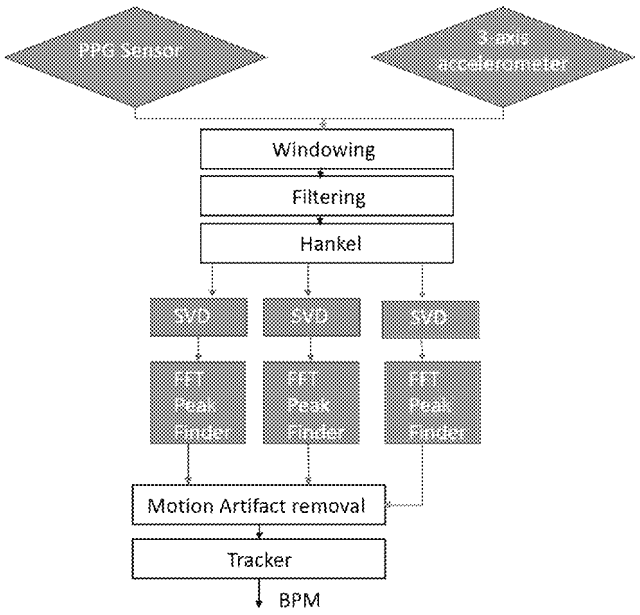


Fig. 13 Flow chart of a system that uses the Hankel matrix to remove motion artefacts [23]

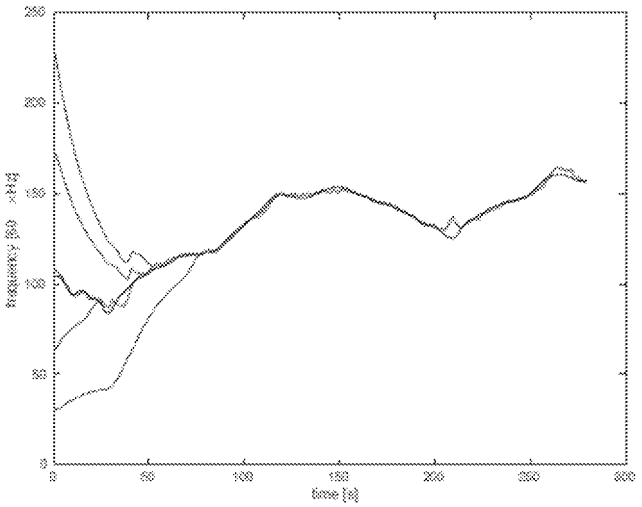


Fig. 14 The proposed algorithm with different starting points (shown in red lines) and ground truth (the black line) [23]

To validate the algorithm, the authors of [23] tested it on 25 test subjects where the subjects wore a wrist type PPG sensors and performed different kind of exercises.[2] In Figure 14, one can see that even for different starting points (red lines) all lines come to the ground truth (black line, an Electrocardiography (ECG) derived signal). The green line is the estimation of the proposed algorithm. They tested their algorithm on subjects that were running and overall had an average absolute error of 2.26 BPM.

5 Results and discussion

In this section, we review and discuss the results of the previously presented algorithms. The results are presented following the same section division as before. In Table 1 we have inserted an overview of the reviewed algorithms and their results. This table provides information on which algorithm is only for detection and which also removes the motion artifact through filtering. The column Acc. shows which algorithm uses an accelerometer signal and which one does not. A pointer on the used method, number of subjects, and a summary of the results are the other information seen in the table. This information can help design engineers to choose the most suitable method for their application, given its constraints and requirements.

For example, if no accelerometer sensor is available and the mere detection of the motion artifacts suffices, a statistical threshold algorithm [18] can be used. This algorithm only uses statistical calculations like kurtosis or standard deviation. If these values exceed their respective

[2] We could not find exactly what kind of exercises were used.

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Table 1 Overview of reviewed algorithms, their method and results

Paper	Method	App.	Acc.	Subjects	Outcome	Before	Sensor	Movement
Hanyu and Xiaohui [18]	Statistical Evaluation	D	No	10	Peak to Peak Error (PPE) 7.85 BPM	PPE 8.1 BPM	TI's AFE4400SPO2EVM	Finger movement, wrist movement and elbow movement
Bashar et al. [20]	VFCDM	D	No	200	6.45% false positive	NA	iPhone camera	
Lin and Ma [21]	DWT	R	No	11	PPE 6.87 BPM	PPE 13.97 BPM	Wearable PPG sensor from DigiO2	Waving the hand
Raghuram et al. [19]	CEMD LMS	R	Syn.	NA	PPE 0.392 BPM	PPE 0.466 BPM	Ni-DAQ Pad-6015	Horizontal motion, vertical motion and bending of the finger.
Hara et al. [22]	NLMS and RLS	R	Syn.	NA	RMSE 6.5 BPM	RMSE 28.26 BPM	Hamamatsu S9706	Walking, running and jumping
Tanweer et al. [16]	SVD and X-LMS	R	Yes	12	PPE 1.37 BPM	NA	NA	Running
Wu et al. [17]	DC remover and RLS	R	Yes	10	STD 3.81	NA	NA	Scratches and slight shaking
Bacá et al. [23]	MAR and AT	R	Yes	12	Mean absolute error of 2.26 BPM	NA	NA	Different exercises

Missing information are shown by "NA". In the App. (Approach) column "D" stands for detection and "R" for removal of the noise from the signal. In the Acc. (Acceleration data), "Syn." stands for synthetic reference generation

thresholds, this means there were motion artifacts in the signal and it can be marked as such. The marked signal can be then cut out or if they are used for any health measurement, the result could be marked as potentially inaccurate. The Peak to Peak Error (PPE) for this method is 7.85 BPM compared to the corrupted PPG signal with 8.1 BPM PPE. Another way to detect motion artifacts without any accelerometer sensor is to look at the frequency components with VFCDM as seen in Section 2.2. This only needs some values without movement to set some ground truth and compare these values to every value to come. If the signal is corrupted it looks different in the frequency domain, just as in the time domain. With this approach out of 449 recordings only 29 were false positive, in other words, 6.45% miclassification in total.

However, we bear in mind that it is still possible to go beyond mere detection without an accelerometer too. For example, despite signal corruption, using Kalman filter and DWT, it is possible to decompose the signal and reconstruct the good parts [21]. Thus, the motion artifacts can be removed and one can extract the heart rate or Respiratory Rate (RR). The PPE of this method is 6.87 BPM comapred to 13.97 BPM without any filtering. It is also possible to generate a reference signal out of a corrupted PPG signal with EMD [19]. After the reference signal is generated, an adaptive filter can be used to remove motion artifacts. With this method the PPE can be reduced to 0.392BPM from 0.466 BPM. In case a second PPG sensor is available, it can be used to generate a movement signal [22]. The second PPG is applied a few millimeters away from the skin, such that if the subject moves, the distance from the sensor to skin is reduced or increased and therefore the signal changes. Using the difference of the two PPG signals a movement signal and the weights of an adaptive filter can be extracted. The RMSE can be reduced to 6.5 BPM compared to 28.26 BPM before filtering.

With an accelerometer data it is easier to differentiate between contaminated and motion-artifact-free signal and remove it. In one approach, out of the accelerometer data a reference signal is generated with an SVD to adjust the weights of an adaptive filter [16]. This approach has the lowest error of all proposed algorithms with only 1.37 BPM. Compared to the LMS algorithm of [16] a faster algorithm is the RLS [17]. It starts by removing the DC component of the signal and applies an RLS adaptive filter to the signal. Although it gains in speed, it loses in precision. This approach predicts the heart rate with a confidence of 95% in the interval of [-4.29–4.26] BPM of the ground-truth value and has a standard deviation of 3.81 BPM. The most complex algorithm uses MAR and AT [23]. Out of the filtered signals (PPG and accelerometer) the Hankel matrix has to be calculated. Out of this matrix, the noise part has to be calculated and subtracted from the original

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

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signal. It does not have the lowest error value (their error rate is 2.26 BPM), however, they claim that they have the most robust approach of all (which we could not evaluate independently since they do not provide metrics such as STD).

6 Conclusion

In this paper, we reviewed eight different algorithms that either detect motion artifacts or filter them based on a synthesized or measured reference signal. We presented their core idea and features, and summarized their characteristics and results to provide a large picture of the literature and existing methods. We hope that this study can be used by engineers to make a better choice in design regarding what algorithm to use in which situations. Although we did our best to provide a comparison between different methods, we keep in mind that to have a fair and proper comparison, one needs to implement all the algorithms and test them on the same dataset under the same conditions and restrictions. We consider this outside the scope of this paper and as an interesting potential future work.

Funding Information Open access funding provided by TU Wien (TUW).

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Accurate Meditech Inc.- May 2023 Response

(b)(4)

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

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IEEE 1708 Clinical Validation Comparison

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

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Hi Megan

Here is the eighth email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTII/DHTIIA
WO66 RM2567
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Premarket Notification 510(k) Review

Date: December 9, 2022

Reviewer: Meaghan Erlewein

510(k)# K222658/S001 Subject: Traditional

Applicant: Accurate Meditech Inc.	**Device Trade Name:** Accurate 24 Non-invasive blood pressure monitor
Contact Name: Wang Jen	**Contact Title:** General Manager
Correspondent Firm: Accurate Meditech Inc.	**Phone:** 886 (2) 299-91196 **Email:** stanley@accurate-meditech.com
Received Date: October 17, 2022	**Due Date:** January 15, 2023
Pro Code(s): DXN **Class:** II **Reg #:** 870.1130	**Reg Name:** Noninvasive Blood Pressure Measurement System

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K190792	DQA, DXN, DRG	Bb-613wp	BioBeat Technologies Ltd.

(b)(5)

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

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Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Monday, May 22, 2023 7:55 AM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) ; k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

> On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:
>
> Hi Doug,
>
> We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.
>
> Thanks,

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

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(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

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*** 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 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

(b)(4)

This is the second of three emails containing those files. Iâ€™m being limited by the server, so an additional email is required.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

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(b)(4) Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Traceability Analysis

Document Number: (b)(4)

Version: (b)(4)

2022/09/01

Presented by

Falcao / Firmware Manager

Approved By (b)(6) ***Date*** 2022-09-01

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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Hi Megan,

(b)(4)

This is the first of two emails containing those files.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

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Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

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Accurate Meditech Inc.-May 2023 Response

(b)(4)

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Hi Megan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

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Records processed under FOIA Request No. 76915; Released by CDRH on 07-09-2024

Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K222658 Date Received by DCC: Sep 2, 2022

Lead Reviewer: Kimberly Crowley

Center: CDRH Office: OHT 2 Division: DHT2A

Decision:

○ Accept. If Accept, notify submitter.

◉ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ○ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* ~~If the product does not appear to be a device or such a combination product, mark "No."~~	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☒	☐
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☒	☐
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

Records processed under FOIA Request 2024-6063 released by CDRH on 07-09-2024

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (*https://www.fda.gov/media/86323/download*).*	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☒		☐	☒	
a) Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators", available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☐	☐	☒		
b) Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*	☐	☒	☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☒		☐		
i) For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that is was not subject to the regulations under 21 CFR 56.104 or 56.105). **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812.	☐	☐	☒		
ii) For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.	☒	☐	☐		
Comments: Please provide Form 3674					
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☐		☒	☐	
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☐	☒		☒	
Comments:	(b)(4)				
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling).	☐	☐	☒	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☐ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☒ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☐	☒	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☐	☒		☒	
Comments: (b)(4)					
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☐	☒		☒	
Comments: (b)(4)					
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	
☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☒ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☒ Does require electrical safety evaluation					
☐ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Records Processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Digital Signature Concurrence Table

Reviewer Sign-Off	Kimberly N. Crowley -S Digitally signed by Kimberly N. Crowley -S Date: 2022.09.12 15:24:01 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

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Accurate Meditech Inc.-June 9 2023, Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

Here is the first email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

eConsult Cover Sheet

Consult Number: CON2224919

Document Number: K222658/S001

Applicant: Accurate Meditech Inc.

Trade Name: Accurate 24 Non-invasive blood pressure monitor

Consult Type: Analytical

Requestor: Meaghan Erlewein [MEAGHAN.ERLEWEIN]

meaghan.erlewein@fda.hhs.gov

Requestor Home: CDRH\ OHT2\ DHT2A\ THT2A1

Requested Consultant:

Gatekeeper / Consultant: Ahmad Suliman [AHMAD.SULIMAN]

ahmad.suliman@fda.hhs.gov ; 240-402-1799

Consultant Home: CDRH\ OSEL\ DBP

Date Requested: November 2, 2022

Due Date: December 1, 2022

Ahmad S. Suliman -S

Digitally signed by Ahmad S. Suliman -S
Date: 2022.12.05 08:42:00 -05'00'

Instructions: Please refer to consult request email sent 11/1/2022. Thank you!

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: Kucukemiroglu, Saryet
To: Erlewein, Meaghan
Subject: RE: K222658/S003
Date: Wednesday, June 14, 2023 3:29:48 PM
Attachments: image001.png

Hi Meaghan,

(b)(5)

Thanks,
Saryet

(b)(5)

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, June 14, 2023 2:17 PM
To: Kucukemiroglu, Saryet <Saryet.Kucukemiroglu@fda.hhs.gov>
Subject: RE: K222658/S003

Hi Saryet,

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

(b)(5)

Thank you!

-Meaghan

From: Kucukemiroglu, Saryet <Saryet.Kucukemiroglu@fda.hhs.gov>
Sent: Monday, June 12, 2023 11:11 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003

Sure Meaghan! I'll look over their responses and try to have my feedback by Thursday.

Best,
Saryet

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Monday, June 12, 2023 10:33 AM
To: Kucukemiroglu, Saryet <Saryet.Kucukemiroglu@fda.hhs.gov>
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003

Hi Saryet,

(b)(5)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Wednesday, June 7, 2023 1:56 PM
To: Kucukemiroglu, Saryet <Saryet.Kucukemiroglu@fda.hhs.gov>
Subject: RE: K222658/S003

Thank you!

From: Kucukemiroglu, Saryet <Saryet.Kucukemiroglu@fda.hhs.gov>
Sent: Wednesday, June 7, 2023 1:55 PM

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: Lu, Hong (Laura) <Hong.Lu@fda.hhs.gov>; Huang, Lan <lan.huang@fda.hhs.gov>
Subject: K222658/S003

Hi Meaghan,

(b)(5)

Best,
Saryet

Saryet Kucukemiroglu, PhD
Mathematical Statistician, Biostatistics Team 3
DCEA2: Division of Biostatistics | OCEA: Office of Clinical Evidence and Analysis
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. G450
Ph: 301-796-4671
Email: Saryet.Kucukemiroglu@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1123&S=E

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Date: June 7, 2023

From: Saryet Kucukemiroglu, Ph.D. (Mathematical Statistician)
CDRH/OCEA/DCEA2/TCEA2C

Saryet Kucukemiroglu -S
Digitally signed by Saryet Kucukemiroglu -S
Date: 2023.06.07 13:51:11 -04'00'

Subject: Statistical Review of K222658/S003 Accurate 24 Non-invasive blood pressure monitor by Accurate Meditech Inc. (DHP yes, SaMD no, not software only, SaMD AI/ML no, RWE no, data reuse no)

To: Meaghan Erlewein, PhD
CDRH\OHT2\DHT2A\THT2A1

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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U.S. FOOD & DRUG ADMINISTRATION

eConsult Cover Sheet

Consult Number: CON2312431

Document Number: K222658/S003

Applicant: Accurate Meditech Inc.

Trade Name: Accurate 24 Non-invasive blood pressure monitor

Consult Type: Analytical

Requestor: Meaghan Erlewein [MEAGHAN.ERLEWEIN]

meaghan.erlewein@fda.hhs.gov

Requestor Home: CDRH\ OHT2\ DHT2A\ THT2A1

Requested Consultant:

Gatekeeper / Consultant: Ahmad Suliman [AHMAD.SULIMAN]

ahmad.suliman@fda.hhs.gov ; 240-402-1799

Consultant Home: CDRH\ OSEL\ DBP

Date Requested: May 18, 2023

Due Date: June 7, 2023

Instructions: Please refer to consult request email sent 5/15. Thank you!

