

# Rhythm Master ECG Patch User Guide

Model: HM-15BB-AX

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# Chapter 1: Overview

## Know Your Device

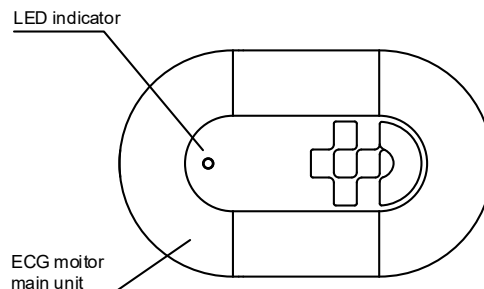
Thank you for choosing the SMW MED ECG (electrocardiogram) Monitor! This single-lead portable Rhythm Master ECG Patch is designed to help you track your heart health. By wearing the device properly and pairing it with the app on your smartphone, you can continuously and conveniently record your ECG. The recorded data is sent to a cloud server [for data viewing and storage](#).

This user guide will show you how to use the Rhythm Master ECG Patch and its key features. For more information, please visit our website [www.smwmed.com](http://www.smwmed.com)

### Rhythm Master ECG Patch Main Unit

The Rhythm Master ECG Patch is designed for high-resolution ECG measurements. It features a built-in Bluetooth chip and is rechargeable and reusable.

- **Topside:** The topside has a blue-white bicolor LED light indicating the monitor's status.

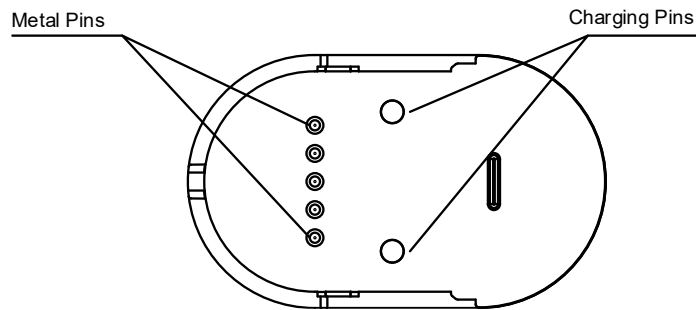


### The meanings of different indicator light:

LED Indicator	What It Means
Blue ON	Battery is charging
Blue OFF	Battery charging is completed
White Flashing	Ready to connect in Bluetooth; unsampled
White OFF	Bluetooth is connected and the status is displayed by the phone, detail can refer to

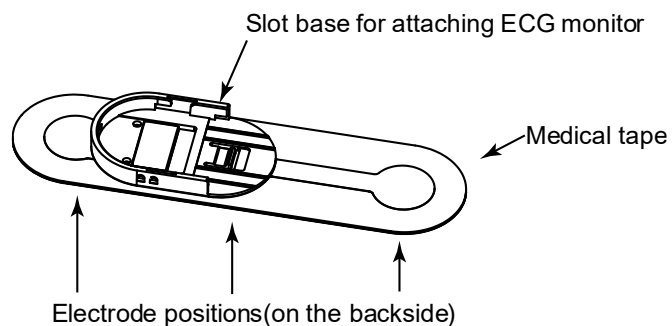
	Annex 1, section 2. Connect the Device to Your Smartphone
White Double blinking	Bluetooth is not connected and the device is working (sampling)

- **Backside:** The backside has two charging pins that can be charged using the included charging dock and cable. It also has five metal pins that connect to the electrodes in the medical electrode patch.



## Medical Electrode Patch

The medical electrode patch is used to attach the Rhythm Master ECG Patch to your body and connect the electrodes for ECG measurement. It has a rigid slot base to hold the monitor securely. The patch uses 3M medical-grade adhesive tape and biocompatible electrode materials to minimize the risk of skin allergies. The patch is disposable. Eight disposable patches will be provided for the first time, and user should purchase new patches separately. The user can contact SMWMED to purchase the additional disposable patch (6 pieces in one box of patches).

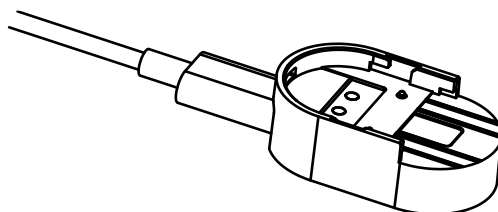


## Charging Dock and Charging Cable

The charging dock and USB charging cable are used to charge the Rhythm Master ECG Patch. Both ends of the cable are USB Type-C connectors - one end plugs into the power adapter (5V/500mA or above), and the other end connects to the charging dock. Place the device on the charging dock to begin charging. It takes approximately 2 hours to fully charge the device.

Our products are packaged with a USB power cable (Type-C line) but not with power adapter. Please purchase the power adapter by yourself before charging. Make sure to buy the power adapter which match the Type-C interface, and please make sure the input power of power adapter is AC 100~240V 50/60 Hz and output power is DC 5V 500 mA or above. 2MOOP between mains supply input and output sides according to IEC 60601-1 or IEC 62368-1 or IEC 60950. protection against electric shock: Class II.

Warning: Use only a certified adapter.



**Inside the Package:**

1x Rhythm Master ECG Patch    1x Charging dock    1x Charging cable

1x pack of medical electrode patches (8 counts)    1x user guide

## Safety Information

Please read the following indications, warnings, precautions, and instructions for your Rhythm Master ECG Patch carefully. Adhering to these guidelines will ensure your safety and the proper functioning of the device:

**Indications for Use:** It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. It is intended for use by patients 18 years or older.

