**DE NOVO CLASSIFICATION REQUEST FOR**

# OMRON BLOOD PRESSURE MONITOR WITH ATRIAL FIBRILLATION (AFIB) DETECTION FEATURE (BP7460 (HEM-7371T1-AZ)); OMRON BLOOD PRESSURE MONITOR WITH ATRIAL FIBRILLATION (AFIB) DETECTION FEATURE (BP5460 (HEM-7372T1-AZAZ))

## REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Oscillometric-based, over-the-counter, atrial fibrillation notification feature.** An oscillometric-based, over-the-counter, atrial fibrillation notification feature is a software algorithm for analysis of signals from an oscillometric, non-invasive blood pressure measurement system to screen for possible atrial fibrillation in the device user.

**NEW REGULATION NUMBER:** 21 CFR 870.1135

**CLASSIFICATION:** Class II

**PRODUCT CODE:** QXY

## BACKGROUND

**DEVICE NAME:** Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ))

**SUBMISSION NUMBER:** DEN230076

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**SPONSOR INFORMATION:**

Omron Healthcare, Inc.
% Veranex, Inc.
224 Airport Parkway
San Jose, California 95110

## INDICATIONS FOR USE

The Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)) is indicated as follows:

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

The device includes the Atrial Fibrillation Detection Feature. The feature analyzes pulse pressure wave data captured during the user's blood pressure measurement to identify episodes of atrial fibrillation (AFib) and provides a notification on the display screen to the user. This feature is intended to be used for home screening for the possibility of AFib.

The Atrial Fibrillation Detection Feature is not intended to provide a notification on every episode of AFib and the absence of detection is not intended to indicate the absence of atrial fibrillation. The feature is not intended to replace traditional methods of diagnosis or treatment or to be used in the management of patients with AFib.

The device is intended for over-the-counter (OTC) use in the home environment. The device is intended for use in adults (22 years or older); it has not been tested for and is not intended for use in pregnant women or people with implanted pacemakers or defibrillators.

**LIMITATIONS**

The possible AFib detection feature evaluates for a possibility of AFib Only. It will not detect other potentially life-threatening arrhythmias or diseases, such as a possibility of other cardiac arrhythmias or heart attack.

Do NOT adjust medication (including altering your use of any drug or treatment) based on readings from this blood pressure monitor.

Do NOT postpone/stop regular checkups or physician visits based on the results that you are getting from this monitor.

DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.

Not intended for use by individuals under age 22.

Not intended for use if you have an implanted defibrillator or pacemaker.

Not intended for use if you are pregnant.

Safety and effectiveness in patients with peripheral arterial disease (PAD) have not been established.

Not intended for the diagnosis, treatment, or management of AFib.

It does NOT continuously monitor your heart and therefore cannot alert you if AFib happens at any other time. This monitor cannot detect all forms of AFib. If the irregularity of the heart rhythm is too small, it may not be detected.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

## DEVICE DESCRIPTION

The Omron Blood Pressure Monitor with AFib Detection Feature is an OTC, at home use, upper arm blood pressure monitor. The device consists of a monitor and an arm cuff designed to be used on the upper arm. It is battery powered and can optionally be connected to an AC adapter. The proposed device measures blood pressure (systolic [SYS] and diastolic [DIA]) and pulse rate (PR), detects the presence of irregular heartbeats, and can also detect the possible presence of AFib by analyzing pulse pressure wave data captured during the user's blood pressure measurement to identify episodes of AFib and provides a notification on the display screen to the user.


*Figure 1*

Additionally, the Monitor may be used with the Omron Connect mobile application ("App"), an optional software-only accessory residing on a consumer smart device which connects to the device via Bluetooth Low Energy (BLE) and transfers information on completed device recordings for storage and redisplay.

When the measurement is complete, if atrial fibrillation has not been detected in the reading, and the time/date appear alternately.

If atrial fibrillation is detected in the reading, the device displays the "Possible AFib" icon and furthermore displays the characters "AF" in place of blood pressure readings. No blood pressure or pulse rate readings are displayed to the user as shown below.


*Figure 2*

## SUMMARY OF NONCLINICAL/BENCH STUDIES

### SOFTWARE

The monitor has a Basic Documentation Level. Appropriate documentation was provided to support the validation of the software for Basic Documentation in accordance with the FDA Guidance Document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," (issued June 14, 2023). Documentation describing the software/firmware, software specifications, architecture design, software development environment, revision level history, unresolved anomalies, and cybersecurity provide the foundation that the software will operate in a manner as described in the specifications. Risk Management/Hazard Analysis was performed to characterize software risks including device malfunction and measurement related errors. The submission included verification and validation (V&V) testing to ensure the mitigation measures were successful.