(b)(5)

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

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 2023-10915; Released by CDRH on 07-09-2024

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 10/17/2022 4:18:31 PM
To: stanley@accurate-meditech.com
CC: DCCLetters@fda.hhs.gov
Subject: K222658/S001 Acknowledgement Letter
Attachments: K222658-S001-Acknowledgement Letter.pdf

October 17, 2022

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.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgement Letter

10/17/2022

Wang Kuan Jen, General Manager
Accurate Meditech Inc.
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.,
New Taipei City,
241406 TAIWAN

Dear Wang Kuan Jen:

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 .

Submision Number: K222658/S001
Received: 10/17/2022
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

We will notify you when the review of this submission 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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thank you. Appreciate you letting me know.

Best

Doug Herrington

> On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:
>
> ï»¿
> Hi Doug,
>
> I just wanted to let you know we received the full response yesterday.
>
> Thanks,
> Meaghan
>
> From: (b)(6)
> Sent: Friday, May 12, 2023 7:53 AM
> To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON'
(b)(6)
> Cc: k222658@docs.fda.gov
> Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> 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 Meaghan,
>
> Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.
>
> Best
> Doug
>
> Herrington Consulting LLC
> Douglas Herrington
> Principal Consultant
>
> From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> Sent: Friday, May 12, 2023 7:40 PM
> To: Douglas HERRINGTON (b)(6)
> Cc: (b)(6) k222658@docs.fda.gov

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

> Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

>

> Hi Doug,

>

> Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

>

> Thanks,

> Meaghan

>

>

> From: Douglas HERRINGTON (b)(6)

> Sent: Thursday, May 11, 2023 9:58 AM

> To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

> Cc: (b)(6) k222658@docs.fda.gov

> Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

>

> 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 Meaghan

> That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

> All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

> Best

> Doug Herrington

>

>

>

> On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

>

> ï»¿

> Hi Doug,

>

> We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

>

> Thanks,

> Meaghan

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

> From: (b)(6)

> Sent: Wednesday, May 10, 2023 10:06 PM

> To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

> Cc: k222658@docs.fda.gov

> Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

> 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 Megan,

> One last email. I verified that the emails sent include all of the files sent with the original response S002.

> Best

> Doug

> Herrington Consulting LLC

> Douglas Herrington

> Principal Consultant

> From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

> Sent: Wednesday, May 10, 2023 8:20 PM

> To: (b)(6)

> Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

> Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

> Hi Doug,

> Can you respond to this email with the full response submitted to the DCC for K222658/S002?

> Thanks,

> Meaghan

> From: (b)(6)

> Sent: Wednesday, May 10, 2023 1:42 AM

> To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

> Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

> 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 Megan,

> I received the email below regarding this response.

> I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

> Best

> Doug

> Douglas Herrington

> Herrington Consulting LLC

> Principal Consultant

> From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>

> Sent: Wednesday, May 10, 2023 2:47 AM

> To: (b)(6)

> Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>

> Subject: K222658/S002 is on Hold Pending Your Response

> May 9, 2023

> We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

> More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

> Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

>

> If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

>

> If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

>

>

>

> *** 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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

(b)(4)

Report Number: (b)(4)

(b)(4)

In Vitro Cytotoxicity Test of

Liquid silicone rubber

using ISO 10993-5: 2009 Test Method

MTT Method

MEM with 10%FBS extract

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(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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December 9, 2022</br></br> We have reviewed your submission. Please see attached.

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

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

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HI Meaghan,

Attached please find our responses to the questions below (b)(4) (b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6); k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,

Meaghan

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov>

<http://www.fda.gov/>

<https://www.facebook.com/FDA> <https://twitter.com/US_FDA>
<http://www.youtube.com/user/USFoodandDrugAdmin>
<http://www.flickr.com/photos/fdaphotos/>
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E> Here

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov
<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov
<mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

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

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To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >; 'Douglas HERRINGTON' (b)(6) (b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 8:20 PM

To: **(b)(6)**

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov> ; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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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PRODUCT TEST REPORT - (b)(4)

Photobiological Safety of Lamps and Lamp Systems

(b)(4)

(b)(4)

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Accurate 24 BPM Clinical Study Summary

Document Number: (b)(4)
Version: (b)(4)
2022/08/30

Presented by
Tony Kuo, Stanley Wang, Falcao Chang

Approved By (b)(6) ***Date*** 2022-08-30

Kuan Jen, Wang (General Manager)

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Accurate Meditech Inc.

Traditional 510(k) Submission

Accurate 24 Non-invasive blood pressure monitor

Document Number: (b)(4)
Version: (b)(4)
2022/09/02

Presented by
Catherine Chi/Product Manager

Approved By (b)(6) *Date* 2022-09-02

Kuan Jen, Wang(General Manager)

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Refuse to Accept Checklist

Contains Nonbinding Recommendations

Appendix A. Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the application.

510(k)#: **Date Received by DCC:**

510(k) Lead Reviewer:

Center: **Office:** **Division:**

Decision: Accept_____ Refuse to Accept_____

If Accept, notify the submitter.

If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: Yes No

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	**Yes**	**No**	**N/A**
1. **Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?** If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☒	☐	

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If the product does not appear to be a device or such a combination product, mark "No."			
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **(a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **(b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☒	☐
Comments:			

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5. **Is this device type eligible for a 510(k) submission?** If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6. **Is there a pending PMA for the same device with the same indications for use?** If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7. **If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?** If "Yes," consult with the CDRH Office of Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☒	☐
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.**
- **If the answer to 5 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or**

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Contains Nonbinding Recommendations

class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.

- **If the answer to 6 is "Yes," then stop review of the 510(k), contact CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.**
- **If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.**

Organizational Elements Failure to include these items should not result in an RTA designation				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☒	☐	iii
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	iii
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	iii
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	i
Comments: Traditional				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed
• Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☒	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):					
		a.	Device trade/proprietary name	☒	☐		Pg.37
		b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☐	☐		
		Comments:					
	3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (https://www.fda.gov/media/86323/download).*		☒	☐		
		Comments: OTC					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☒	☐		Pg.48
		Comments: 510(k) Summary					

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	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(*i*). *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*		☒	☐		Pg.53
		Comments:					
	6.	Submission is a class III 510(k) Device. *Select "N/A" only if submission is not a class III 510(k).*		☐		☒	
		a.	Contains class III Summary and Certification per 21 CFR 807.87(k). *See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a class III 510(k).*	☐	☐	☐	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.*		☒		☐	
		a.	Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☐	☒	☐	

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		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at lttps://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j).*	☐	☒	☐	
		c.	Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☒		☐	Pg 86

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			i.	For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that it was not subject to the regulations under 21 CFR 56.104 or 56.105). **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812. *Select "N/A" if the clinical investigations were conducted solely OUS.*	☐	☐	☒	
			ii.	For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. *Select "N/A" if the clinical investigations were conducted solely inside the US.*	☒	☐	☐	Pg.88
			Comments:					

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	8.		The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*	☒	☐		Pg.39
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☒	☐	☐	Pg.88
			Comments:				
	9.		The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.*	☒		☐	
		a.	The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐	Pg.43

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			i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐		Pg.44
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).		☐		☒	
			i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☐	☐		
		Comments: The submission cites FDA recognized voluntary consensus standards.						
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.						☒	
	10.	Submission identifies the product as a combination product.			☐	☒		
	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.			☐		☒	

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		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	☐	☐		
			Comments:				
B.	**Device Description**						
	12.		The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐		☒	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

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		b.	The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
	13.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☒	☐		
		Comments:					
	14.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐		
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐		
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☐	☐	☒	

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		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☒	☐		Pg.66
			Comments:				
	15.	Device is intended to be marketed with accessories and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☐		☒	
		a.	Submission includes a list of all accessories to be marketed with the subject device.	☐	☐		
		b.	Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. *Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☐	☐	☐	
		c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☐	☐		
			Comments: Our accessory (USB cable) only for charging.				

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C.	**Substantial Equivalence Discussion**						
	16.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐		
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒	☐		
			Comments: Predicate device BB-613 WP, 510(k)number: K190792				
	17.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*					

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		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☒	☐		
		b.	Technology, including technical specifications, features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☒	☐		
			Comments:				
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☒	☐		Pg.72
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐		
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐		

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			Comments:				
	19.		Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		
			Comments:				
	20.		Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *Select "N/A" if not indicated for prescription use.*	☐	☐	☒	
			Comments: OTC				
	21.		The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*	☐		☒	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

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		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
	22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☐	☒	
		Comment:					
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					☒	

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	Submission states that the device and/or accessories, if applicable, are: (*one of the below must be checked*) ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*			☒		
	Comments:					
	23.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

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		a.	Identification of device and/or accessories, if applicable, that are provided sterile. *Select "N/A" if no part of the device or accessories are provided sterile.*	☐	☐	☒	
		b.	Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected. *Select "N/A" if no part of the device are accessories are end user sterilized or disinfected.*	☐	☐	☒	
		c.	Identification of device and/or accessories, if applicable, that are reusable. *Select "N/A" if no part of the device or accessories, are reusable.*	☒	☐	☐	
			Comments:				
	24.	If the device and/or accessories, if applicable, are provided sterile: *Select "N/A" if no part of the device or accessories are provided sterile, otherwise complete a-f below.*				☒	
		a.	Sterilization method is stated for each device (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		

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		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☐	☐	☐	
			Comments:				
	25.	If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				☒	
		a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.*	☐	☐	☐	
		b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.*	☐	☐	☐	
		c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.*	☐	☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable). *Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*		☐		☒	
			i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*	☐	☐	☒	
			Comments:					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*			☐		☒	

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		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
F.	**Shelf-Life**						
	27.		Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation.	☒	☐		Pg.73

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		Comments: We have proposed and stated shelf life in page 75				
	28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☒	
		Comments:				
	29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐	☐	
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	

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	Submission states that there: (*one of the below must be checked*) ☒ Are direct or indirect tissue-contacting components ☐ Are no direct or indirect tissue-contacting components ☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Tissue contact information not needed for this device (e.g., software-only device) ☐ Tissue contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."* *An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissue-contacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue.*			☐		
	Comments:					
	30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		
		Comments:				
	31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☒	☐		
		Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	32.	For a biocompatibility assessment of tissue-contacting components, submission includes: • Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. • For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		Pg.74
		Comments:				
H.	**Software**					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Submission states that the device: (*one of the below must be checked*) ☒ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*			☐		Pg.76
	Comments:					
	33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☒	☐		
		Comments:				
	34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☒	☐		

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		Comments:				
I.	**Cybersecurity**					
	Submission states that the device: (*one of the below must be checked*) ☐ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) ☐ Does not contain external interfaces as described above ☐ Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) ☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom) ☐ Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."*			☒		
	35.	All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☐	☒		
		Comments:				
J.	**Electrical Safety and EMC**					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☒ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation is not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		Pg.78
	36.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		
		Comments:				

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	EMC: Submission states that the device: (*one of the below must be checked*) ☒ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		
	Comments:					
	37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		
		Comments:				

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K.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section L.*					☐	
	Comments:						
	38.	Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. *Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.*		☒	☐	☐	Pg.80
		a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☒	☐	☐	
			Comments:				

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	39.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				

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	40.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				☒	
		a.	Legible reprints or a summary of each article.	☐	☐		
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☐		
			Comments:				
	41.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				☒	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), OR, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
			Comments:				

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L.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device ☒ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						
	42.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
			Comments:				
	43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☐	☐	

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		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				

Contains Nonbinding Recommendations

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

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

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1. Medical Device User Fee Cover Sheet (Form FDA 3601)

2022/8/22 下午2:39 Site: MDUFMA Cover Sheet

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) Accurate Meditech Inc. 8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd. New Taipei City 241406 TW 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2. CONTACT NAME Kuan Jen Wang 2.1 E-MAIL ADDRESS stanley@accurate-meditech.com 2.2 TELEPHONE NUMBER (include Area code) 2-29991596 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 2-29991196

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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
[ ] De Novo Request	[ ] 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: SBD2281068

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	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] 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 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

https://userfee.fda.gov/OA_HTML/mdufmaCSodCfgItemsPopup.jsp?ordnum= (b)(4) 1/2

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

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2022/8/22 下午2:39 Site: MDUFMA Cover Sheet

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)

Form FDA 3601 (5/22)

"Close Window" Print Cover sheet

Online payment

userfeesconfirmation@fda.hhs.gov

(b)(4)

Your payment has been submitted to Pay.gov. Please refer to the details below.

Account Holder Name:	(b)(4)
Pay.gov Tracking ID:	
Agency Tracking ID:	
Transaction Type:	
Payment Amount:	
Transaction Date :	

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

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

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2. CDRH Premarket Review Submission Cover Sheet(Form FDA3514)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
08/12/2022	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☒ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Expanded Access to Devices
- ☐ Compassionate Use Request NOT associated with an IDE
- ☐ Follow-up Report for Compassionate Use NOT associated with an IDE
- ☐ Emergency Use Follow-up Report NOT associated with an IDE

SECTION B — APPLICANT / SPONSOR

Company/Institution Name	Establishment Registration Number/FEI *(if known)*
Accurate Meditech Inc.	

Street Address	City
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.,	New Taipei City

State/Province	ZIP/Postal Code	Country
	241406	Taiwan

Contact Name	Contact Title
Wang, Kuan Jen	General Manager

Division Name *(if applicable)*	Phone Number *(including area code)*
	+886 2 29991596

Fax Number *(including area code)*	Contact Email Address
+886 2 29991196	stanley@accurate-meditech.com

FORM FDA 3514 (8/20) Page 1 of 9

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

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name: Accurate Meditech Inc.		Establishment Registration Number/FEI *(if known)*:
Street Address: 8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.		City: New Taipei City
State/Province:	ZIP/Postal Code: 241406	Country: Taiwan

Contact 1 Name: Wang, Kuan Jen	Contact 1 Title: General Manager
Contact 1 Division Name *(if applicable)*:	Contact 1 Phone Number *(including area code)*: +886 2 29991196
Contact 1 Fax Number *(including area code)*: +886 2 29991196	Contact 1 Email Address: stanley@accurate-meditech.com
Contact 2 Name:	Contact 2 Title:
Contact 2 Division Name *(if applicable)*:	Contact 2 Phone Number *(including area code)*:
Contact 2 Fax Number *(including area code)*:	Contact 2 Email Address:
Contact 3 Name:	Contact 3 Title:
Contact 3 Division Name *(if applicable)*:	Contact 3 Phone Number *(including area code)*:
Contact 3 Fax Number *(including area code)*:	Contact 3 Email Address:

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☒ Adults Only (greater than 21 years of age)
- ☐ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	Accurate 24 Non-invasive blood pressure monitor
2	
3	
4	
5	

Common/Generic Name *(Include if no Trade Name)*: Noninvasive Blood Pressure Measurement System

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

(b)(4)		3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

DXX

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
21 CFR 870.1130	Cardiovascular

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ Bundle Submission – *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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

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SECTION H2 REASON FOR APPLICATION – IDE

- ☐ Original IDE
- ☐ Supplement:
  - ☐ New Study/New Protocol
  - ☐ Change in Correspondent
  - ☐ Change in Manufacturer
  - ☐ Change in Sponsor
  - ☐ Change in Design
  - ☐ Change in Informed Consent
  - ☐ Change in Manufacturing
  - ☐ Change in Protocol
  - ☐ 5-Day Notice – Device or Manufacturing
  - ☐ 5-Day Notice – Protocol
  - ☐ Compassionate Use Request (under an IDE)
  - ☐ Live Case Request
  - ☐ Request Deviation from Protocol
  - ☐ Expansion of Study (Study/Sites)
  - ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter
- Supplement *(Continued)*
  - ☐ Request for Waiver
  - ☐ IRB Certification
  - ☐ Request for CMS Recategorization
  - ☐ Study Resumed
  - ☐ Study Suspension
  - ☐ Other *(Specify below)*
- ☐ Report:
  - ☐ Adverse Effect
  - ☐ Final, Study Completed
  - ☐ Annual Progress
  - ☐ Interim Progress
  - ☐ Semiannual Investigator List
  - ☐ Failure to Obtain Informed Consent
  - ☐ Compassionate Use Follow-up
  - ☐ Emergency Use
  - ☐ Live Case Follow-up
  - ☐ Completion of Patient Enrollment
  - ☐ Completion of Patient Follow-up
  - ☐ Other *(Specify below)*
- ☐ Amendment to Original IDE:
  - ☐ Amendment Before Final Decision
  - ☐ Response to Refuse to Accept
  - ☐ Response to Disapproval
  - ☐ Response to Approval with Conditions
  - ☐ Withdrawal
  - ☐ Other *(Specify below)*
- ☐ Amendment to Supplement:
  - ☐ Response to Disapproval
  - ☐ Response to Approval with Conditions
  - ☐ Withdrawal
  - ☐ Amendment Before Final Decision (additional Information)
  - ☐ Other *(Specify below)*
- ☐ Amendment to Report:
  - ☐ Response to Deficiency Letter
  - ☐ Withdrawal
  - ☐ Amendment Before Final Decision (additional Information)
  - ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