### Intended Users/Intended Use Environment

Intended Users: Healthcare professionals (e.g. Physicians, nurses) and lay users (patients and their respective care givers).

**Intended Use Environment:** The Rhythm Master ECG Patch is intended for use in hospital/health care facilities and in a home setting.

### Intended Population

The Rhythm Master ECG Patch is intended for use by patients 18 years or older.

### Contraindications

- Pregnant women or breast-feeding mothers.
- Patients with current symptoms or medical history of skin cancer, rash, skin disorder, keloid, and/or any injury.

**Warning:** The parts that come into contact with the skin are made with medical-grade, skin-friendly materials. However, some individuals may experience skin allergies after wearing the device. Typically, the skin will recover on its own after removing the device.

- The device is for continuous ECG monitoring only and is not intended for spot-check or instantaneous diagnostic use. The “ECG detection” feature is for signal quality assessment purposes only.
- The device does not provide analysis or diagnostic results.

- The device has not been evaluated to support its use on infants, or on pregnant and/or breastfeeding women.
- Do not use the device in an X-ray, computed tomography (CT) or magnetic resonance imaging (MRI) environment. This may affect the scanning results, may lead to malfunction of the device and it may injure the patient.
- Use the device with compatible accessories supplied by the manufacturer. Otherwise, electrical shock or damage to the ECG Recorder may occur. In addition, the ECG signal quality could be affected.
- Use of other equipment or accessories not specified in this instructions for Use document might lead to skin irritations, allergy, electrical shock and malfunction of the device. Use of other charging cable may damage the device and/or the accessories.
- Battery Caution: Please Only use the provided charger and battery to charge the battery. Do not disassemble or replace the battery. Additionally, do not strike, open, or dispose of the device near a heat source. Please fully charge the device before use.
- Charging Caution: Avoid overcharging, as it may cause excessive heat and damage the battery. Do not use the device while charging to prevent the risk of electric shock and damage to the device.
- Usage Caution: Do not use the device in dangerous environments, such as those with high temperatures, humidity, explosive atmospheres, or chemical corrosion. Also Avoid using the device in areas with severe electromagnetic interference, as this may affect its normal operation.
- Maintenance Caution: Do Not disassemble the device to avoid electric shock or damage. For maintenance or servicing, please contact the manufacturer or a designated professional.



**MR unsafe:** Do not expose the device to a magnetic resonance (MR) environment due to

the following:

- The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.

- Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
- The device may generate artifacts in the MR image.

## Precautions

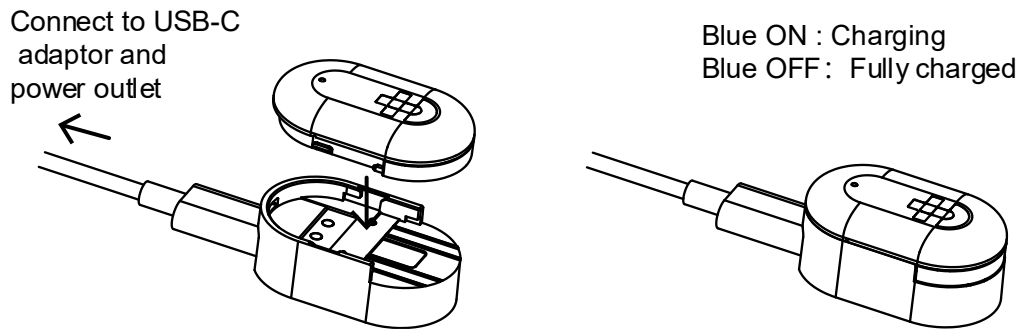
- Please remove the Rhythm Master ECG Patch from patient body before using external defibrillator. [The device is contradicted for use during defibrillation since it's not defibrillation-proof.](#)
- DO NOT use the device on infants or children. Do not let it be used by children or those with reduced physical and mental abilities, because a long USB cable may cause strangulation. Close supervision is necessary when this device is used, cleaned, or stored near children or those with reduced physical or mental abilities.
- DO NOT swallow the device or wind the cable around the neck. Keep components away from children.
- Please use this device under doctor's prescription. A healthcare professional should explain the proper use of the device to a patient.
- DO NOT use dried out electrodes or re-use electrodes. New electrodes must be used for each use.
- DO NOT place the device on top of excessive body hair. Excessive body hair may cause noise in the recording. Body hair should be removed prior to placement of the device.
- DO NOT drop or bump with excessive force.
- After completing the testing, peel the Rhythm Master ECG Patch off the skin. Prolonged use of electrodes may cause skin irritation. Discontinue use and consult your healthcare provider if skin irritation occurs.
- Please follow local laws for disposal of battery and/or electronic products.
- Contact the manufacturer if there is a change in the performance of the device.
- No warranty is provided for any erroneous data collected by the device due to misuse or malfunction as a result of abuse, accidents, alteration, neglect, or failure to maintain the products as instructed.
- Dispose Electrode Patch should not contact other conductive parts including earth.