### PERFORMANCE TESTING – BENCH

| Test | Purpose | Method | Acceptance Criteria | Results |
|---|---|---|---|---|
| Bench Testing for confirming the influence of body movement on possible Afib detection | The purpose of this test is to demonstrate that low levels of motion below the error threshold of the device do not have a clinically significant effect on the atrial fibrillation detection accuracy of the proposed device. | (b) (4) | (b) (4) | PASS |

### USABILITY TESTING

Usability Testing was provided in accordance with the FDA Guidance Document,

"Applying Human Factors and Usability Engineering to Medical Devices- Guidance for Industry and Food and Drug Administration Staff" (issued February 02, 2016).

Sixty (60) participants participated in the human factors validation study to demonstrate the usability of the blood pressure monitor. The testing was performed in a simulated-use environment associated with self-selecting, setting up, and using the blood pressure monitor. All subjects responded to critical tasks by responding to the output of the monitor.

Testing identified critical tasks as those tasks where the user does not understand the output from the device, fails to seek medical care despite symptoms or modifies their treatment plan based on the output. Each task was assessed for completion and success criteria were clearly defined. Overall, usability testing demonstrated that the AFib Detection Feature is safe and has appropriate performance for the intended users, uses, and use environments.

## SUMMARY OF CLINICAL INFORMATION

The study objective is to assess the AFib classification performance of OMRON BPMs with the AFib Detection Feature. The performance of the BPM-A (OMRON BPM with cuff HEM-FL31: BP7460) and BPM-B (OMRON BPM with cuff HEM-RML31: BP5460) was evaluated by sensitivity and specificity as calculated by comparing output data of the subject devices to ground truth. Ground truth for AFib identification was established from ECG adjudication performed by multiple independent expert adjudicators.

### Methods

The overall study was a prospective, non-randomized, multi-center study. The study enrolled 267 subjects with and 292 without a known diagnosis of atrial fibrillation into two separate cohorts. Key exclusion criteria included the presence of a pacemaker or implantable cardioverter-defibrillator, heart failure class III or IV, and arterio-venous shunt. Subjects in the without cohort must not have any known diagnosis of AF. To be enrolled in the AF cohort, the subject must be in atrial fibrillation at the time of data collection.

Upon enrollment, the participant had the 12-lead ECG electrodes applied by the Investigator, and participants used the requisite cuff of the Omron BP Monitor with AFib screening on their upper arm. Then the participant would sit in a chair with their feet on the floor, rest their arm on a table so that the cuff is same level as their heart. Lastly, the investigator started the 12-lead ECG recording device and Omron monitor simultaneously. The participant was coached to remain still and do not talk until the measurement process was complete.

Three independent board-certified cardiologists reviewed all ECG recordings and assigned a classification of "Interpretable" or "Uninterpretable.". "Uninterpretable" classification means that it is difficult to perform interpretation of AFib due to low signal quality in the ECG reading. If the ECG is "Interpretable", the adjudicators classified the ECG readings into "AFib is observed (AFib)" or "AFib is not observed (non-AFib)". If "AFib is observed (AFib)", the

adjudicator will indicate which ECG Lead(s) the AFib is observed. If the readers disagreed on the diagnosis, the final interpretation was determined by the simple majority rule.

**Study Endpoints**

Primary Endpoint

Sensitivity and specificity of the AFib Detection Feature in detecting AF compared with physician-adjudicated 12-lead ECG. The acceptance criteria that the sensitivity and specificity should be statistically significant to the target goal (85%).

Secondary Endpoint

- Subgroup analyses of sensitivity and specificity (Age, Gender, Race, Weight/BMI, Arm size and Site)
- Comparison of ECG reading results of the clinical study and ECG reading results by independent adjudicators.

**Results**

Subject characteristics

The study enrolled a total of 573 subjects at 5 investigational sites. Subject disposition is provided in Figure 4.