- ☐ Pre-Submission:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Request Email Response
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-con
- ☐ Submission Issue Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Request Email Response
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-con
- ☐ Additional Information
- ☐ Change in Legal Entity:
  - ☐ Change in Correspondent
  - ☐ Change in Sponsors
  - ☐ Change in Manufacturer
  - ☐ Other *(Specify below)*
- ☐ Agreement Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
- ☐ Determination Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
- ☐ Informational Meeting:
  - ☐ Request Face-to-Face Meeting
  - ☐ Request Teleconference
  - ☐ Submit Meeting Minutes
  - ☐ Request Meeting Minutes Disagreement T-Con
- ☐ Other *(Specify)*:

FORM FDA 3514 (8/20) **Page 4 of 9**

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

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SECTION H4 REASON FOR SUBMISSION – 510(k)

- [x] Original
- [ ] Withdrawal of Original
- [ ] Amendment Before Final Decision:
  - [ ] Change in Ownership
  - [ ] Change in Correspondent
  - [ ] Withdrawal
- [ ] Amendment After Final Decision
- [ ] Supplement:
  - [ ] Response to Refuse to Accept (RTA)
  - [ ] Response to Additional Information Request
  - [ ] Withdrawal
- [ ] Reprocessed SUD
- [ ] Corrective Action
- [ ] STED
- [ ] Third Party *(Complete Section C)*
- [ ] Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K190792	BB-613WP	BioBest Technologies Ltd.	DXN, DQA, DRG
Predicate or Reference Device (B)				
Predicate or Reference Device (B)				
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

- [ ] Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- [ ] Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- [ ] CLIA Categorization Record (CR):
  - [ ] CLIA Categorization of marketed device (include marketing submission number)
  - [ ] CLIA Categorization of device exempt from premarket review
  - [ ] Additional information regarding an open CR (include CR number)
- [ ] CLIA Waiver by Application (CW):
  - [ ] Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - [ ] Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - [ ] Response to FDA correspondence
  - [ ] Additional information regarding an open CW (include CW number)
- [ ] Other Reason *(Specify)*

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

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.

FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete

Facility Establishment Identifier (FEI) Number

☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution Name

Establishment Registration Number/FEI *(if known)*

Street Address

City

State/Province

ZIP/Postal Code

Country

Contact 1 Name

Contact 1 Title

Contact 1 Division Name *(if applicable)*

Contact 1 Phone Number *(including area code)*

Contact 1 Fax Number *(including area code)*

Contact 1 Email Address

Contact 2 Name

Contact 2 Title

Contact 2 Division Name *(if applicable)*

Contact 2 Phone Number *(including area code)*

Contact 2 Fax Number *(including area code)*

Contact 2 Email Address

Contact 3 Name

Contact 3 Title

Contact 3 Division Name *(if applicable)*

Contact 3 Phone Number *(including area code)*

Contact 3 Fax Number *(including area code)*

Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

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

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SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write NR.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use, Deviation?*	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use, Deviation?* Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	2-258	Declaration of Conformity	*If General Use, Deviation?*	ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.	Section 9, Pg. 56
2 X	2-276	Declaration of Conformity	*If General Use, Deviation?*	ISO 10993-18 : 2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device	Section 9, Pg. 56
3 X			*If General Use, Deviation?*	materials within a risk management process.	
4 X	2-245	Declaration of Conformity	*If General Use, Deviation?*	ISO 10993-5 : 2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity	Section 9, Pg. 56
5 X	2-174	Declaration of Conformity	*If General Use, Deviation?*	ISO 10993-10 : 2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	Section 9, Pg. 56
6 X	2-214	Declaration of Conformity	*If General Use, Deviation?*	ASTM F619-14:2016 Standard Practice for Extraction of Medical Plastics	Section 9, Pg. 56
7 X	5-125	Declaration of Conformity	*If General Use, Deviation?*	ISO 14971 3rd Edition 2019-12 Medical devices - Application of risk management to medical devices	Section 9, Pg. 56
8 X	5-129	Declaration of Conformity	*If General Use, Deviation?*	IEC 62366:2020 Medical devices - Part 1: Application of usability engineering to medical devices	Section 9, Pg. 56
9 X	3-186	Declaration of Conformity	*If General Use, Deviation?*	ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type	Section 9, Pg. 56
10 X			*If General Use, Deviation?*	Including: Amendment 1 (2020)]	
11 X	13-79	Declaration of Conformity	*If General Use, Deviation?*	IEC 62304:2015 Medical device software - Software life cycle processes	Section 9, Pg. 56
12 X	19-8	Declaration of Conformity	*If General Use, Deviation?*	IEC 60601-1-2 : 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance	Section 9, Pg. 57
13 X			*If General Use, Deviation?*	Collateral Standard: Electromagnetic disturbances - Requirements and tests	

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

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14 X	I9-14	Declaration of Conformity	If General Use, Deviation?	IEC 60601-1-11 : 2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance	Section 9, Pg. 57
15 X			If General Use, Deviation?	Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare	
16 X			If General Use, Deviation?	environment	
17 X	I9-4	Declaration of Conformity	If General Use, Deviation?	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Section 9, Pg. 57
18 X			If General Use, Deviation?	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	
19 X	I2-249	Declaration of Conformity	If General Use, Deviation?	IEC62471:2006 Photobiological safety of lamps and lamp systems	Section 9, Pg. 56
20 X	I9-13	Declaration of Conformity	If General Use, Deviation?	IEC62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed	Section 9, Pg. 57
21 X			If General Use, Deviation?	secondary cells, and for batteries made for them, for use in portable applications [Including: Corrigendum 1(2013)]	
22 X	I-123	Declaration of Conformity	If General Use, Deviation?	IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance	Section 9, Pg.57
23 X	I-168	Declaration of Conformity	If General Use, Deviation?	Standard for Wearable, Cuffless Blood Pressure Measuring Devices [Including: Amendment 1 (2019)]	Section 9, Pg. 56

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*.

Entries for Utilization of CDRH Guidance Documents

	Title of Guidance Document
1 X	Design Considerations for Devices Intended for Home Use, 2014
2 X	Guidance for Industry General/Specific Intended Use, 1998
3 X	Device Labeling Guidance #G91-1 (Blue Book Memo), 1991
4 X	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, 2018
5 X	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)], 2014
6 X	Non-Invasive Blood Pressure (NIBP) Monitor Guidance, 1997
7 X	Safety and Performance Based Pathway, 2019
8 X	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, 2018
9 X	Applying Human Factors and Usability Engineering to Medical Devices, 2016
10	General Principles of Software Validation;Final Guidance for Industry and FDA Staff, 2002

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

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X	
11 X	Electromagnetic Compatibility (EMC) of Medical Devices, 2020
12 X	Guidance for the Content of Premarket Submissions for Software Contained in Medical Device, 2005
13 X	Refuse to Accept Policy for 510(k)s Guidance for Industry and Food and Drug Administration Staff

To add another row for Section K, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Document

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 .5 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

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3. Cover Letter

Accurate Meditech Inc. 2022 *Accurate 24 BPM 510(k)*

510(k) Cover Letter

September 02, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation [510(K)]
Document Control Center HFZ-401
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Traditional 510(k) Premarket Notification for the
Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

In compliance with the Federal Food, Drug and Cosmetic Act (As amended) and as required in 21 CFR § 807 · Subpart E, Accurate Meditech Inc submits this subject Premarket Notification for your review. In accordance with 21 CFR § 807.90(c), this document is submitted in duplicate with this original cover letter, and two additional copies of the cover letter are provided.

(b)(4)

Accurate 24 Non-Invasive blood pressure monitor(Model: Accurate 24 BPM) will be shown to be substantially equivalent to the BioBeat BB-613 WP(**K190792**). The purpose device(Accurate 24 BPM) is a Class II device per 21 CFR 870.1130, ProCode: DXN.

Accurate Meditech Inc considers the intent to market this device as confidential commercial information. Therefore, Accurate Meditech Inc. considers the information provided under this submission to be a trade secret and confidential commercial information under 21 CFR § 20.61 and requests that the Food and Drug Administration not disclose this information either in response to a Freedom of Information Request or by any other means.

Sincerely,

(b)(6)

Kuan-Jen, Wang
Accurate Meditech Inc.
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4. Indications for Use Statement(Form FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 08/30/2023
See PRA Statement below.

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CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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5. 510(k) Summary

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6. Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(l)]

Premarket Notification Truthful And Accurate Statement

[As Required by 21 CFR 807.87(l)]

I certify that, in my capacity as General Manager of Accurate Meditech Inc., 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.

(b)(6)

(Signature)

Kuan-Jen Wang

(Typed Name)

(b)(6)

(Date)

*(Premarket Notification [510(k)] Number)

*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].

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7. Class III Summary and Certification

Accurate 24 Non-invasive blood pressure monitor is a class II medical device

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

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8. Financial Certification or Disclosure Statement

Accurate 24 Non-invasive blood pressure monitor is a class II medical device and FORM FDA 3454(4/21) CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS. is not applicable to Accurate 24 Non-invasive blood pressure monitor.

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

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9. Declarations of Conformity and Summary Reports

On behalf of the General Manager of Accurate Meditech Inc., I hereby declared that the Accurate 24 Non-invasive blood pressure monitor conforms to all of the requirements of voluntary recognized consensus standards listed below.

Item.	Standards Number	Standard Name	Standard Version	FDA Recognition No.	Reference
1	ISO 10993-1	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Fifth edition 2018-08	2-258	Appendix 4: VOL_004/ 001
2	ISO 10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.	Second edition 2020-01	2-276	Appendix 4: VOL_004/ 012,013,014, 015,016,017
3	ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Third edition 2009-06-01	2-245	Appendix 4: VOL_004/ 003,006,009,018
4	ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Third edition 2010-08-01	2-174	Appendix 4: VOL_004/ 004,005,007, 008,010,011
5	ASTM F619-14	Standard Practice for Extraction of Medical Plastics	2016	2-214	Appendix 4: VOL_004/ 013,014, 015,016,017
6	IEC 62471	Photobiological safety of lamps and lamp systems	First edition 2006-07	12-249	Appendix 4: VOL_004/ 002
7	ISO 14971	Medical devices - Application of risk management to medical devices	Third edition 2019-12	5-125	Appendix 7: VOL_007/ 001
8	IEC 62366	Medical devices - Part 1: Application of usability engineering to medical devices	Edition 1.1 2020-06	5-129	Appendix 6: VOL_006/ 001
9	ISO 81060-2	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type [Including: Amendment 1 (2020)]	Third edition 2018-11	3-166	Appendix 8: VOL_008/ 001
10	IEEE Std 1708-2019a	Standard for Wearable, Cuffless Blood Pressure Measuring Devices [Including: Amendment 1 (2019)]	06/07/2021	3-168	Appendix 8: VOL_008/ 001
11	IEC 62304	Medical device software - Software life cycle processes	Edition 1.1 2015-06	13-79	Appendix 5:VOL_005/ 001

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12	IEC 62133	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including: Corrigendum 1 (2013)]	Edition 2.0 2012-12	19-13	Appendix 5: VOL_005/ 002,003
13	IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	2014-09-07	19-4	Appendix 5: VOL_005/ 005
14	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Edition 4.0 2014-02	19-8	Appendix 5: VOL_005/ 006
15	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	Edition 2.0 2015-01	19-14	Appendix 5: VOL_005/ 007
16	IEC 80601-2-30	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	Edition 2.0 2018-03	3-123	Appendix 5: VOL_005/ 010

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Signature of Certifier

2022-08-24

Date

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10. Executive Summary

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11. Device Description

11.1 General Device Description / Principle of Operation

The Accurate 24 BPM device is a small, lightweight, wrist-worn device intended to measure and display blood pressure trending (Systolic and Diastolic) and spot-check pulse rate. Measurement is performed on the wrist of the radial artery. This blood pressure monitor uses the pulse wave transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and heart rate of adults in a non-invasive manner.

The Accurate 24 BPM is a novel wrist-worn spot-checking device comprised of two pressure sensors and two optical sensors. This PWTT based device tracks changes in blood pressure by utilizing pulse measurement obtained from the radial artery in the wrist.

The device performs a spot check only after the user presses a button to begin measurement, also the design location of the button with Power to control the device on and off, and button of record to review the historical records quickly through the PMOLED screen display unit. Both predicate devices contain an integrated digital screen used to display the measurement results.

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The Accurate 24 BPM operated on poly-lithium battery. It has power management profiles to optimize battery life. The battery provides approximately 150 times of continuous use, depending on the frequency of PMOLED display and measurement.

11.2 Intended Use

Accurate 24 Non-Invasive blood pressure monitor is a small, lightweight, wrist-worn device intended for spot-checking and displaying blood pressure (Systolic and Diastolic) and pulse rate. So that the users may have a better understanding of their long-term health trending.

The Accurate 24 Non-invasive BPM is intended for spot-checking adult patients in hospitals, clinics, long-term care, and home use and can obtain results. The measurement results store in the device locally.

11.3 Indication for use

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally.

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The Accurate 24 Non-invasive BPM tracks changes in blood pressure based on Pulse Wave Transit Time (PWTT), which is obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

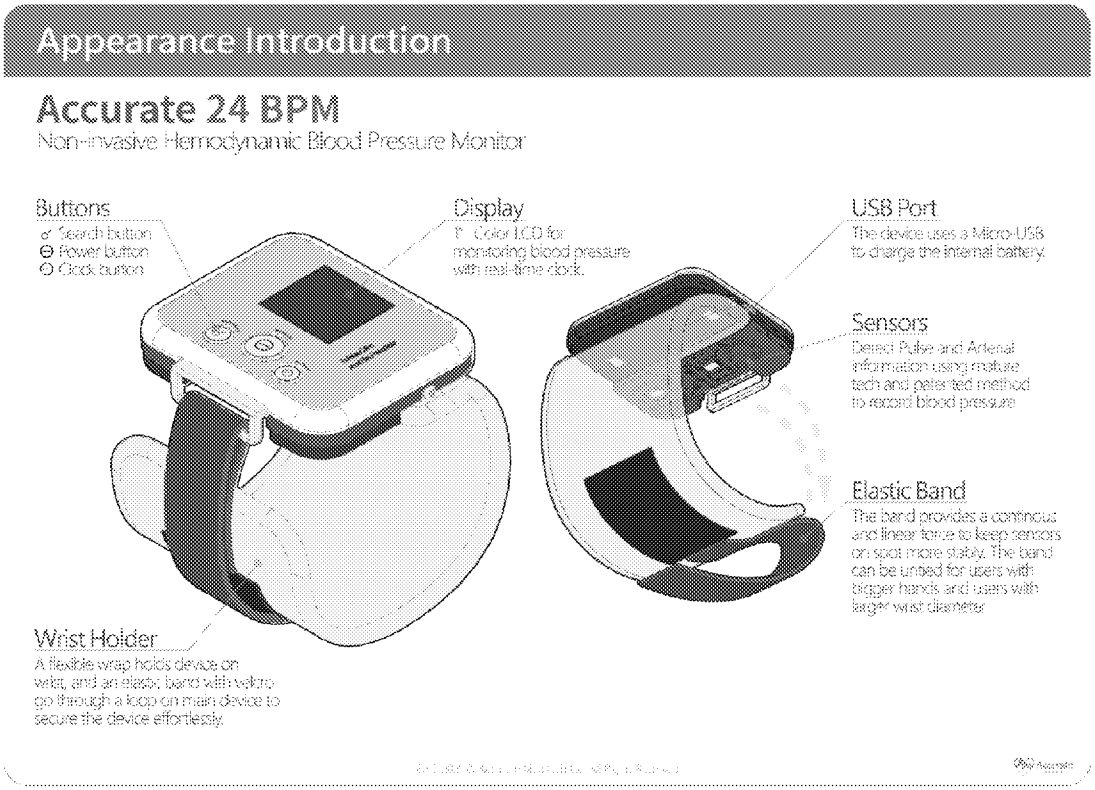
11.4 List of Critical components

Component/ Part No.	Manufacture/ Trademark	Type No./ Model No./	Technical data	Standard No./, Edition	Reference
(b)(4)				UL 94	Appendix 9: VOL_009/001 Appendix 5: VOL_005/011
				UL 94 IEC 60695-11-10	Appendix 4: VOL_004/013
				IEC 62133:2012	Appendix 9: VOL_009/004 Appendix 4: VOL_004/012 Appendix 5: VOL_005/002 VOL_005/003
				UL 1642	Appendix 9: VOL_009/003 Appendix 5: VOL_005/012
					Appendix 9: VOL_009/002
				IEC 62471:2006	Appendix 4: VOL_004/002
					Appendix 9: VOL_009/005

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11.5 Compositions of Main Components



(b)(4)

The Sensors:
Please refer to Appendix 1/Vol_001/007 to explain this feature.