- The device cannot determine a PAUSE—absence of a heart action potential for a prolonged time interval.
- If you have any customer complaints, feedback or issues, reports from organizations within the Rhythm Master ECG Patch system, please contact Smwmed Inc.
- When the environment is 20 ° C, it takes 10 minutes for the device to be ready for the intended use from the lowest/ highest storage temperature after use.

## Chapter 2: Getting Started

### Charge Battery

Use the provided charging dock and USB charging cable to charge the Rhythm Master ECG Patch as shown in the figure below. Before the first use, charge the Rhythm Master ECG Patch for at least 2 hours to ensure the battery is fully charged. You can check the battery level in the Health Assistant app.



#### LED indicator for charging:

The LED indicator light on the Rhythm Master ECG Patch shows the battery charging status. Refer to the table below to determine if the battery is charging or fully charged. After installing Health Assistant, you can also check the actual battery level of the connected Rhythm Master ECG Patch in the My Devices section in the Profile page of mobile software. (Details about Health Assistant are provided on the Annex 1.)

Charger Connected	LED Indicator	What It Means
Yes	Blue ON	Battery is charging
Yes	Blue OFF	Battery charging is completed

Note:

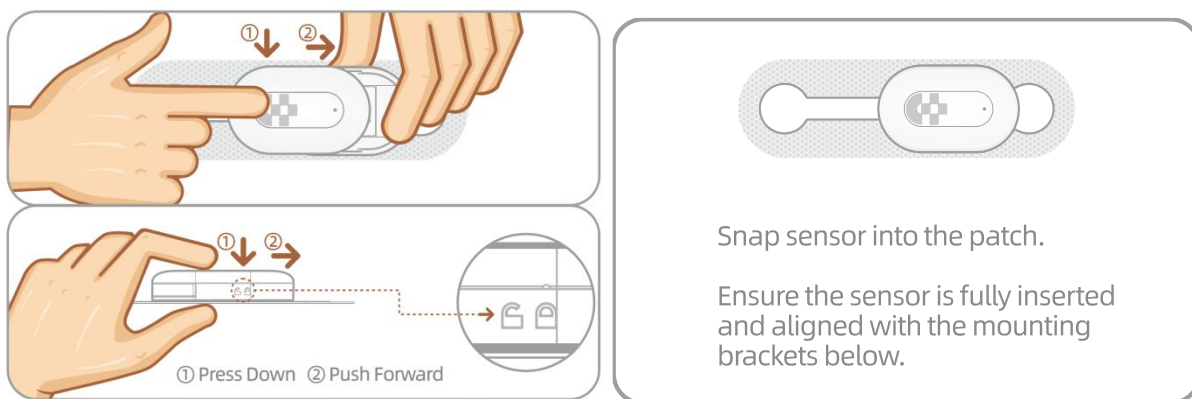
- The device should not be used during charging.
- According to the expected minimum cycle life of the current lithium battery is 500 cycles, the battery can support the Rhythm Master ECG Patch (Main unit) to work at full load for about  $5.49 \times 500 = 2745$  days during its life. Taking into account the power loss caused

by the charge and discharge cycle of the lithium battery (about 20%), it is equivalent to about  $2745 \times 0.8 = 2196$  days, that is,  $2196 / 365 = 6.02$  years.

## Install and Use Device

### Install the Rhythm Master ECG Patch:

1. Take out one medical electrode patch and the charged Rhythm Master ECG Patch. Hold the monitor with your fingers and align it with the slot on the patch base.
2. Slide the Rhythm Master ECG Patch along the notch into the slot on the base. Press downward while pushing forward.
3. Push the Rhythm Master ECG Patch all the way to the front end of the slot. Check the alignment between the monitor and the base to ensure the installation is complete. When the Rhythm Master ECG Patch is properly installed, the white indicator will flash. Please make sure the Rhythm Master ECG Patch is fully charged before use.



### Attach the Rhythm Master ECG Patch Patch:

#### 1) Skin conditions before Attaching to the Human Body

You can start using your monitor after this process

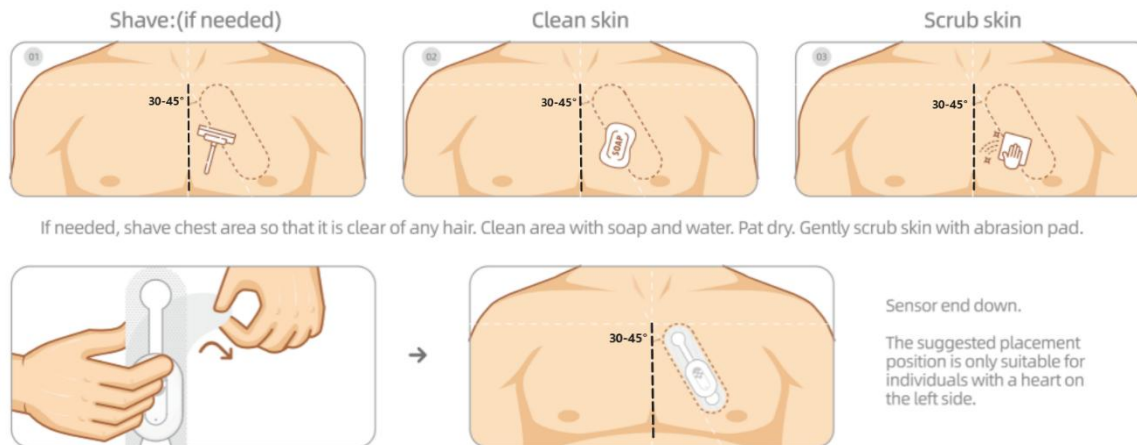
1. Before use, clean the skin on your left chest area (larger than the area where the Patch is attached) with soap and water, then a clean towel or tissue to dry the skin, the target area is as shown in the figure 1, 2. If there is hair on the target area, please shave the hair of this area then clean it again.