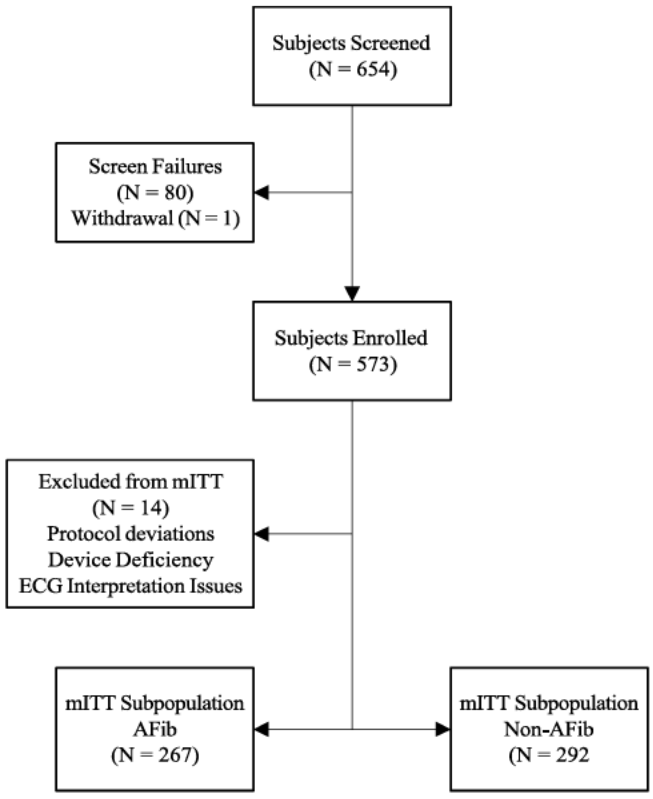


*Figure 3*

The median age was 69 years, ranging from 22-93. Comparing to the Non-Afib cohort, subjects in the AFib cohort were older (mean age 73.0 vs 57.4) and less likely to be female (32.2% vs 67.1%).

There were 14 cases excluded from the study and their subject information included:

- Three (3) cases where the quality of the ECG waveform was poor, and the reader was not confident in interpreting them.
- One (1) case where measurement was not possible due to device deficiency in the ECG device.
- Four (4) cases of protocol deviation where BP measurement was not performed.
- Four (4) cases of protocol deviation where ECG data was missing.
- One (1) case of protocol deviation where the subject was a patient with an implanted pacemaker.
- One (1) case of protocol deviation of inappropriate cuff size.

The results indicate that the study met the protocol specified primary endpoint as shown below.

| Device | Sensitivity | | | Specificity | | |
|---|---|---|---|---|---|---|
| | Result | 95% CI | p-value | Result | 95% CI | p-value |
| OMRON BP Monitor with HEM-FL31 cuff | 0.9509 | 0.9249 – 0.9769 | < 0.0001 | 0.9864 | 0.9655 – 0.9963 | < 0.0001 |
| OMRON BP Monitor with HEM-RML31 cuff | 0.9472 | 0.9202 – 0.9741 | <0.0001 | 0.9830 | 0.9608 – 0.9945 | < 0.0001 |

| | BP7460 (HEM-FL31-B cuff) | | | BP5460 (HEM-RML31-B cuff) | | |
|---|---|---|---|---|---|---|
| | Afib Reference | | | | | |
| Afib Final Alert | Afib | No Afib | Total | Afib | No Afib | Total |
| Monitor does not output "Afib alert" with error output | 1 | 0 | 1 | 1 | 0 | 1 |
| Monitor does not output "Afib alert" without error output | 12 | 290 | 302 | 13 | 289 | 302 |
| Monitor output "Afib alert" | 252 | 4 | 256 | 251 | 5 | 256 |
| Total | 265 | 294 | 559 | 265 | 294 | 559 |

Safety

There were no adverse events reported for this study.

Pediatric Extrapolation

The device is indicated for use only in adults – that is, persons aged 22 years and older. The Federal Food, Drug, and Cosmetic Act defines pediatric patients as persons up to but not including the 22nd birthday. In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

## LABELING

The labeling for the device is sufficient and satisfies the requirements of 21 CFR 801.109. The labeling consists of Instructions for Use. The Instructions for Use include the indications for use; a description of the device, precautions; a detailed summary of the clinical data collected in support of the device; a list of potential adverse events; and instructions for the safe use of the device.

Please see the Limitations section above for important contraindications, warnings and precautions presented in the device labeling.

## RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of the oscillometric-based, over-the-counter, atrial fibrillation notification feature and the measures necessary to mitigate these risks.

| Risks to Health | Mitigation Measures |
|---|---|
| False positive resulting in unnecessary medical intervention | Clinical performance testing<br>Non-clinical performance testing<br>Software verification, validation, and hazard analysis<br>Human factors testing<br>Labeling |
| False negative resulting in failure to detect atrial fibrillation and delayed treatment. | Clinical performance testing<br>Non-clinical performance testing<br>Human factors testing<br>Software verification, validation, and hazard analysis<br>Labeling |
| Misinterpretation and/or over-reliance on device output, leading to failure to seek treatment despite symptoms, or inappropriate treatment changes. | Human factors testing<br>Software verification, validation, and hazard analysis<br>Labeling |

## SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the oscillometric-based, over-the-counter, atrial fibrillation notification feature is subject to the following special controls:

1) Clinical performance testing must compare the device algorithm performance against readings from patients with and without AFib that have been clinically adjudicated and evaluate the sensitivity and specificity of the output measurement. Justification for the clinical adjudication procedures to determine ground truth must be provided.
2) Non-clinical performance testing of the algorithm must include:
    a. Evaluation and qualification of interoperability with the oscillometric hardware components; and
    b. Validation of the device to detect adequate motion/noise artifacts during measurement.
3) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the diagnostic algorithm and its inputs and outputs.
4) Human factors and usability testing must demonstrate the following:

a. The user can correctly use the device based solely on reading the device labeling;
b. The user can correctly interpret the device output and understand when to seek medical care; and
c. The user understands situations during which the device should not be used.

5) Labeling must include:
a. A description of what the device measures and outputs to the user;
b. Situations in which the device may not operate at an expected performance level and when its use may pose risks to the user;
c. A summary of the clinical performance testing conducted with the device, including user demographics;
d. Guidance on interpretation of any measurements, detection results, and error messages; and
e. Hardware platform requirements.

## BENEFIT-RISK DETERMINATION

The device is a digital monitor intended for use in analyzing pulse pressure wave data captured during the user's blood pressure measurement to identify episodes of AFib and provides a notification on the display screen to the user. As a blood pressure cuff, there is a possibility of bruising, due to blood flow interference. Overall, there are minimal safety concerns.

The risks of the device include unnecessary medical attention, over-reliance on the device outputs, and misinterpretation of the device output. A false positive result can lead to additional unnecessary medical procedures, which uses unnecessary medical resources leading to the clinician's workload being disrupted. A false negative result may falsely reassure the user and cause delay or inappropriate changes in medical evaluation and treatment. There is a potential risk of a patient self-adjusting AF treatments.

For asymptomatic undiagnosed AF patients, the device's probable benefit is to provide early detection of the disease. The device can identify AF with high sensitivity and specificity with an easy to use, familiar device to most patients, while obtaining blood pressure data.

Overall, the probable benefits outweigh the probable risks given the available information. There is reasonable assurance of the safety and effectiveness for this device for the intended use.

## PATIENT PERSPECTIVES

This submission did not include specific information on patient perspectives for this device.

## BENEFIT/RISK CONCLUSION

In conclusion, given the available information above, for the following indication statement:

> *The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.*

*The device includes the Atrial Fibrillation Detection Feature. The feature analyzes pulse pressure wave data captured during the user's blood pressure measurement to identify episodes of atrial fibrillation (AFib) and provides a notification on the display screen to the user. This feature is intended to be used for home screening for the possibility of AFib.*

*The Atrial Fibrillation Detection Feature is not intended to provide a notification on every episode of AFib and the absence of detection is not intended to indicate the absence of atrial fibrillation no disease process is present. The feature is not intended to replace traditional methods of diagnosis or treatment or to be used in the management of patients with AFib.*

*The device is intended for over-the-counter (OTC) use in the home environment. The device is intended for use in adults (22 years or older); it has not been tested for and is not intended for use in pregnant women or people with implanted pacemakers or defibrillators.*

The probable benefits outweigh the probable risks for the Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)). The device provides benefits, and the risks can be mitigated by the use of general and the identified special controls.

## CONCLUSION

The De Novo for the Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP7460 (HEM-7371T1-AZ)); Omron Blood Pressure Monitor with Atrial Fibrillation (AFib) Detection Feature (BP5460 (HEM-7372T1-AZAZ)) is granted, and the device is classified as follows:

Product Code: QXY

Device Type: Oscillometric-based, over-the-counter, Atrial Fibrillation Notification

Regulation Number: 21 CFR 870.1135

Class: Class II