- **The Charging and discharging of the lithium battery**

Please refer to Appendix 1/Vol_001/008. to explain this feature.

- **The Wrist Holder:**

The holder design consists of 2 sections to accommodate different wrist diameters. The wrist wrap, the upper section of the holder, provides the needed grasp, while the elastic band, the lower section of the holder, makes sure the sensors can be affixed to the desired position stably and comfortably.

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11.6 Performance Specifications

(b)(4)

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11.7 Device Photos/Drawings

Figure 1: Accurate 24 Non-Invasive blood pressure monitor/Model Accurate 24 BPM





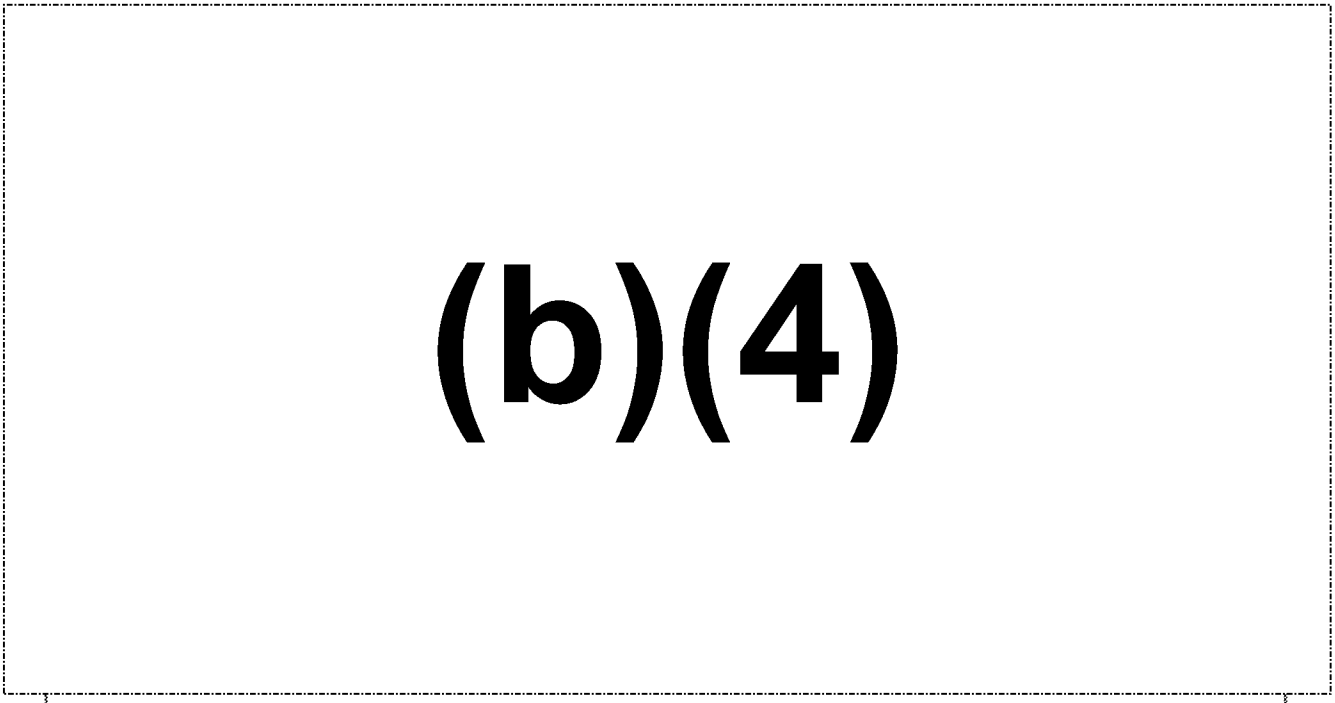




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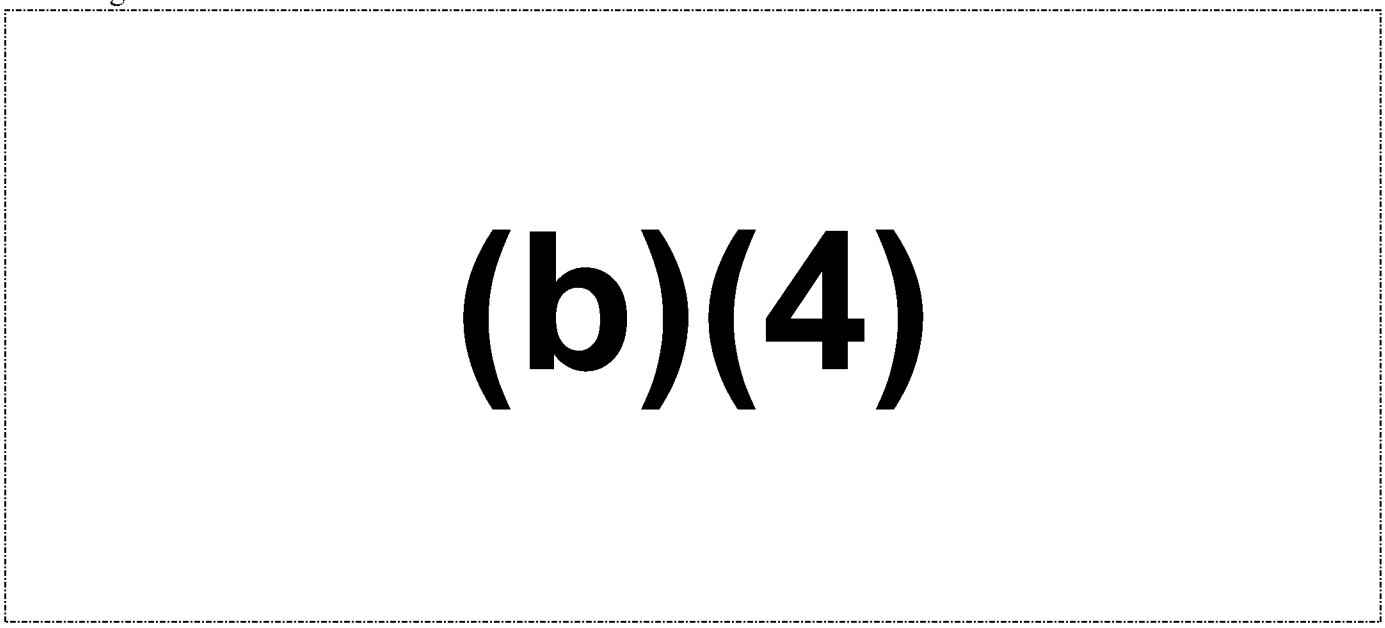
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Figure 2: Expanded View of Accurate 24 Non-Invasive blood pressure monitor/
Model Accurate 24 BPM



(b)(4)	Product name : Accurate 24 Non-invasive blood pressure monitor
Presented by Chloe, Bai / Mechanical Engineer	Accurate Meditech Inc.
Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail : info@accurate-meditech.com	

Figure 3: Accurate 24 BPM Mechanical Part List



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(b)(4)

The detail complete device description can refer to Appendix 1: VOL_001/001,002,003,004,005.

11.6 Device Full View

(b)(4)

(b)(4)	Product name : Accurate 24 Non-invasive blood pressure monitor
Presented by Chloe, Bai / Mechanical Engineer	Accurate Meditech Inc.
Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail : info@accurate-meditech.com	

11.7 Risk Management

Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM using a process compliant with ISO 14971:2019 Risk Management for Medical Devices, and specific procedures and practices outlined by division Standard Operating Procedures. Please refer to Appendix 7: VOL_007/001.

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

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12. Substantial Equivalence Discussion

(b)(4)

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13. Proposed Labeling

Labeling/Instructions for Use

Copies of the proposed labeling for the Accurate 24 Non-invasive blood pressure monitor (i.e., the user manual and primary box) are included in Appendix 3:VOL_003/001,002,003 of this submission. The user manual also includes directions for routine care and maintenance of the device. Note that as required by the latest revision of the electromagnetic compatibility (EMC) standard (IEC-60601-1-2), specific results for EMC testing are included in the user manual for the Accurate 24 Non-invasive blood pressure monitor.

Each primary box contains one (1) Accurate 24 Non-invasive blood pressure monitor, the user manual, Micro USB cable.

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14. Shelf Life

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15. Biocompatibility

15.1 Overview

This section is the protection of humans from potential biological risks arising from the materials use of Accurate 24 Non-invasive Blood Pressure Monitor which direct contact with lower arm of wrist skin and need to validate the results and provides the user safety and effective for daily use purposes. The ISO 10993-1:2018 is applicable to interpret, judge the outcome of the biological evaluation for Accurate 24 Non-invasive Blood Pressure Monitor. Taking into consideration all the biological factors, intended use, the current knowledge of the scientific literature and previous clinical experience. This document specifies Accurate 24 Non-Invasive Blood Pressure Monitor's biological evaluation within a risk management process, categorization based on the nature and duration of their contact with the body.

Following list are the Accurate 24 Non-Invasive Blood Pressure Monitor skin contact materials biocompatibility tests reports and other COA, MSDS data in the reference appendix.

Result	Description	Methodology	Reference
(b)(4)			

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15.2 Conclusion

According to the list as supplier's information, test reports. The products evaluation showed it meet the Biocompatibility FDA recognized consensus standards and guidance requirements. We conclude that the Accurate 24 Non-Invasive Blood Pressure Monitor is safe for the biocompatibility character concerning the skin direct contact type and short-term contact duration.

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

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16. Software

16.1 Overview

Because Accurate 24 BPM contains embedded software, Accurate Meditech Inc. reviewed the Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11,2005 (CDRH/FDA). This document requires the completion and submission of Section 2 (Level of Concern) by the manufacturer. Section 3 of the document outlines the documentation required by Section 3 varies depending on the level of concern established by Section 2. Accurate Meditech Inc. has determined that this embedded software has (b)(4), as illustrated in the following paragraphs of this section.

(b)(4)

Because Accurate Meditech Inc. determined that the Level of Concern for the Accurate 24 BPM (b)(4), Accurate Meditech Inc. has provided the documentation listed in Table 16-1 below, in accordance the Guidance document.

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

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Table 16-1:Software Documentation Required in the Premarket Submission

(b)(4)

16.2 Conclusion

Based on the information and supporting data noted above, Accurate Meditech Inc considers the level of concern (b)(4) According to "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11,2005 (CDRH/FDA)

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17. Electromagnetic Compatibility and Electrical Safety

Accurate 24 Non-invasive blood pressure monitor was tested for compliance with EMC standards and FCC requirements. The detail complete test reports can refer to Appendix 5:VOL_005/004 and Appendix 5:VOL_005/006.

(b)(4)

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18. Performance Testing-Bench

18.1 Basic Safety Testing

The Accurate 24 BPM was tested for compliance with "Medical electrical equipment Part 1: General requirements for basic safety and essential performance" (IEC 60601-1). For the complete report, please refer to FCC SDoC REPORT(Appendix 5:VOL_005/004).

Table 18-1:Basic Safety Testing Summary

Test	Reference Standard	Test Result	Test Lab & Report No.	Reference
Medical Electrical Equipment – Part 1: General Requirements for Safety Part 1-2 Part 1-6 Part 1-11	IEC 60601-1:2005, AMD1:2012	(b)(4)		Appendix 5: VOL_005/005
	IEC 60601-1-2:2014			Appendix 5: VOL_005/006
	IEC-60601-1-11:2015+A1:2012			Appendix 5 VOL_005/007
	IEC 60601-1-6 (IEC 62366-1:2015)			Appendix 6: VOL_006/001
Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometer	IEC 80601-2-30			Appendix 5: VOL_005/010

18.2 Bench Testing

Device were subjected to integrate testing as part of design verification testing, as summarized in Table 18-2. The device tested to confirm functional performance.

Table 18-2:Testing Summary

Test Item	Test Result (Pass/Fail)	Documentation Reference	
Software Integrate Test (50 Test cases)	(b)(4)	Appendix 2	VOL_002/010_Accurate 24 BPM Software Test Report.pdf
Verification of Accurate 24 BPM		Appendix 5	VOL_005/009_Verification Report of Accurate 24 BPM.pdf

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19. Performance Testing-Animal

Accurate 24 Non-invasive blood pressure monitor intended use/indication for use are for human use. In addition, the animal performance testing data is not suitable for Accurate 24 Non-invasive blood pressure monitor.

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20. Performance Testing-Clinical

The objective of the clinical study was to compare non-invasive blood pressure measurements between the standard Korotkoff manometry device and the Accurate 24 BPM device. (Refers to NIBP's standard ISO81060-2:2018 and cuffless blood pressure measuring devices standard, IEEE Std 1708a:2019)

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21. Performance Testing-Usability

Accurate Meditech Inc. evaluated Accurate 24 BPM using a process compliant with IEC 62366-1:2015 Application of usability engineering to medical devices.

Accurate Meditech Inc. conducted the usability study report to confirm that Accurate 24 BPM (1) protects users from potentially harmful use errors that could lead to patient harm, and (2) can be used effectively (i.e., users can use the device to deliver efficacious blood pressure monitor).

The detail complete usability study reports can refer to Appendix 6: VOL_006/001.