NOTE: If a wound or bleeding occurs when removing body hair, the Patch should be attached after the bleeding stops.

2. Gently rub the skin using the exfoliation pad (if possible) in a circular motion for 1 minute. Remove dead skin cells and foreign substances and clean the attachment area with alcohol

swaps. Then you should dry the skin for at least 1 minute before attaching the Patch. This step may help in providing a better ECG signal.

3. Confirmation of Patch attachment area: Place the end of the patch about a finger's distance below the clavicle, and confirm the attachment site at a 30-45° degree angle as shown in the figure 5. Keep the tape straight and do not fold or bend it during the application.



## 2) How to attach the Patch to the body

1. After installing the Rhythm Master ECG Patch, please peel off the backing film from the electrode patch (avoid touching the adhesive surface) as shown in the figure 4.

2. Attach the Patch so that it is tilted toward the left nipple area, using the line in the middle between the two clavicles as the center. However, if the patient has a fuller chest or if diagonally attaching the device is difficult, the part directed toward the nipple should be raised a bit higher and then attached.

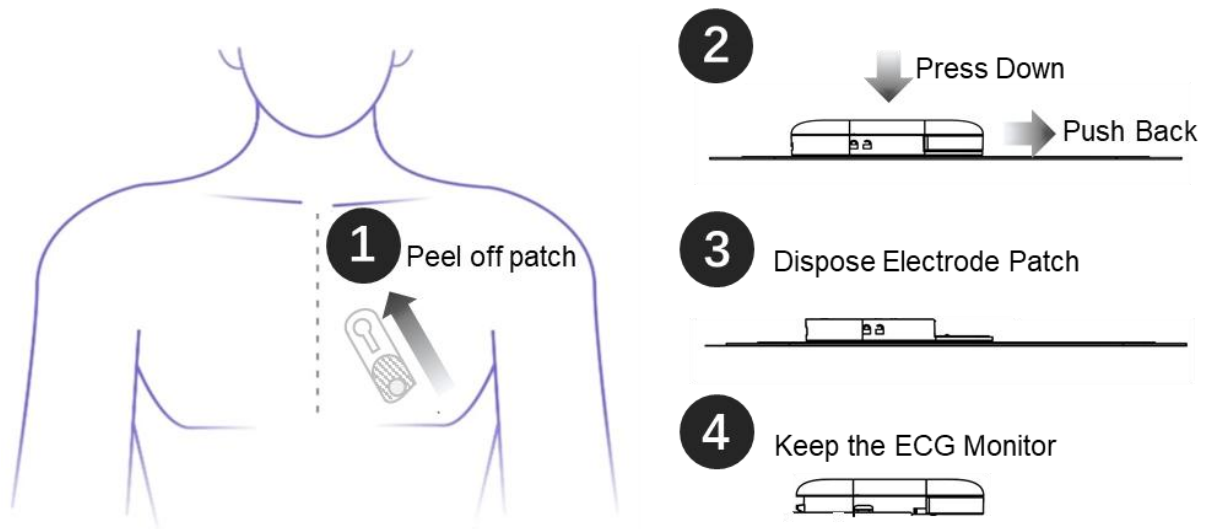
3. Press the sides of the tape and the Rhythm Master ECG Patch for 30 seconds to ensure good contact.

4. Confirm the signal quality through the Bluetooth-connected mobile software.

## Remove the Rhythm Master ECG Patch Patch:

Please follow these instructions to remove the patch from your skin to avoid damaging:

1. Firmly press the Rhythm Master ECG Patch with your fingers against the chest, and then gently pull the patch with the other hand downwards and then outwards in a direction away from the body and the ECG Recorder, as shown in the figure 1. The adhesive residue can be removed by washing the area with soap and water.
2. Put the monitor on a flat surface horizontally. Please gently press the monitor and push it back to remove the Rhythm Master ECG Patch from the electrode patch, as shown in the figure 2. It is not necessary to use a tool to remove, as it may damage the monitor.
3. Please dispose of the used electrode patch according to local regulations, it is a disposable patch for single use, please do not reuse it. The monitor is a reusable device, please clean and store it according to the Chapter 6-Maintenance.



Note:

When the Rhythm Master ECG Patch was correctly inserted into the patch, water splashed onto the enclosure from any direction had no adverse effect. When showering, it is recommended to stay away from the shower head, cover the Rhythm Master ECG Patch with a hand or cloth, and stay away from the shower to prevent shower water from directly hitting the Rhythm Master ECG Patch.

After showering, check the connection of the Rhythm Master ECG Patch to the patch and the adhesion of the patch to the skin. Replace the patch if it is not firmly attached with the skin. It may affect the effectiveness of Rhythm Master ECG Patch that continuously using the damaged patch.