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

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22. Prior Submission

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List of the Appendices

Appendix No.	Volume	File Name
Appendix 1	VOL_001_ Device Description	001_Accurate 24 BPM PCB.pdf 002_Accurate 24 BPM SCH.pdf 003_Accurate 24 BPM Exploded Drawing.pdf 004_Accurate 24 BPM Part List.pdf 005_Accurate 24 BPM Assembly Drawing.pdf 006_Accurate 24 BPM Full View.pdf 007_Description of sensor characteracts.pdf 008_Lithium battery Specifications.pdf
Appendix 2	VOL_002_ Software	001_Accurate 24 BPM Level of Concern.pdf 002_Accurate 24 BPM Software Description.pdf 003_Accurate 24 BPM Software Hazard Analysis.pdf 004_Accurate 24 BPM Software Requirement Specifications.pdf 005_Accurate 24 BPM Software Architecture Design Chart.pdf 006_Accurate 24 BPM Software Design Specifications.pdf 007_Accurate 24 BPM Software Traceability Analysis.pdf 008_Accurate 24 BPM Software Development Environment Description.pdf 009_Accurate 24 BPM Software Verification and Validation Description.pdf 010_Accurate 24 BPM Software Test Report.pdf 011_Accurate 24 BPM Revision Level History.pdf 012_Accurate 24 BPM Unresolved Anomalies.pdf
Appendix 3	VOL_003_ Labeling	001_Accurate 24 BPM Purposed Label.pdf 002_Accurate 24 BPM User Manual.pdf 003_Accurate 24 BPM Package.pdf
Appendix 4	VOL_004_ Biocompatibility	001_ISO 10993-1_Risk Management Report of Biological Evaluation.pdf 002_IEC 62471 Maxim Test Report.pdf 003_PU coated TC fabric In Vitro Cytotoxicity Test Report.pdf 004_PU coated TC fabric Skin Irritation Test Report.pdf 005_PU coated TC fabric Skin Sensitization Test Report.pdf 006_Composite fabric Cytotoxicity Test Report.pdf 007_Composite fabric Skin Irritation Test Report.pdf 008_Composite fabric Skin Sensitization Test Report.pdf 009_Nylon In Vitro Cytotoxicity Test Report.pdf 010_Nylon Skin Irritation Test Report.pdf 011_Nylon Skin Sensitization Test Report.pdf 012_MSDS- Rechargeable Lithium Ion Battery Test Report.pdf 013_2015_RoHS_PA707_EN_report_ABS.pdf 014_2021_RoHS_PB575_EN_report_TPE_rubber.pdf 015_2021_RoHS_PC175_EN_report_Polycarbonate.pdf 016_COMAX_2015_ROHS_INK.pdf 017_Silicone Rubber test repot_10993.pdf 018_ISO-10993-5 Test Report.pdf
Appendix 5	VOL_005_ Test report	001_IEC 62304 Evaluation Report.pdf 002_IEC 62133_Rechargeable Lithium Ion Battery Test Report.pdf 003_IEC 62133_Rechargeable Lithium Ion Battery Certificate.pdf 004_FCC_SGS Test Report.pdf 005_IEC 60601-1_SGS Test Report.pdf 006_IEC 60601-1-2_ SGS Test Report.pdf 007_IEC 60601-1-11_ SGS Test Report.pdf 008_Accurate 24 BPM Shelf Life Test Report.pdf 009_Verification Report of Accurate 24 BPM.pdf 010_IEC 80601-2-30_SGS Test Report.pdf 011_PCB_Test Report.pdf 012_RTC_Test Report.pdf
Appendix 6	VOL_006_ Usability	001_Accurate 24 BPM_Human Factors and Usability Engineering Report.pdf

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Appendix 7	VOL_007_ Risk Analysis	001_ISO 14971_Risk Analysis.pdf
Appendix 8	VOL_008_ Clinical Test	001_Accurate 24 BPM Clinical Study Summary.pdf 002_ IEEE 1708 Clinical Validation Comparison.pdf
Appendix 9	VOL_009_ Specification	001_Accurate 24 BPM PCB Specification.pdf 002_Accurate 24 BPM LCD Panel Specification.pdf 003_Accurate 24 BPM RTC Specification.pdf 004_Accurate 24 BPM Lithium Ion Battery Specification.pdf 005_Accurate 24 BPM Charging IC Specification.pdf
Appendix 10	VOL_010_ Prior Submission	(b)(4)

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510(k) Cover Letter

FDA/CDRH/DCC
MAY 09 2023
RECEIVED

May 08, 2023

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

K222658/S002

Re: This refuse-to-accept (RTA) for K222658 response is being submitted for the Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

(b)(4)

We have contacted Douglas Herrington, the principal consultant of Herrington Consulting LLC, to act as our official correspondent. He should be contacted directly for any questions, comments or issues arising from review of this submission.

Sponsor & Manufacturing Address:

Accurate Meditech Inc
8F-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.
Sanchong District
New Taipei City 241406
Taiwan (R.O.C.)
Phone: +886.937.987.729
Fax: +886.2.2999.1196

Official Contact Name

Douglas Herrington
No 64, Haijing 3rd St
Sanzhi District
New Taipei City 252, Taiwan (R.O.C.)
Telephone: 1.248.369.5564
Fax: 1.877.881.4412
E-mail: **(b)(6)**

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

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Sincerely,

(b)(6)

Signature

Kuan-Jen, Wang

CEO, Accurate Meditech Inc.

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

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: User Manual

Document Number: (b)(4)
Version: (b)(4)
2022/09/13

Presented by
Catherine Chi/Product Manager

Approved By (b)(6) ***Date*** 2022-09-13

Kuan Jen, Wang **(General Manager)**

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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(b)(4)

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

CB TEST CERTIFICATE

Product	Battery Pack
Name and address of the applicant	(b)(4)
Name and address of the manufacturer	
Name and address of the factory	
Note: *When more than one factory, please report on page 2*	
Ratings and principal characteristics	
Trademark (if any)	
Customer's Testing Facility (CTF) Stage used	
Model / Type Ref.	
Additional information (if necessary may also be reported on page 2)	
A sample of the product was tested and found to be in conformity with	IEC 62133:2012 National Differences:
As shown in the Test Report Ref. No. which forms part of this Certificate	(b)(4)

This CB Test Certificate is issued by the National Certification Body

(b)(4)

(b)(4)

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(b)(4)

Produkte
Products

Prüfbericht - Nr.: *Test Report No.:*	(b)(4)	**Seite 1 von 5** *Page 1 of 5*
Auftraggeber: *Client:*	(b)(4)	
Gegenstand der Prüfung: *Test Item:*		
Bezeichnung: *Identification:*		
Anlieferungszustand: *Delivery condition:*		
Prüfort: *Testing location:*		
Prüfgrundlage: *Test specification:*	According to RoHS (recast): Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment, 2011/65/EU Annex II and its amendment Directive (EU) 2015/863: Total Content of Lead, Cadmium, Mercury, Chromium VI, Polybrominated Biphenyls, Polybrominated Diphenyl Ethers; and Benzylbutyl phthalate (BBP), Dibutyl phthalate (DBP), Bis(2-ethylhexyl) phthalate (DEHP), Diisobutyl phthalate (DIBP)	
Prüfergebnis: *Test result:*	(b)(4)	

geprüft: *tested by:* **kontrolliert:** *checked by:*

(b)(4)

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Part List

Document Number: (b)(4)

Version: (b)(4)

2021/6/28

Presented by
Stanley Wang / General Manager

Approved By (b)(6) *Date* 2021-06-28

Kuan Jen, Wang (General Manager)

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Telephone: +886 2 2999-1596 / Fax: +886 2 2999 1196 / E-mail: info@accurate-meditech.com

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C2	15A2073A32	
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C4	1542458A32	
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C7	1542458A32	
C8	1542458A32	
C9	1511509A32	
C10	1511509A32	
C11	1511514A04	GRM1555C1H220JA01D
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C13	15A2487004	GRM188R71A225KE15D
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C15	1541458032	
C16	15D2K87A04	
C17	15D2K87A04	
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C32	15A2487004	GRM188R71A225KE15D
C33	DNP	
C34	DNP	

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C69	1552467002	
C70	15A2487004	GRM188R71A225KE15D

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D5	203900210405	
D8	201820530031	
D9	202840290205	NSR0320
D10	204840750234	1N4148WS T/R
D11	204840750234	1N4148WS T/R
D21	202840290205	
D1	202840290205	
IC2	2500516310	LD3985M33R
IC4	2500516310	LD3985M33R
IC5	2500516310	LD3985M33R
IC7	2500235710	LD2985AM18R
IC8	2500516310	LD3985M33R
IC9	2500235710	LD2985AM18R
L1	2923301308	

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L3	151052GA32	
L5	281061261J	
Q2	210522000705	MMBT2222ALT1G
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R3	0351061701	
R4	0351142701	
R5	0351066701	
R6	DNP	
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R8	0351092701	
R9	0351105701	RC0402FR-07 560KL
R10	0351082701	RC0402FR-07 68KL
R11	0351107701	
R12	0351107701	
R13	0351061701	
R14	0351142701	
R15	0351066701	
R16	DNP	
R17	0351092701	
R18	0351092701	
R19	0351098701	RC0402FR-07 270KL
R20	0351077701	RC0402FR-07 47KL
R21	0351059701	
R22	DNP	
R23	0351059701	
R24	0351059701	
R25	DNP	
R26	0351016701	
R27	0351016701	
R28	0343000301	
R29	0353000701	

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R30	0351066701	
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R35	0353685701	RC0402JR-07 6M8L
R36	0351746701	RC0402FR-07 10ML
R37	0351746701	RC0402FR-07 10ML
R38	0351105701	RC0402FR-07 560KL
R39	0351082701	RC0402FR-07 68KL
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R58	0351026701	
R59	0351274701	
R60	0351041701	
R61	0351092701	
R62	0351092701	
R63	0351041701	

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R86	0353105701	
R87	0353105701	
R88	0351041701	
R89	0351092701	
R90	0353000701	
R91	0353000701	
R92	DNP	
R93	0353000701	
R94	0353000701	
R95	0353000701	
R96	DNP	
R97	0353000701	
R98	DNP	

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

R99	0353000701	
R100	0351041701	
R101	DNP	
R102	0343000301	
R103	0343000301	
R104	DNP	
R105	0353000701	
R106	0351052701	
R107	0343000301	
R108	0343000301	
R109	0343000301	
R110	0343000301	
R111	0343000301	
R112	0343000301	
R113	0351041701	
R114	0353000701	
R115	0351105701	
R116	0341087301	
R117	0341087301	
R118	0351092701	
R119	0351092701	
R120	0351092701	
R121	0351092701	
R122	DNP	
R123	0351071701	
R124	0351092701	
R125	0351446701	
R126	0351052701	
R268	0351059701	
R269	0351059701	
R270	0351059701	
~~R271~~	~~0353000701~~	—
R272	0353000701	
S2		

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

S3		
S4		
T1	2600271111	
T2	2600271111	
T3	2600271111	
T4	2600271111	
T5	2600271111	
T6	2600271111	
T7	2600271111	
T8	2600271111	
U1		STM32F405VGT6
U2	203727030007	PRTR5V0U2X-215
U3		LM2704MF-ADJ/NOPB
U4		AD8669
U5		AD8669
U6	2540460806	LIS3DHTR
U7		RT9361AGE
U8	262606731H	NRF52810-QFAA-R
U101	2510983710	STNS01PUR
U52	0731027412	X3S008000BI1H-Z
U55	2924003126	FCM1608KF-601T03
U59		ANK7B 3216 2.4G T00
U510	0730293543	XTL501150-I159-001
U512	0730152724	FC-135
U513	0730152724	FC-135
USBAB		MUYF-05
X1		I-PEX:20607-018E-01
X2		FH34SRJ-6S-0.5SH
X4		FH34SRJ-6S-0.5SH
J2		BM03B-ACH
CN1		Pressure Sensor
CN2		Pressure Sensor
LED1		LRTBR48G-P9Q7-1+R7S5-26+NP-6
LED2		LRTBR48G-P9Q7-1+R7S5-26+NP-6

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

R71	0351023701	RC0402FR-07 56RL
R129	0351023701	RC0402FR-07 56RL
R130	0351026701	RC0402FR-07 100RL
R131	0351023701	RC0402FR-07 56RL
R132	0351023701	RC0402FR-07 56RL
R133	0351026701	RC0402FR-07 100RL
R127	0353000701	
R128	0353000701	
TP5.1		PIZEO
TP5.2		PIZEO
X2		PPG sensor
X4		PPG sensor

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-June 9 2023, Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

ELSEVIER

1 July 1996

OPTICS COMMUNICATIONS

Optics Communications 128 (1996) 99–107

Full length article

Diffusing-wave absorption spectroscopy in homogeneous turbid media

G. Nishimura*, K. Katayama, M. Kinjo, M. Tamura

Research Institute for Electronic Science, Hokkaido University, Sapporo 060, Japan

Received 6 November 1995; accepted 18 January 1996

Abstract

The intensity autocorrelation function of light through a dense intralipid suspension in the presence of an absorber was investigated by the photon correlation method. Then, we demonstrated that the parameter of the scattering can be obtained through the absorption effect with the diffusing-wave spectroscopy: diffusing-wave absorption spectroscopy. Firstly, the relation of the Laplace transform between the autocorrelation and path distribution functions was confirmed by using the time-of-flight method. Then, the linear shifts along the time axis of the autocorrelation function due to the absorption were also validated and the transport mean free path was obtained. Furthermore, this was also estimated from the intensity change by absorption.

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: (b)(6)

Sent: Monday, June 19, 2023 6:33 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Here is our response to your questions along with a revised 510k summary.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, June 16, 2023 8:12 PM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan

(b)(6)

Sent: Friday, June 16, 2023 2:18 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Here is our response to your questions along with a revised 510k summary.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, June 16, 2023 1:52 AM

To: (b)(6)

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Dog,

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Thursday, June 15, 2023 1:41 PM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, June 14, 2023 1:20 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Monday, June 12, 2023 7:43 PM

To: (b)(6)

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Hi Doug,

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Monday, June 12, 2023 5:44 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, June 9, 2023 3:00 AM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan

From: Erlewein, Meaghan

Sent: Thursday, June 8, 2023 2:31 PM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Friday, June 2, 2023 9:30 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Please find attached our response to the question below.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 26, 2023 11:29 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

discussed during the presubmission.

Thanks,

Meaghan

(b)(6)

Sent: Monday, May 22, 2023 10:24 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Tuesday, May 23, 2023 3:17 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Monday, May 22, 2023 7:55 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

(b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan

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

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<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

[cid:image018.png@01D9A2DB.CA5117F0]<http://www.fda.gov/>

[cid:image019.jpg@01D9A2DB.CA5117F0]<https://www.facebook.com/FDA>
[cid:image020.jpg@01D9A2DB.CA5117F0] <https://twitter.com/US_FDA>
[cid:image021.jpg@01D9A2DB.CA5117F0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image022.jpg@01D9A2DB.CA5117F0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image023.jpg@01D9A2DB.CA5117F0]
<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>

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan

That is very strange as I verified all of the files were included with the emails. Can

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

I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated

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

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If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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(b)(4)

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Meaghan

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One last email. I verified that the emails sent include all of the files sent with the original response S002.

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Douglas Herrington
Principal Consultant

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Sent: Wednesday, May 10, 2023 8:20 PM
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5. 510(k) Summary

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR Part 807.92

5.1 Submitter

Accurate Meditech Inc.
8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.,
Sanchong Dist., New Taipei City 241406, Taiwan

Phone: +886 2 2999 1596
Fax: +886 2 2999 1196
Contact Person: Kuan-Jen, Wang

Date Prepared: 2023/6/17

5.2 Subject Device Information

Trade/Device Name	Accurate 24 Non-invasive blood pressure monitor
Model	Accurate 24 BPM
Common Name	Non-invasive blood pressure monitor
Regulatory Classification	Class II 870.1130 Noninvasive blood pressure measurement system
Submission type	Traditional 510(k)
Product Code	DXN

5.3 Predicate Device Information

Predicate Device	Sponsor: Biobeat Technologies Ltd. Device: BB-613 WP 510(K) Number: K190792

5.4 Device Description:

Accurate 24 Non-Invasive blood pressure monitor device is a small, lightweight, handheld device intended to measure and display blood pressure trending (Systolic and Diastolic) and spot-check of pulse rate. Measurement is performed on the wrist of the radial artery. This blood pressure monitor uses the pulse wave transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and pulse rate of adults in a non-invasive manner.

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

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5.5 Indications for Use:

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and is able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

5.6 Comparison to the Predicate Device

The intended use of Accurate 24 BPM has the same intended use as predicate device BB-613 WP(K190792). The technological characteristics of Accurate 24 BPM are substantially similar to the technological characteristics of the predicate device BB-613 WP(K190792). The subject device and predicate device are considered NIBP monitors; both the subject device and predicate device are based on obtaining pulse wave transit time for blood pressure and pulse rate calculation. At a high level, the subject and predicate devices are based on the following same technological elements:

Functionality	New Device Accurate 24 BPM	Predicate Device BB-613WP
Indications for use	The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40. The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally. The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using oscillometric blood pressure monitor. The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.
Product Codes	DXN	DXN, DQA, DRG
Regulation No.	21 CFR 870.1130	21 CFR 870.1130
Classification	Class II	Class II
Classification Name	Noninvasive Blood Pressure	Noninvasive Blood Pressure

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	Measurement System	Measurement System
Use Population	Adults (age 20-70)	Adults
User Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use
Monitoring	Spot-checking	Spot-checking
Principle of Operation	Accurate 24 BPM estimates blood pressure based on the Moens-Korteweg equation. The dual piezo sensors obtain the pulse wave transit time by positioned in a fixed length on radial artery for PWV and pulse rate. By utilizing arterial changes captured by the first NIRS optic, hemodynamic process is able to conclude the pulse pressure for SBP and DBP.	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time which is obtained utilizing pulse measurements from the integrated skin attached SpO2 sensor
Internal Power supply	Rechargeable lithium-polymer battery	Rechargeable lithium-polymer battery
Measurement Site	Wrist area and skin	Wrist area and skin
Measurement type	Spot	Spot
Measurement Range, Pulse rate	40 to 250 bpm	40 to 250 bpm
Pulse rate	±5%	±3%(Arms)
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg
Accuracy blood Pressure	±5 mmHg	±5 mmHg
Contact material	Wrist Skin Cushion: Medical Silicone Wrist Holder: Nylon and Fabric Plastic Parts: ABS	Polycarbonate, photodiode window, silicone, adhesive patch
Data Display	PMOLED on device.	LCD on device or handheld display unit (e.g., mobile phone)
Screen	65K Full Color	Black and White
Data Storage	Yes, Storage in the NAND flash.	No, but can transmit the data to handheld device

5.7 Performance Data

Performance Data - Bench Tests

The performance evaluation of the proposed Accurate 24 BPM included testing conducted following the FDA Guidance Documents and international standards:

- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "major" concern since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
- Electrical safety and EMC testing were conducted on the Accurate 24 BPM device. The system complies with the IEC 60601-1、IEC 60601-1-11 and IEC80601-2-30 standards for safety and the IEC 60601-1-2 standard for EMC.

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- Cytotoxicity, sensitization, irritation, and systemic toxicity of Accurate24 BPM passed ISO 10993 standard.

Performance Data - Clinical Tests

Our clinical study is evaluated according to ISO 81060-2:2018 and IEEE 1708:2014 [Including: Amendment 1(2019). In total, 376 subjects were included in the clinical validation study. The subjects were included according to the subject selection criteria outlined in ISO 81060-2:2018 and IEEE 1708-2014 [Including: Amendment 1(2019)]. At least 85 subjects were included for the following confounding factors: (1) Fitzpatrick Scale Type 5 and 6, (2) Subjects Ages 51-70 years, (3) Body Mass Index Grade I & II. All confounding factor groups were assessed independently. All analysis met the accuracy requirements outlined in ISO 81060-2:2018. The obtained clinical results are as follows.

Characteristic		**Actual subjects**	
Subject, n		376	
overall results for all study subjects			
	Pass requirements	**Achieved**	
		SBP	***DBP***
Means (*mmHg*)	± 5	1.67	1.01
SD (*mmHg*)	≤ 8	4.04	5.32
Results		**pass**	**Pass**
Criterion 2			
SD (*mmHg*)	≤ 6.76/6.87	2.73	3.55
Results		**pass**	**pass**

General study participants (The subject requirements for ISO 81060-2:2018) of accuracy study:

This was a study of 114 subjects. Participants' age ranged from 20 – 70 and 73 were male and 41 were female. The study was conducted in accordance with ISO 81060-2:2018 standard. The Accurate 24 BPM accuracy was compared to "Welch Allyn DuraShock DS66 Trigger Aneroid".

Primary endpoint
The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid measurement in the accuracy validation data set were as follows: (1) mean bias of systolic BP: 2.00±2.97 and (2) mean diastolic bias: 1.33 ±4.17 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

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

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Confounding factors of the study participants accuracy study:

This were three groups (Group-01: Fitzpatrick Skin Type 5 & Type 6), Group-02:Age 51-70 years and Group-03:BMI Grade I & II) are independently recruited participants study of 286 subjects. The Accurate 24 BPM accuracy was compared to Welch Allyn DuraShock DS66 Trigger Aneroid.

Primary endpoint

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Fitzpatrick Scale (Type 5 & Type 6) population validation data set were as follows: (1) mean bias for systolic BP: 1.81 ± 4.44 mmHg (2) mean bias of diastolic BP: -0.90 ± 5.13 mmHg (3) PR accuracy: 0.175 beats/min.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Age (51-70 years) population validation data set were as follows: (1) mean bias for systolic BP: 1.53 ± 4.04 mmHg and (2) mean bias of diastolic BP: 2.13 ± 6.50 mmHg.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the BMI (Grade I & II) population validation data set were as follows: (1) mean bias for systolic BP: 1.11 ± 4.55 mmHg and (2) mean bias of diastolic BP: 1.36 ± 4.87 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

5.9 Conclusion

The Accurate 24 BPM is as safe and effective as the predicate devices. The Accurate 24 BPM has the same intended uses and similar indications, technological characteristics, and principles of operation. In addition, the minor technical differences between the Accurate 24 BPM and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Accurate 24 BPM is as safe and as effective as the predicate. Thus, the Accurate 24 BPM is substantially equivalent.

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Hi Meaghan

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All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

> On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:
>
> ï»¿
> Hi Doug,
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> We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.
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> Thanks,
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> From: (b)(6)
> Sent: Wednesday, May 10, 2023 10:06 PM
> To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> Cc: k222658@docs.fda.gov
> Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> 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.
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> Hi Megan,
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> One last email. I verified that the emails sent include all of the files sent with the original response S002.
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> Best
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>
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> Herrington Consulting LLC
> Douglas Herrington
> Principal Consultant

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

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Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
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Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

August 7, 2023

Accurate Meditech Inc.
% Douglas Herrington
Official Correspondent
Herrington Consulting LLC
No 64, Haijing 3rd St
Sanzhi District
New Taipei City, 252
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN

Dear Douglas Herrington:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 21, 2023. Specifically, FDA is updating this SE Letter to correct the official contact name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Stephen Browning OHT2: Office of Cardiovascular Devices, 240-402-5241, Stephen.Browning@fda.hhs.gov.

Sincerely,

Stephen C. Browning -S

Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

June 21, 2023

Accurate Meditech Inc.
Wang Kuan-Jen
General Manager
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.,
New Taipei City, 241406
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 15, 2023
Received: May 15, 2023

Dear Wang Kuan-Jen:

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.

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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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. 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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 2023-1015; Released by CDRH on 07-09-2024

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)*
K222658

Device Name
Accurate 24 Non-invasive blood pressure monitor

Indications for Use *(Describe)*
The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

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 2023-10915; Released by CDRH on 07-09-2024

5. 510(k) Summary

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR Part 807.92

5.1 Submitter

Accurate Meditech Inc.
8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.,
Sanchong Dist., New Taipei City 241406, Taiwan

Phone: +886 2 2999 1596
Fax: +886 2 2999 1196
Contact Person: Kuan-Jen, Wang

Date Prepared: 2023/6/17

5.2 Subject Device Information

Trade/Device Name	Accurate 24 Non-invasive blood pressure monitor
Model	Accurate 24 BPM
Common Name	Non-invasive blood pressure monitor
Regulatory Classification	Class II 870.1130 Noninvasive blood pressure measurement system
Submission type	Traditional 510(k)
Product Code	DXN

5.3 Predicate Device Information

Predicate Device	Sponsor: Biobeat Technologies Ltd. Device: BB-613 WP 510(K) Number: K190792

5.4 Device Description:

Accurate 24 Non-Invasive blood pressure monitor device is a small, lightweight, handheld device intended to measure and display blood pressure trending (Systolic and Diastolic) and spot-check of pulse rate. Measurement is performed on the wrist of the radial artery. This blood pressure monitor uses the pulse wave transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and pulse rate of adults in a non-invasive manner.

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

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5.5 Indications for Use:

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and is able to obtain results. The measurement results store in the device locally.

The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

5.6 Comparison to the Predicate Device

The intended use of Accurate 24 BPM has the same intended use as predicate device BB-613 WP(K190792). The technological characteristics of Accurate 24 BPM are substantially similar to the technological characteristics of the predicate device BB-613 WP(K190792). The subject device and predicate device are considered NIBP monitors; both the subject device and predicate device are based on obtaining pulse wave transit time for blood pressure and pulse rate calculation. At a high level, the subject and predicate devices are based on the following same technological elements:

Functionality	New Device Accurate 24 BPM	Predicate Device BB-613WP
Indications for use	The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40. The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally. The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using oscillometric blood pressure monitor. The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.
Product Codes	DXN	DXN, DQA, DRG
Regulation No.	21 CFR 870.1130	21 CFR 870.1130
Classification	Class II	Class II
Classification Name	Noninvasive Blood Pressure	Noninvasive Blood Pressure

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

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	Measurement System	Measurement System
Use Population	Adults (age 20-70)	Adults
User Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use
Monitoring	Spot-checking	Spot-checking
Principle of Operation	Accurate 24 BPM estimates blood pressure based on the Moens-Korteweg equation. The dual piezo sensors obtain the pulse wave transit time by positioned in a fixed length on radial artery for PWV and pulse rate. By utilizing arterial changes captured by the first NIRS optic, hemodynamic process is able to conclude the pulse pressure for SBP and DBP.	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time which is obtained utilizing pulse measurements from the integrated skin attached SpO2 sensor
Internal Power supply	Rechargeable lithium-polymer battery	Rechargeable lithium-polymer battery
Measurement Site	Wrist area and skin	Wrist area and skin
Measurement type	Spot	Spot
Measurement Range, Pulse rate	40 to 250 bpm	40 to 250 bpm
Pulse rate	±5%	±3%(Arms)
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg
Accuracy blood Pressure	±5 mmHg	±5 mmHg
Contact material	Wrist Skin Cushion: Medical Silicone Wrist Holder: Nylon and Fabric Plastic Parts: ABS	Polycarbonate, photodiode window, silicone, adhesive patch
Data Display	PMOLED on device.	LCD on device or handheld display unit (e.g., mobile phone)
Screen	65K Full Color	Black and White
Data Storage	Yes, Storage in the NAND flash.	No, but can transmit the data to handheld device

5.7 Performance Data

Performance Data - Bench Tests

The performance evaluation of the proposed Accurate 24 BPM included testing conducted following the FDA Guidance Documents and international standards:

- Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "major" concern since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
- Electrical safety and EMC testing were conducted on the Accurate 24 BPM device. The system complies with the IEC 60601-1、IEC 60601-1-11 and IEC80601-2-30 standards for safety and the IEC 60601-1-2 standard for EMC.

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

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- Cytotoxicity, sensitization, irritation, and systemic toxicity of Accurate24 BPM passed ISO 10993 standard.

Performance Data - Clinical Tests

Our clinical study is evaluated according to ISO 81060-2:2018 and IEEE 1708:2014 [Including: Amendment 1(2019). In total, 376 subjects were included in the clinical validation study. The subjects were included according to the subject selection criteria outlined in ISO 81060-2:2018 and IEEE 1708-2014 [Including: Amendment 1(2019)]. At least 85 subjects were included for the following confounding factors: (1) Fitzpatrick Scale Type 5 and 6, (2) Subjects Ages 51-70 years, (3) Body Mass Index Grade I & II. All confounding factor groups were assessed independently. All analysis met the accuracy requirements outlined in ISO 81060-2:2018. The obtained clinical results are as follows.

Characteristic		**Actual subjects**	
Subject, n		376	
overall results for all study subjects			
	Pass requirements	**Achieved**	
		SBP	***DBP***
Means (*mmHg*)	± 5	1.67	1.01
SD (*mmHg*)	≤ 8	4.04	5.32
Results		**pass**	**Pass**
Criterion 2			
SD (*mmHg*)	≤ 6.76/6.87	2.73	3.55
Results		**pass**	**pass**

General study participants (The subject requirements for ISO 81060-2:2018) of accuracy study:

This was a study of 114 subjects. Participants' age ranged from 20 – 70 and 73 were male and 41 were female. The study was conducted in accordance with ISO 81060-2:2018 standard. The Accurate 24 BPM accuracy was compared to "Welch Allyn DuraShock DS66 Trigger Aneroid".

Primary endpoint
The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid measurement in the accuracy validation data set were as follows: (1) mean bias of systolic BP: 2.00±2.97 and (2) mean diastolic bias: 1.33 ±4.17 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

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

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Confounding factors of the study participants accuracy study:

This were three groups (Group-01: Fitzpatrick Skin Type 5 & Type 6), Group-02:Age 51-70 years and Group-03:BMI Grade I & II) are independently recruited participants study of 286 subjects. The Accurate 24 BPM accuracy was compared to Welch Allyn DuraShock DS66 Trigger Aneroid.

Primary endpoint

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Fitzpatrick Scale (Type 5 & Type 6) population validation data set were as follows: (1) mean bias for systolic BP: 1.81 ± 4.44 mmHg (2) mean bias of diastolic BP: -0.90 ± 5.13 mmHg (3) PR accuracy: 0.175 beats/min.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Age (51-70 years) population validation data set were as follows: (1) mean bias for systolic BP: 1.53 ± 4.04 mmHg and (2) mean bias of diastolic BP: 2.13 ± 6.50 mmHg.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the BMI (Grade I & II) population validation data set were as follows: (1) mean bias for systolic BP: 1.11 ± 4.55 mmHg and (2) mean bias of diastolic BP: 1.36 ± 4.87 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

5.9 Conclusion

The Accurate 24 BPM is as safe and effective as the predicate devices. The Accurate 24 BPM has the same intended uses and similar indications, technological characteristics, and principles of operation. In addition, the minor technical differences between the Accurate 24 BPM and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Accurate 24 BPM is as safe and as effective as the predicate. Thus, the Accurate 24 BPM is substantially equivalent.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.-June 16 2023, Response

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Unresolved Anomalies

Document Number: (b)(4)

Version: (b)(4)

2021/07/05

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) *Date* 2021-07-05

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: (b)(6)

Sent: Friday, June 16, 2023 2:18 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Here is our response to your questions along with a revised 510k summary.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, June 16, 2023 1:52 AM

To: (b)(6)

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Dog,

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Thursday, June 15, 2023 1:41 PM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Thank you for getting all of these interactive requests to me. We have a request for an edits to the 510(k) Summary. Please respond as soon as possible but no later than COB on 6/19.

(b)(4)

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

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[cid:image001.png@01D9A05C.A1191030]

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, June 14, 2023 1:20 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Monday, June 12, 2023 7:43 PM

To: (b)(6)

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Monday, June 12, 2023 5:44 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, June 9, 2023 3:00 AM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Thursday, June 8, 2023 2:31 PM

To: (b)(6)

Cc: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thanks,

Meaghan

(b)(6)

Sent: Friday, June 2, 2023 9:30 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Please find attached our response to the question below.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 26, 2023 11:29 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan

(b)(6)

Sent: Monday, May 22, 2023 10:24 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Tuesday, May 23, 2023 3:17 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Monday, May 22, 2023 7:55 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

(b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4) (b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 17, 2023 10:36 PM

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow Devices Team

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices | Office of Cardiovascular Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

[cid:image006.png@01D9A05C.A1191030]<http://www.fda.gov/>

[cid:image007.jpg@01D9A05C.A1191030]<https://www.facebook.com/FDA>
[cid:image008.jpg@01D9A05C.A1191030] <https://twitter.com/US_FDA>
[cid:image009.jpg@01D9A05C.A1191030] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image010.jpg@01D9A05C.A1191030] <http://www.flickr.com/photos/fdaphotos/>
[cid:image011.jpg@01D9A05C.A1191030]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>
Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

(b)(4)

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

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

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024
included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

NP-140TL

■ FEATURES

(b)(4)

(b)(4)

■ PERFORMANCE LIST

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Tuesday, May 23, 2023 3:17 AM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Monday, May 22, 2023 7:55 AM

To: (b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Confirming receipt.

Thank you!

-Meaghan

(b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov> ; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov>

<http://www.fda.gov/>

<https://www.facebook.com/FDA> <https://twitter.com/US_FDA>
<http://www.youtube.com/user/USFoodandDrugAdmin>
<http://www.flickr.com/photos/fdaphotos/>
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E> Here

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

ï»¿

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I just wanted to let you know we received the full response yesterday.