## Chapter 3: Specification

<b>Product name</b>	Rhythm Master ECG Patch
<b>Model</b>	HM-15BB-AX
<b>ECG Dynamic Range</b>	-10mV to + 10mV
<b>Applied Part Category</b>	Type CF (cardiac floating)
<b>Battery</b>	LIR1654 3.6V 110mAh Rechargeable lithium-ion button battery
<b>Data Stored and Transfer</b>	Yes
<b>Communication Protocol</b>	Bluetooth Low Energy <a href="#">5.1</a> (2402MHz – 2480 MHz)
<b>Viewing Software Platform</b>	APP on smartphone
<b>Data Encryption</b>	huffman Encoding encryption
<b>Type of ECG Recorder</b>	Patch
<b>Number of ECG Channels</b>	1
<b>Recording Format</b>	Continuous
<b>Sensor Dimensions</b>	37.0x22.5x7.7 (H) mm
<b>Sensor Weight</b>	6.8 grams
<b>Frequency Response</b>	0.5-40Hz
<b>Input Impedance</b>	>10GOhms
<b>Resolution</b>	15bit
<b>Hear rate measurement range</b>	30-200bpm
<b>Accuracy of heart rate measurement</b>	$\pm 1$ bpm or $\pm 2\%$ compared with reference ECG
<b>Sampling rate</b>	256Hz
<b>Recording Standard</b>	Holter

<b>Patch Placement</b>	Left chest, a finger's distance below the clavicle, tilted toward the left nipple at a 30-45° degree
<b>Tolerance range for patch placement deviation from the target position</b>	Upward offset (Y+): $\leq 20\text{mm}$ Downward offset (Y-): $\leq 20\text{mm}$ Outward offset (X+): $\leq 40\text{mm}$ Inward offset (X-): $\leq 30\text{mm}$ Clockwise rotation: $\leq 45^\circ$ Counterclockwise rotation: Not recommended
<b>Recording Period</b>	up to 3 days
<b>Wear time</b>	up to 3 days The patch has been tested to have a wear time (adhesive performance) of 7 days
<b>Operation conditions</b>	Temperature: 0°C to +45°C (32°F to 113°F) Humidity: 10% to 95% RH, non-condensing Atmosphere: 70 kPa to 106 kPa
<b>Service Life</b>	3 years
<b>Hardware version</b>	V1.0
<b>PCB version</b>	V1.62
<b>Firmware version</b>	V1.00.29
<b>Mobile software version</b>	V1.0.66

#### Heart Rate Measurement Method:

The heart rate is determined from the ECG signal by detecting R-wave peaks using a template-matching and derivative-based algorithm. The instantaneous heart rate is calculated from the time interval between consecutive R-peaks.

The signal is filtered by a 0.5–30 Hz band-pass to reduce baseline wander and high-frequency noise. The algorithm uses an initialization phase to establish a QRS template through auto-correlation. R-peaks are continuously detected with 4 ms precision at a sampling frequency of 256 Hz. Outlier RR intervals are rejected based on physical limits (0.3–2 s), median absolute deviation (MAD), and Kubios-style adaptive IQR filtering.

The heart-rate output is updated upon each validated R-peak and smoothed over a sliding window to ensure stability.

### **Signal processing mode:**

Models HM-15BB-AX adopts AC ECG channel (AX Mode), which consists of an instrument amplifier (IA AC) with a higher gain of 20, high-pass filter (HPF) integrated in the IA\_AC, an anti-aliasing filter (AAF), and a low-power delta-sigma analog-to-digital converter (LPADC). This mode focuses on processing the dynamic components of ECG signals, enhancing the dynamic parts of the signal through a series of signal conditioning steps while filtering out unwanted baseline drift, making it suitable for routine ECG monitoring scenarios. This mode configures the device for AC-coupled signal acquisition, optimizing the sampling and amplification settings to emphasize the alternating components of the ECG waveform. The design provides a more stable display under typical patient motion and reduces overall power consumption. Its primary clinical utility is in continuous or ambulatory monitoring scenarios where waveform stability and extended operation time are prioritized.

## Chapter 4: Troubleshooting

### FAQs

**Q1: Can I wear the Rhythm Master ECG Patch during exercising?**

Yes, the monitor is IP24 waterproof and can handle sweat from exercise. However, intense motion may introduce some noise to the ECG detection. It is recommended to minimize movement during ECG Detection mode to ensure accurate results.

**Q2: Can I wear the Rhythm Master ECG Patch while showering?**

Yes, the monitor's IP24 waterproof rating means it can handle strong water jets, so wearing it while showering will not damage the device. However, water can interfere with the Bluetooth connection between the monitor and your smartphone, so live Rhythm Master ECG Patching and data transmission may not be available during a shower.

**Q3: Can I wear the Rhythm Master ECG Patch while bathing, swimming or diving?**

No, while the monitor is IP24 rated for strong water jets, it is not designed for continuous water immersion. Bathing, swimming, or diving may cause temporary or permanent damage to the Rhythm Master ECG Patch, leading to device malfunction or loss of function.

**Q4: Can I reuse the medical electrode patch?**

No, the electrode patch is for one-time use only. After removal, the adhesive loses its ability to securely attach to the skin, which can affect the quality of ECG signals. New electrode patches are included in the package, and additional patches can be purchased from authorized stores or contact Smwmed Inc.

**Q5: How can I do if the patch is loose?**

Stick the electrode patch back on your skin by pressing down the adhesive edges. If that does not work, please replace a new patch or contact your healthcare professional for additional electrode patch.