Thanks,

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >; 'Douglas HERRINGTON' (b)(6) (b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: (b)(6) ; k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan

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All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> > wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov <mailto:k222658@docs.fda.gov> ; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

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If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

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(b)(4)

(b)(4)

Report Number: (b)(4)

(b)(4)

Skin Irritation Test of Reusable Blood Pressure cuff Using ISO 10993-10:2010 Test Method 0.9% Sodium Chloride Injection Extract

Sponsor

(b)(4)

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

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(b)(4)

FCC SDoC REPORT

Test Report No.	: (b)(4)
Applicant	: Accurate Meditech Inc.
Address	: 8F-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406, Taiwan
Manufacturer	: Accurate Meditech Inc.
Address	: 8F-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406, Taiwan

Equipment Under Test (EUT) :

Product Name	: Accurate 24 Non-invasive blood pressure monitor
Brand Name	: Accurate 24
Model No.	: Accurate 24_BPM
Added Model(s)	: N/A

Standards : 47 CFR FCC Part 15 Subpart B (Class B)

Date of Sample Receipt	: (b)(4)
Date of Test	:
Date of Issue	:
Test Result :	(b)(4)

In the configuration tested, the EUT complied with the standards specified above.

Remarks :

(b)(4)

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(b)(4)

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Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

From: (b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Cc: k222658@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

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I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

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May 9, 2023

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(b)(4)

Sanitation & Environment Technology Institute,
Soochow University,
Final Report

(b)(4)

Report Number: (b)(4)

In Vitro Cytotoxicity Test of
Reusable One-piece Blood Pressure Cuff
using ISO 10993-5: 2009 Test Method
MTT Method
MEM with 10%FBS extract

(b)(4)

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From: Suliman, Ahmad
To: Erlewein, Meaghan
Cc: Scully, Christopher
Subject: RE: K222658/S003 - (b)(5)
Date: Thursday, June 15, 2023 4:52:34 PM
Attachments: image001.png

Hi Meaghan,

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(5)

Thanks,
Ahmad

From: Suliman, Ahmad
Sent: Tuesday, June 13, 2023 3:27 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003 - (b)(5)

Hi Meaghan,

(b)(5)

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

(b)(5)

Happy to hop in a call to discuss if that is more convenient.

Thanks,
Ahmad

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Monday, June 12, 2023 10:28 AM
To: Suliman, Ahmad <Ahmad.Suliman@fda.hhs.gov>
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: K222658/S003 - (b)(5)

Hi Ahmad,

(b)(5)

Thank you!

-Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 8, 2023 2:39 PM
To: Suliman, Ahmad <Ahmad.Suliman@fda.hhs.gov>
Subject: RE: K222658/S003 - (b)(5)

Thanks, Ahmad!

(b)(5)

Thanks,
Meaghan

From: Suliman, Ahmad <Ahmad.Suliman@fda.hhs.gov>

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Wednesday, June 7, 2023 6:21 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: Scully, Christopher <Christopher.Scully@fda.hhs.gov>
Subject: RE: K222658/S003 - (b)(5)

Hi Meaghan,

I hope you are doing well.

(b)(5)

Thanks,
Ahmad

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Monday, May 15, 2023 2:34 PM
To: Suliman, Ahmad <Ahmad.Suliman@fda.hhs.gov>; Kucukemiroglu, Saryet <Saryet.Kucukemiroglu@fda.hhs.gov>
Cc: Scully, Christopher <Christopher.Scully@fda.hhs.gov>; Lu, Hong (Laura) <Hong.Lu@fda.hhs.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: K222658/S003 - (b)(5)

Hello All,

(b)(5)

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(b)(5)

Thanks,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

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Blood Pressure and Flow 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
Meaghan.Erlewein@fda.hhs.gov



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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Risk Management Report

Document Number: (b)(4)
Version: (b)(4)
2022/08/10

Presented by
Kuan Jen, Wang / General Manager

Approved By (b)(6) ***Date*** 2022-08-12

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Lane. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com:

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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 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Level of Concern

Document Number: (b)(4)

Version: (b)(4)

2021/07/05

Presented by
Falcao/Firmware Manager

Approved By (b)(6) ***Date*** 2021-07-05

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Reversion history

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

For the Accurate 24 BPM contain the software inside. Thus we evaluate the software by "Guidance for FDA Reviewers and Industry Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – 2005". Chapter Determining Level of Concern.

Major Level of Concern:

1. Does the Software Device qualify as Blood Establishment Computer Software?

(b)(4)

2. Is the Software Device intended to be used in combination with a drug or biologic?

(b)(4)

3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?

(b)(4)

4. Does the device software control a life supporting or life sustaining device?

(b)(4)

5. Does the device software control the delivery of potentially harmful energy which could result in death or serious injury, such as radiation treatment systems, defibrillators, and so forth?

(b)(4)

6. Does the device software control treatment delivery, such that an error or malfunction with the delivery could result in death or serious injury?

(b)(4)

7. Does the device software provide diagnostic information on which treatment or therapy is based, such that if misapplied it could result in serious injury or death?

(b)(4)

8. Does the device software provide vital signs monitoring and alarms for potentially life

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

threatening situations in which intervention is necessary?

(b)(4)

Moderate Level of Concern

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

(b)(4)

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

(b)(4)

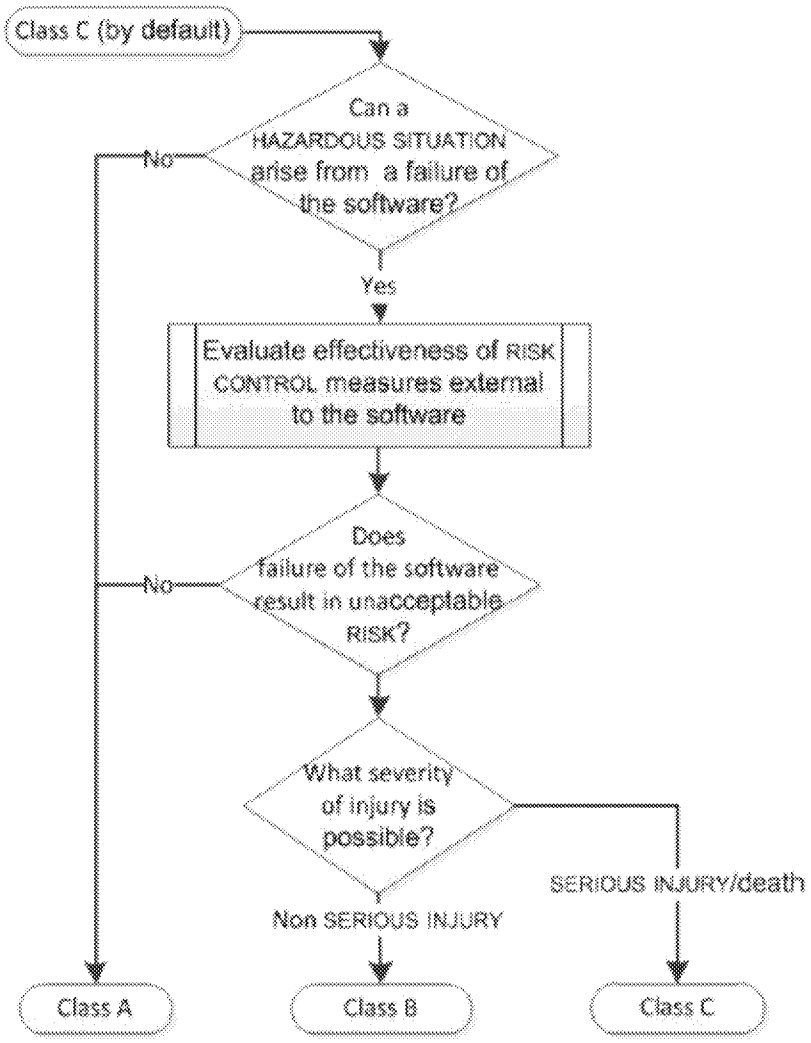
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

(b)(4)

(b)(4)

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

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Flowchart of evaluate software class

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

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Accurate Meditech Inc.-June 9 2023, Response

(b)(4)

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

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5.4 Device Description:

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan

Here is the seventh email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

1 more clarification needed. If possible, please provide a response by COB 5/24.

(b)(4)

[cid:image009.png@01D98CBF.4355F810]

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Monday, May 22, 2023 7:55 AM

To: (b)(6)

Cc: k222658@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

(b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

(b)(4)

Best

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

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

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

[cid:image012.png@01D98CBF.4355F810]<http://www.fda.gov/>

[cid:image013.jpg@01D98CBF.4355F810]<https://www.facebook.com/FDA>
[cid:image014.jpg@01D98CBF.4355F810] <https://twitter.com/US_FDA>
[cid:image015.jpg@01D98CBF.4355F810] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image016.jpg@01D98CBF.4355F810] <http://www.flickr.com/photos/fdaphotos/>
[cid:image017.jpg@01D98CBF.4355F810]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

From: Douglas HERRINGTON (b)(6)

Sent: Tuesday, May 16, 2023 8:05 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.

Best

Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Meaghan

(b)(6)

Sent: Friday, May 12, 2023 7:53 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas HERRINGTON' (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,

Meaghan

From: Douglas HERRINGTON (b)(6)

Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

May 9, 2023

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

Here is the tenth email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Shelf-Life Report of Accurate 24 BPM

Document Number: (b)(4)
Version: (b)(4)
2022/08/09

Presented by
Falcao Chang/ Firmware Manager

Approved By (b)(6) *Date* 2022-08-09

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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From: Mukibi, Sherifah * [Sherifah.Mukibi@fda.hhs.gov]
Sent: 5/9/2023 5:50:08 PM
To: (b)(6)
Subject: K222658/S002 Acknowledgment Notification
Attachments: Acknowledgment Letter-K222658_S002.pdf

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

Acknowledgment Letter

5/9/2023

Douglas Herrington, Official Correspondent
Accurate Meditech Inc.
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.,
New Taipei City 241406
TAIWAN

Dear Douglas Herrington:

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: K222658/S002
Received: 05/02/2023
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

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.

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sincerely yours,

Center for Devices and Radiological Health

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Hi Megan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
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Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: **Software Hazard Analysis**

Document Number: (b)(4)

Version: (b)(4)

2021/07/05

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2021-07-05

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
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Sent: Wednesday, May 10, 2023 1:42 AM
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(b)(4)

Datasheet - production data

(b)(4)

This is information on a product in full production. (b)(4)

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(b)(4)

Report Number: (b)(4)

Skin Sensitization Test of Reusable Blood Pressure cuff using ISO 10993-10:2010 Test Methods Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract

(b)(4)

(b)(4)

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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 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

5. 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 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Date: December 2, 2022

From: Saryet Kucukemiroglu, Ph.D. (Mathematical Statistician)
CDRH/OCEA/DCEA2/TCEA2C

Saryet Kucukemiroglu -S
Digitally signed by Saryet Kucukemiroglu -S
Date: 2022.12.02 16:16:23 -05'00'

Subject: Statistical Review of K222658/S001 Accurate 24 Non-invasive blood pressure monitor by Accurate Meditech Inc. (DHP yes, SaMD no, not software only, SaMD AI/ML no, RWE no, data reuse no)

To: Meaghan Erlewein, PhD
CDRH\OHT2\DHT2A\THT2A1

(b)(5)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Form Approved: OMB No. 0910-0616. Expiration Date: 4/30/2024. See PRA Statement below.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance

Under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. Name of Sponsor/Applicant/Submitter
Accurate Medtech Inc.

2. Date of the Application/Submission
10/14/2022

3. Address

Address 1 *(Street address, P.O. box, company name c/o)*
8F-10, No.12, Ln.609, Sec. 3, Chongxin Rd. Sanchong Dist.,

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City
New Taipei City

State/Province/Region

Country
Taiwan

ZIP or Postal Code
241406

4. Telephone and Fax Numbers *(include country code if applicable and area code)*

(Tel): 886-2-2999-1596

(Fax): 886-2-2999-1196

PRODUCT INFORMATION

5. **For Drugs/Biologics:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s).
For Devices: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)

Accurate 24 Non-invasive blood pressure monitor
Class II per 21 CFR 870.1130
Model: Accurate 24 BPM

Continuation Page for #5

APPLICATION / SUBMISSION INFORMATION

6. Type of Application/Submission Which This Certification Accompanies

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. Include IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number *(if number previously assigned)*
222658

If BLA was selected in item 6, provide Supplement Number

8. Serial Number Assigned to Application/Submission Which This Certification Accompanies

CERTIFICATION STATEMENT / INFORMATION

9. Check only one of the following boxes *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that the requirements of 42 U.S.C. 282(j), including any applicable provisions of 42 CFR part 11, have been met.

Certification Statement / Information section continued on page 2

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

CERTIFICATION STATEMENT / INFORMATION *(Continued)*

10. If you checked box C. in number 9, provide the National Clinical Trial (NCT) Number(s) for any "applicable clinical trial(s)," for which you (the sponsor/applicant/submitter) are the "responsible party" under 42 U.S.C. § 282(j)(1)(a)(i), section 402(j)(1)(a)(i) of the Public Health Service Act referenced in the application/ submission which this Certification accompanies. (Add continuation page as necessary.)

NCT Number(s):

Continuation Page for #10

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.

Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. Name and Title of the Person who Signs Number 15

Name	Title
Wang, Kuan Jen	General Manager

12. Address

Address 1 *(Street address, P.O. box, company name c/o)*	13. Telephone and Fax Numbers *(Include country code if applicable and area code)*
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.,	(Tel): 886-2-2999-1596
Address 2 *(Apartment, suite, unit, building, floor, etc.)*	(Fax): 886-2-2999-1196
City: New Taipei City / State/Province/Region:	
Country: Taiwan / ZIP or Postal Code: 241406	

14. Date of Certification

(b)(6)

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 15 minutes and 45 minutes (depending on the type of application/ submission) 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 2023-10915; Released by CDRH on 07-09-2024

INSTRUCTIONS FOR COMPLETION OF FORM FDA 3674 – CERTIFICATION OF COMPLIANCE

Under 42 U.S.C. § 282(j)(5)(B), with Requirements for ClinicalTrials.gov Data Bank

Form FDA 3674 must accompany an application/submission, including certain amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. Name of Sponsor/Applicant/Submitter – This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. Date – This is the date of the application/submission which the certification accompanies or should have accompanied, if submitted at a subsequent date.

3. & 4. Provide complete address, telephone number, and fax number of the sponsor/applicant/submitter.

5. Product Information – ***For Drugs/Biologics:*** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/ gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. ***For Devices:*** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

Use a continuation page only if you have filled in all available spaces.

6. Type of Application/Submission – Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified (i.e. a new IND clinical protocol), check the box labeled "Other."

7. IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number – If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. Serial Number – In some instances a sequential serial number is assigned to the submission/application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.

9. Certification – This section contains three different check-off boxes.

Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply because no data from clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, including 42 CFR part 11, do not apply at the time of submission of the certification to any clinical trials for which data are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials for which data are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/applicant/submitter is the "responsible party" of the applicable clinical trial included in the application/submission. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, and any provisions of 42 CFR part 11 that apply to one or more of the applicable clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies have been met by the sponsor/applicant/submitter as the "responsible party."

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

10. National Clinical Trial (NCT) Numbers – If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from *www.ClinicalTrials.gov* for each applicable clinical trial for which the sponsor/applicant/submitter is the "responsible party" and for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" for which data is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies and for which the sponsor/applicant/submitter is the "responsible party." Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT number(s) for the "applicable clinical trial(s)" for which data is included, relied upon, or otherwise referred to in the application/ submission. Use a continuation page only if you have filled in all available spaces.

11. Name and Title of Person Who Signed in number 11 – Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

12 & 13. Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 15.

14. Provide the date the certification is signed. This date may be different from the date provided in number 2.

15. Signature of Sponsor/Applicant/Submitter or an Authorized Representative – The person signing the certification must sign in this field.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

*** 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 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

Here is the tenth email.

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
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Meaghan

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Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

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Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

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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 2023-10915; Released by CDRH on 07-09-2024

October 28, 2022</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K222658/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, Meaghan Erlewein. The file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 A. The first line supervisor is the Assistant Director, Blood Pressure and Flow Devices. You may contact me at any point during the review if you have questions or concerns. 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.

We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information.

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

Dear Applicant,

Please refer to the attached addendum for details on the correction.

Best regards,

Edwena R. Jones
Program Analyst
Premarket Notification (510(k))
Division of Regulatory Programs |Office of Regulatory Programs
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 1623 |10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6308
edwena.jones@fda.hhs.gov



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Please take a moment to provide feedback regarding the customer service you have received:

https://www.research.net/s/cdrhcustomerservice?ID=1212&S=E

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

June 21, 2023

Accurate Meditech Inc.
Wang Kuan-Jen
General Manager
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.,
New Taipei City, 241406
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 15, 2023
Received: May 15, 2023

Dear Wang Kuan-Jen:

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.

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 2023-10915; Released by CDRH on 07-09-2024

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. 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,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
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 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

There are two emails that were composed but are not listed in my email files. They contain files 006 â€" 010 and 026 â€" 029. I am resending them.

Also, file 021 was inadvertently sent twice.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6)
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

> On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:
>
> Hi Doug,
>
> We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.
>
> Thanks,
> Meaghan
>
> ---
> **From:** (b)(6)
> **Sent:** Wednesday, May 10, 2023 10:06 PM
> **To:** Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> **Cc:** k222658@docs.fda.gov
> **Subject:** RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> 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 Megan,
>
> One last email. I verified that the emails sent include all of the files sent with the original response S002.
>
> Best
> Doug
>
> Herrington Consulting LLC
> Douglas Herrington

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Requirement Specifications

Document Number: (b)(4)

Version: (b)(4)

2022/09/01

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2022-09-01

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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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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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(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: (b)(6)
Sent: Friday, June 16, 2023 2:18 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Here is our response to your questions along with a revised 510k summary.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, June 16, 2023 1:52 AM
To: (b)(6)
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Dog,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 15, 2023 1:41 PM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

(b)(4)

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, June 14, 2023 1:20 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Monday, June 12, 2023 7:43 PM
To: (b)(6)
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Monday, June 12, 2023 5:44 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, June 9, 2023 3:00 AM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Thursday, June 8, 2023 2:31 PM
To: (b)(6)
Cc: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, June 2, 2023 9:30 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Please find attached our response to the question below.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 26, 2023 11:29 PM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Monday, May 22, 2023 10:24 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Tuesday, May 23, 2023 3:17 AM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

(b)(4)

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Monday, May 22, 2023 7:55 AM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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.

Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

> On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:
>
> Hi Doug,
>
> (b)(4)
>
> Thanks,
> Meaghan
>
> ---
>
> **From:** (b)(6)
> **Sent:** Wednesday, May 10, 2023 10:06 PM
> **To:** Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> **Cc:** k222658@docs.fda.gov
> **Subject:** RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> 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 Megan,

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

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

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(b)(4)

Report Number: (b)(4)

Skin Sensitization Test of Reusable One-piece Blood Pressure Cuff Using ISO 10993-10:2010 Test Methods Guinea Pig Maximization Test 0.9% Sodium Chloride Injection Extract

(b)(4)

(b)(4)

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 5/15/2023 5:01:31 PM
To: (b)(6)
CC: DCCLetters@fda.hhs.gov
Subject: K222658/S003 Acknowledgement Letter
Attachments: K222658-S003-Acknowledgement Letter.pdf

May 15, 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.

*** 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 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgement Letter

05/15/2023

Douglas Herrington, Official Correspondent
Herrington Consulting LLC
No 64, Haijing 3rd St Sanzhi District
New Taipei City,
252 TAIWAN

Dear Douglas Herrington:

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: K222658/S003
Received: 05/15/2023
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

eConsult Cover Sheet

Consult Number: CON2312431

Document Number: K222658/S003

Applicant: Accurate Meditech Inc.

Trade Name: Accurate 24 Non-invasive blood pressure monitor

Consult Type: Analytical

Requestor: Meaghan Erlewein [MEAGHAN.ERLEWEIN]

meaghan.erlewein@fda.hhs.gov

Requestor Home: CDRH\ OHT2\ DHT2A\ THT2A1

Requested Consultant:

Gatekeeper / Consultant: Ahmad Suliman [AHMAD.SULIMAN]

ahmad.suliman@fda.hhs.gov ; 240-402-1799

Consultant Home: CDRH\ OSEL\ DBP

Date Requested: May 18, 2023

Due Date: June 7, 2023

Instructions: Please refer to consult request email sent 5/15. Thank you!

(b)(5)

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

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(b)(5)

Ahmad Suliman
Division of Biomedical Physics
OSEL / CDRH / FDA

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

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Hi Doug,

(b)(4)

Thanks,

Meaghan

From: (b)(6)

Sent: Monday, May 22, 2023 10:24 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Cc: k222658@docs.fda.gov

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Tuesday, May 23, 2023 3:17 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

Thanks,

Meaghan

From: Erlewein, Meaghan

Sent: Monday, May 22, 2023 7:55 AM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

(b)(6)

Sent: Saturday, May 20, 2023 10:07 PM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

HI Meaghan,

Attached please find our responses to the questions below (b)(4)

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 17, 2023 10:36 PM

To: Douglas HERRINGTON (b)(6)

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

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We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

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(b)(4)

Thank you,

Meaghan

Meaghan Erlewein (she/her/hers)

Biomedical Engineer

Blood Pressure and Flow 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

Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>

[cid:image004.png@01D98FC0.C8433200]<http://www.fda.gov/>

[cid:image005.jpg@01D98FC0.C8433200]<https://www.facebook.com/FDA>
[cid:image006.jpg@01D98FC0.C8433200] <https://twitter.com/US_FDA>
[cid:image007.jpg@01D98FC0.C8433200] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image008.jpg@01D98FC0.C8433200] <http://www.flickr.com/photos/fdaphotos/>
[cid:image009.jpg@01D98FC0.C8433200]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received:
Here<https://www.research.net/s/cdrhcustomerservice?ID=1414&S=E>

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Sent: Tuesday, May 16, 2023 8:05 AM

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<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

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Doug Herrington

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ï»¿

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Meaghan

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To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>; 'Douglas HERRINGTON' (b)(6)

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Friday, May 12, 2023 7:40 PM

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Thanks,

Meaghan

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Sent: Thursday, May 11, 2023 9:58 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: (b)(6)
k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan

That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.

All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.

Best

Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>> wrote:

ï»¿

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 10:06 PM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best

Doug

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov<mailto:k222658@docs.fda.gov>; Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan
<Meaghan.Erlewein@fda.hhs.gov<mailto:Meaghan.Erlewein@fda.hhs.gov>>

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN]
<meaghan.erlewein@fda.hhs.gov<mailto:meaghan.erlewein@fda.hhs.gov>>

Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

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If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

*** 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 2023-10915; Released by CDRH on 07-09-2024

From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 9/2/2022 5:09:19 PM
To: stanley@accurate-meditech.com
CC: DCCLetters@fda.hhs.gov
Subject: K222658 Acknowledgement Letter
Attachments: K222658-Acknowlegement Letter.pdf

September 2, 2022

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.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

U.S. FOOD & DRUG ADMINISTRATION

Acknowlegement Letter

09/02/2022

Wang Kuan Jen, General Manager
Accurate Meditech Inc.
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd., Sanchong Dist.,
New Taipei City,
241406 TAIWAN

Dear Wang Kuan Jen:

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 .

Submision Number: K222658
Received: 09/02/2022
Applicant: Accurate Meditech Inc.
Device: Accurate 24 Non-invasive blood pressure monitor

We will notify you when the review of this submission 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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(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 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6)
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6)
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan
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>
> ---
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> **From:** (b)(6)
> **Sent:** Wednesday, May 10, 2023 10:06 PM
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Cc: k222658@docs.fda.gov
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Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
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Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thanks,
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Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024
Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

September 12, 2022</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your submission K222658. Our review indicates that your submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit one eCopy of your response, referencing your submission K222658, addressing the elements identified as missing or inconsistent in the attached checklist 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

Your submission will remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by 03/11/2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your submission. We will contact you if we require any additional information during the course of our administrative review. FDA aims to apply the least burdensome principles when requesting additional information.

The lead reviewer assigned to your submission is me, Kimberly Crowley. The file is being reviewed in Office of Health Technology 2, Division of Health Technology 2 A. The first line supervisor is the Assistant Director, Blood Pressure and Flow Devices. You may contact me at any point during the review if you have questions or concerns. 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.

For additional information about the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Doug,

(b)(4)

Thanks,
Meaghan

From: (b)(6)
Sent: Monday, May 22, 2023 10:24 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

(b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Tuesday, May 23, 2023 3:17 AM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

(b)(4)

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

(b)(4)

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Thanks,
Meaghan

From: Erlewein, Meaghan
Sent: Monday, May 22, 2023 7:55 AM
To: (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Confirming receipt.

Thank you!

-Meaghan

From: (b)(6)
Sent: Saturday, May 20, 2023 10:07 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@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*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6)
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
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Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

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From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
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Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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> Hi Doug,
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> We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.
>
> Thanks,
> Meaghan
>
> ---
>
> **From:** (b)(6)
> **Sent:** Wednesday, May 10, 2023 10:06 PM
> **To:** Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
> **Cc:** k222658@docs.fda.gov
> **Subject:** RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response
>
> 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.
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One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
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Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

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Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

One last email. I verified that the emails sent include all of the files sent with the original response S002.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 8:20 PM
To: (b)(6)
Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 1:42 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best
Doug

Douglas Herrington
Herrington Consulting LLC
Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Sent: Wednesday, May 10, 2023 2:47 AM
To: (b)(6)
Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov>
Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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*** 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 2023-10915; Released by CDRH on 07-09-2024

510(k) Cover Letter

FDA/CDRH/DCC
MAY 09 2023
RECEIVED

K222658/A001

May 08, 2023

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

Re: This refuse-to-accept (RTA) for K222658 response is being submitted for the Accurate 24 Non-Invasive blood pressure monitor, Model Accurate 24 BPM

Dear Sir or Madam:

(b)(4)

We have contacted Douglas Herrington, the principal consultant of Herrington Consulting LLC, to act as our official correspondent. He should be contacted directly for any questions, comments or issues arising from review of this submission.

Sponsor & Manufacturing Address:

Accurate Meditech Inc
8F-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd.
Sanchong District
New Taipei City 241406
Taiwan (R.O.C.)
Phone: +886.937.987.729
Fax: +886.2.2999.1196

Official Contact Name

Douglas Herrington
No 64, Haijing 3rd St
Sanzhi District
New Taipei City 252, Taiwan (R.O.C.)
Telephone: 1.248.369.5564
Fax: 1.877.881.4412
E-mail: **(b)(6)**

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Sincerely,

(b)(6)

Signature
Kuan-Jen, Wang
CEO, Accurate Meditech Inc.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Hi Megan,

(b)(4)

Best

Doug

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

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Doug

Douglas Herrington

Herrington Consulting LLC

Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

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Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

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Principal Consultant

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Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: User Manual

Document Number: (b)(4)
Version: (b)(4)
2022/08/09

Presented by
Catherine Chi/Product Manager

Approved By (b)(6) *Date* 2022-08-12

***Kuan Jen, Wang* (General Manager)**

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Lithium battery Specifications

Document Number: (b)(4)
Version: (b)(4)
2022/08/08

Presented by
Falcao/Firmware Manager

Approved By (b)(6) *Date* 2022-08-08

***Kuan Jen, Wang* (General Manager)**

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rd., Sanchong Dist., New Taipei City 241406 Taiwan
Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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HI Meaghan,

Attached please find our responses to the questions below (b)(4)

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Wednesday, May 17, 2023 10:36 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

We have begun to review the K222658 Accurate 24 Non-Invasive Blood Pressure Monitor AINN response. We have the following questions. If possible, please provide a response by COB Monday, 5/22.

(b)(4)

Thank you,
Meaghan

Meaghan Erlewein (she/her/hers)
Biomedical Engineer

Blood Pressure and Flow 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
Meaghan.Erlewein@fda.hhs.gov

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

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Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received: *Here*

From: Douglas HERRINGTON (b)(6)
Sent: Tuesday, May 16, 2023 8:05 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Thank you. Appreciate you letting me know.
Best
Doug Herrington

On May 16, 2023, at 7:34 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

I just wanted to let you know we received the full response yesterday.

Thanks,
Meaghan

From: (b)(6)
Sent: Friday, May 12, 2023 7:53 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>; 'Douglas HERRINGTON' (b)(6)
Cc: k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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Hi Meaghan,

Thank you for getting back to me but we decided to send another flash drive which was sent today. This seems the safest way to make sure the files are uploaded before the due date.

Best
Doug

Herrington Consulting LLC
Douglas Herrington
Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Sent: Friday, May 12, 2023 7:40 PM
To: Douglas HERRINGTON (b)(6)
Cc: (b)(6) k222658@docs.fda.gov
Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Do you have confirmation from the courier that it was delivered to the DCC? If so, what is the date it was delivered?

Thanks,
Meaghan

From: Douglas HERRINGTON (b)(6)
Sent: Thursday, May 11, 2023 9:58 AM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: (b)(6) k222658@docs.fda.gov
Subject: Re: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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safe.

Hi Meaghan
That is very strange as I verified all of the files were included with the emails. Can I assume you did not receive those emails.
All of the responses sent to the DCC were contained on a flash drive and DVD. Can the flash drive or DVD be found by the DCC? If not then please confirm that we need to send another FedEx to the DCC with the response files.
Best
Doug Herrington

On May 11, 2023, at 8:48 PM, Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov> wrote:

Hi Doug,

We only received the files with the reference articles for the S002 response. Can you please submit a response to the Incomplete Response hold notification with all of the documentation (responses to the deficiencies) to the Document Control Center.

Thanks,
Meaghan

From: (b)(6)
Sent: Wednesday, May 10, 2023 10:06 PM
To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>
Cc: k222658@docs.fda.gov
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Subject: K222658/S002 is on Hold Pending Your Response

May 9, 2023

We have received your response, which was logged in as K222658/S002, to deficiencies regarding your submission. We are not able to review your response at this time because you did not provide a complete response to our email hold notification dated 12/09/2022.

More specifically, no response was provided to any of the deficiencies provided in the Additional Information Notification dated December 9, 2022. Additional references were included in the supplement; however, it is unclear how to interpret these in the context of the deficiencies communicated on December 9, 2022.

Therefore, your submission has been placed back on hold as of the original hold date, 12/09/2022.

If a complete response is not received in CDRH's Document Control Center by June 7, 2023, we will consider this submission to be withdrawn, and we will delete it from our review system.

If you have questions about this email, you may contact Meaghan Erlewein, the lead reviewer assigned to your submission.

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

Records processed under FOIA Request 2023-10915; Released by CDRH on 07-09-2024

Accurate Meditech Inc.

Product name: Accurate 24 Non-invasive blood pressure monitor

Document name: Software Design Specifications

Document Number: (b)(4)

Version: (b)(4)

2022/09/01

Presented by
Falcao/ Firmware Manager

Approved By (b)(6) ***Date*** 2022-09-01

Kuan Jen, Wang (General Manager)

Address: 8F.-10, No. 12, Ln. 609, Sec. 5, Chongxin Rrd., Sanchong Dist., New Taipei City 241406 Taiwan

Telephone: +886 2 2999-1596 /Fax: +886 2 2999 1196/E-mail : info@accurate-meditech.com

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

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Hi Megan,

Heer is the third email.

Herrington Consulting LLC

Douglas Herrington

Principal Consultant

From: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Sent: Wednesday, May 10, 2023 8:20 PM

To: (b)(6)

Cc: k222658@docs.fda.gov; Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov>

Subject: RE: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

Hi Doug,

Can you respond to this email with the full response submitted to the DCC for K222658/S002?

Thanks,

Meaghan

(b)(6)

Sent: Wednesday, May 10, 2023 1:42 AM

To: Erlewein, Meaghan <Meaghan.Erlewein@fda.hhs.gov <mailto:Meaghan.Erlewein@fda.hhs.gov> >

Subject: [EXTERNAL] RE: K222658/S002 is on Hold Pending Your Response

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 Megan,

I received the email below regarding this response.

I received two acknowledgement letters from the DCC. They are Submission Number: K222658/A001 and Submission Number: K222658/S002. I believe it should be A001 but need to get confirmation.

(b)(4)

Best

Doug

Douglas Herrington

Herrington Consulting LLC

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Principal Consultant

From: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

Sent: Wednesday, May 10, 2023 2:47 AM

To: (b)(6)

Cc: Meaghan Erlewein [MEAGHAN.ERLEWEIN] <meaghan.erlewein@fda.hhs.gov <mailto:meaghan.erlewein@fda.hhs.gov> >

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June 21, 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, Meaghan Erlewein.

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