**Q6: How can I prevent skin irritation from the patch adhesive?**

The electrode patch uses 3M medical-grade adhesive to minimize skin irritation, but some individuals may still experience sensitivity. To reduce discomfort, follow these tips:

1. Avoid using the same patch site repeatedly.
2. Maintain skin health: Avoid wearing the Rhythm Master ECG Patch patch for more than 24 hours and moisturize your skin between sessions to prevent dryness.

If you experience significant irritation, such as itching, burning, or rashes, contact your healthcare provider and inform us.

### **Q7: Why does Holter Mode not display the ECG signal lively when I check it?**

Ensure your Rhythm Master ECG Patch is connected to your smartphone. Verify the connection by going to "My Devices" in the Profile page. If the connection is confirmed but the signal is still not displaying, wait for about 10 seconds as the display may refresh. If the issue persists, rest assured that your ECG data is still being recorded and will be uploaded later. Take a screenshot of the error page and provide a description of the issue to help us assist you further.

### **Q8: Why does the Rhythm Master ECG Patch not connect to the mobile app?**

Please check if the device has enough battery power and make sure Bluetooth is enabled on the smartphone, then activate the Bluetooth and re-connect the Bluetooth again according to the instructions.

Although your phone and device are paired, the Bluetooth connection may disconnect when the devices are out of range. When brought back within the effective range, your phone should automatically reconnect to the device. If the connection is not automatically restored after moving the devices closer together, please try restarting the mobile app and wait for the reconnection process to complete.

### **Q9: How can I do if the mobile software prompt "Signal disturbance"?**

The mobile software is equipped with a function to recognize and indicate transient interference events during ECG signal acquisition. This software function provides real-time detection and identification of signal segments that may have been affected by transient electrical disturbances (such as ESD or other electromagnetic interference). When such interference is detected, the software will prompt "Signal disturbance". Under this situation,

the patient can remain still and wait a few seconds for the transient disturbance to pass. If the prompt persists, the patient should identify potential interference sources in the environment or move to a location free from electrical disturbances. This function helps distinguish the disordered waveforms under transient electrical disturbances from the waveforms when the patient's heart is abnormal, so as to prevent misinterpretation of unreliable ECG waveform segments by healthcare professionals or post-processing algorithms.

**Q10: How can I do if the Rhythm Master ECG Patch could not operate normally?**

Please check if the device is fully charged, or put it back to the charging dock and install it to the electrode patch again. If it doesn't work and presents an issue that prevents normal operation and that cannot be solved after consulting the Troubleshooting above, please contact Customer Support or your distributor and specify the type of problem.

## Chapter 5: Maintenance

### Preventative Maintenance

Check periodically that the Rhythm Master ECG Patch and its compatible accessories and components are not broken, have no external damage and that the performance is acceptable (i.e. length of recording has not diminished from a fully charged battery).

If issues are detected that cannot be solved, please contact Smwmed Inc. or your distributor.

During transportation, storage, and uses, it is recommended to store the Rhythm Master ECG Patch, the Charge cable in the provided packaging.

Only use the Rhythm Master ECG Patch with compatible accessories supplied by the manufacturer.

### Cleaning

The Rhythm Master ECG Patch is a reusable device. It is necessary to clean after each use. The following cleaning procedures are recommended.

Make sure the used electrodes are removed from the patch, and use a soft dry cloth to wipe the device surface thoroughly. If the surface is very dirty, please use disinfecting wipe to clean the surface.

After cleaning, please conduct visual inspection to check whether the device is visually clean, if it's not, repeat the above cleaning steps.

Note:

- DO NOT expose this device to water or other liquid.
- DO NOT reuse the electrode patch, or it may cause infection. It is a disposable accessory for single person use.

### Storage and Transportation environment

The device should be transported and stored under the following environmental conditions:  
Temperature: 5°C to +35°C

Humidity:  $\leq 90\%$  RH, non-condensing

Atmosphere: 70 kPa to 106 kPa

## Storage and Transportation requirements

The following requirements must be met when transporting the device:

- 1) Avoid heavy objects squeezed;
- 2) Avoid direct sunlight;
- 3) Avoid getting wet from the rain;
- 4) Handle with care during the moving process.















## Disposal

In order to avoid environmental pollution, please dispose this device according to local environmental requirements and do not discard casually.



In order to minimize hazards to health and the environment and ensure that materials can be recycled. This product should be disposed of at a separate collection facility for waste electrical and electronic equipment.

## Chapter 6: Symbols

Symbol	Meaning	Symbol	Meaning
	Batch Code		Serial number
	Refer to instruction manual/ booklet		Type CF Applied Part
	Manufacturer		Manufacture Date
	General warning sign		"WEEE (Waste Electrical and Electronic Equipment) ". The waste products should be handled legally.
IP24	IP Classification		Keep dry
	Keep away from sunlight		Fragile, handle with care
	MR unsafe symbol is a medical device which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.		FCC certification
	Prescription only		

## Chapter 7: Warranty and Contact information

### Warranty

Free warranty after-sales service for one year from the date of purchase.

1) This warranty covers all defects encountered in the normal use of the product, but does not apply to the following:

- a. Malfunctions caused by unauthorized disassembly and modification of the product.
- b. Faults caused by careless falling during use and handling.
- c. Failure caused by lack of reasonable maintenance
- d. Faults caused by improper operation, abuse or failure to follow the correct instructions in the instruction manual.
- e. Faults caused by improper repairs carried out by repair shops not authorized by our company.
- f. Failures caused by battery leakage, human damage, natural disasters and force majeure factors.

2) Repair services not covered by the warranty will be charged as specified.

3) Before requesting warranty service, please contact us for advice.

4) MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair.

### Contact information

Manufacturer: Smwmed Inc.

Address: 9920 Pacific Heights Blvd Ste 410, San Diego CA 92121, United States of America

Tel: +1 650 546 5942

E-mail: [support@smwmed.com](mailto:support@smwmed.com)

Web: [www.smwmed.com](http://www.smwmed.com)

## Chapter 8: Cybersecurity instruction

The device has the function of data transmission to mobile terminal software.

### Operating environment requirements

Software type	Hardware Configuration	Software Environment	Network conditions
Mobile software	RAM: Minimum 2GB Storage Space: Minimum 100MB free space Screen Resolution: 720 x 1280 pixels or higher	Android: Android <a href="#">12.0</a> or later	Initial app download Software updates Data synchronization

**Note:** The mobile software can only be operated under the specified operating environment. When it detects that the operating environment is outdated, the mobile software will issue a prompt to remind the user.

### Recommended Cybersecurity Controls

#### Security software

Users can choose conventional international mainstream antivirus software, such as Kaspersky, Symantec, McAfee, Norton, etc. [Recommendation: Enable real-time scanning and keep virus definitions updated.](#)

#### Firewall Requirements

[Enable the built-in firewall on Android devices \(Settings > Security\).](#)

[Configure firewall to allow only necessary Bluetooth communications.](#)

[Block unauthorized incoming connection.](#)

#### Password Requirements

All users must create accounts with passwords that meet the security requirements. Password specifications, including minimum length, complexity requirements (uppercase letters and numbers), and authentication methods for different user types (general users and equipment maintenance personnel), are detailed in Section 8. "User Access Control Mechanism" of this chapter.

## Data and equipment interface

Rhythm Master ECG Patch follows the BLE protocol to realize the communication between embedded devices and other Bluetooth devices.

## Network Ports and Interfaces

### ECG Patch (HM-15BB-AX) Interface:

Interface Type	Port/Protocol	Direction	Functionality	Approved Endpoints
Bluetooth BLE	BLE 5.1	Bidirectional (Incoming/Outgoing)	ECG data transmission between Rhythm Master ECG Patch and mobile app	Health Assistant Mobile App only

### Bluetooth Interface Specifications:

Specification	Details
Protocol Standard	BLE 5.1
Maximum Communication Rate	12 Mbps (protocol specification)
Actual Data Throughput	1M PHY: 790 kbps; 2M PHY: 1380 kbps

Direction	Bidirectional
Connected Device	Android devices (Android 12.0 and above)
Purpose	Data transmission with Health Assistant mobile software

**Note:** The Rhythm Master ECG Patch communicates exclusively via Bluetooth BLE 5.1. No other network ports (such as Wi-Fi, Ethernet, or USB data) are available on the ECG Patch device.

### Mobile App (Health Assistant) Network Interfaces:

Interface Type	Port/ Protocol	Direction	Functionality	Approved Endpoints
HTTPS	TCP 443	Outgoing	Cloud data upload, user authentication, software update checks	<a href="https://ctrl.healthassistant.app">https://ctrl.healthassistant.app</a>
HTTPS	TCP 443	Incoming	Cloud data download, push notifications, update availability	<a href="https://ctrl.healthassistant.app">https://ctrl.healthassistant.app</a>

**Note:** The Health Assistant mobile app uses the Android device's internet connection (Wi-Fi or mobile data) to communicate with the cloud platform for data synchronization, user management, and software updates. These network connections are established through the mobile device, not through the ECG Patch.

### User access control mechanism

User type	User rights	User authentication method	Password strength setting
General user	Access device measurement data	Individual user accounts, users can register independently by themselves.	Personal account: The account name matches the password. The password must have English capitalization and numbers, and the length should not be less than 6 digits.

Equipment maintenance personnel	Access device data, perform software update and maintenance	Pass account password	The account name matches the password. The password must have English capitalization and numbers, and the length should not be less than 6 digits.
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## Interoperability

Intended user: All interface operations shall be conducted by medical examination professionals, or trained doctors and nurses, or laboratory workers. The patient does not conduct any interface-related operations.

### Interface

Interface type	Device to be connected	Device type and system version to be connected	Interface standard/specification	Purpose of the interface	Transmission rate
Bluetooth	Android	Android 12 and above	BLE 5.1	Data transmission with mobile software	1MPHY: 790kbps  2MPHY: 1380kbps

**Note 1:** The Bluetooth of the device supports BLE 5.1, which meets the FCC specifications.

**Note 2:** Users can check the connection status with the Rhythm Master ECG Patch main unit through the home page of the mobile software.

**Caution:** Do not connect the device to any other medical devices or products through the above interfaces!

### Summary of the testing performed on the interfaces

Manufacture and model of devices installed with the software	Test interface	Test summary

Motorola – Android 12	BLE	<p>Connection test between Rhythm Master ECG Patch and mobile software;</p> <p>The mobile software controls the Rhythm Master ECG Patch to conduct function test.</p>
HUAWEI ALN-AL10 - Android 12		
Xiaomi 15 – Android 15		
Xiaomi 13 – Android 13\14		

## Supporting Infrastructure Requirements

### Minimum Networking Requirements

Requirement	Specification
Bluetooth Version	BLE 5.1 or higher
Maximum Communication Rate	12 Mbps
Encryption Interface	AES-128 encryption for Bluetooth communication
Network for Cloud Sync	Wi-Fi (802.11 b/g/n/ac) or Mobile Data (4G/5G LTE)
Minimum Bandwidth for Cloud Sync	1 Mbps upload speed

### Technical Instructions for Secure Network Deployment

**Initial Setup:** Before using the Rhythm Master ECG Patch system, users should ensure that their mobile device operating system is updated to the latest security patch to protect against known vulnerabilities. The Health Assistant app should only be downloaded through official channels provided by the manufacturer to ensure authenticity. Users should verify that the app is obtained from a trusted source to ensure authenticity and security.

**Secure Configuration:** For optimal security, users should enable device encryption on their mobile device and configure screen lock protection using PIN, pattern, or biometric authentication to prevent unauthorized access. To minimize potential attack surfaces, Bluetooth should be enabled only when actively using the ECG patch and disabled when not in use.

Network Security: When performing cloud synchronization or data upload, users should connect to secured Wi-Fi networks that use WPA2 or WPA3 encryption protocols. Public or unsecured Wi-Fi networks should be avoided for transmitting sensitive health data. For users who must access the system via public networks, enabling a VPN (Virtual Private Network) is recommended as an additional layer of protection, though this is optional.

## **Cybersecurity maintenance and security incident response**

### **Method for cybersecurity maintenance and device update**

- 1) Update Notifications: When a new version is released, the app will send in-app notifications about updates. Users can configure notification preferences in the app settings to enable or disable update reminders.
- 2) Customer support: Customers can obtain information about fixes, patches and updates by contacting the manufacturer's customer support department. Customer support and maintenance personnel usually provide detailed information and help customers to complete the installation process.
- 3) Security Bulletin: Manufacturers may publish information about fixes, patches, and updates in their security bulletin when app updates are available. These announcements usually include fixes, installation instructions, and release dates.
- 4) Agent/after-sales engineer's return visit: Agent/after-sales engineer will assist customers to complete the installation and update during the product after-sales service process.

### **Network use of the device**

- 1) Only when logging in for the first time, user needs to go online to verify the account password.
- 2) The use of application does not require network connection for basic functions. The test data is stored locally and will be uploaded to cloud storage when network is available.

### **Cybersecurity incident response**

- 1) Disconnect from the network: If you suspect that the network has been attacked or infected, you can temporarily disconnect from the network to prevent the malware from further spreading or stealing data. This can be achieved by cutting off the network and turning off the WiFi.
- 2) Use security tools for detection and removal: Conduct comprehensive inspection using tools such as anti-virus software and security scanning tools to find and remove malware. Make sure to use the latest version of antivirus software and update viruses regularly.
- 3) Contact the manufacturer's agent/after-sales engineer for assistance: If you cannot solve the problem by yourself, you can contact the agent/after-sales engineer for help.

## IT network

### Network description

Software version:

- Embedded Software version: [V1.00.29](#)
- Software name: Mobile Software (Health Assistant), Version number: [V1.0.66](#)

<p>The purpose of the device's connection to an IT-NETWORK</p>	<p>The Rhythm Master ECG Patch is designed for high-resolution ECG measurements. The Mobile Software (Health Assistant) is connected to the main unit of the Rhythm Master ECG Patch (Model:HM-15BB-AX) through Bluetooth, and collects human dynamic ECG signals in real time, amplifies, transforms and transmits the signals.</p>
<p>The required characteristics of the IT-NETWORK incorporating the device</p>	<p>Please refer to section "Operating environment requirements" of Chapter 8: Cybersecurity instruction in User Manual.</p>
<p>The required configuration of the IT-NETWORK incorporating the device</p>	<p>Support Bluetooth BLE 5.1 protocol. The maximum communication rate shall be 12Mbps.</p>
<p>The technical specifications of the network connection of the device including security specifications</p>	<p>Support Bluetooth BLE 5.1 protocol. The maximum communication rate shall be 12Mbps.  <a href="#">Encryption: AES-128 for Bluetooth data transmission.</a></p>
<p>The intended information flow between the device, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK</p>	<p>Not applicable.  <a href="#">The device communicates only between the Rhythm Master ECG Patch and the authorized Health Assistant mobile application via Bluetooth. No direct communication with other devices on the IT-NETWORK is intended or supported.</a></p>

### IT-network connection-related risks

Hazard No.	Hazard	Risk control measures
H11.1	Mobile Software Function Failure: Thread deadlock	Implement watchdog timers to detect UI freezes and automatically restart threads when unresponsive.
H11.2	Mobile Software Function Failure: Bluetooth reception malfunction	Implement data integrity checks and automatic reconnection protocols with error notifications to users.
H11.3	Mobile Software Function Failure: Background process crash	Implement robust error recovery mechanisms and automatic process restart with data integrity verification.
H11.4	Mobile Software Function Failure: Data parsing error	Implement strict data validation checks and error handling for all incoming data formats.
H11.5	Function failure of mobile software: Database corruption	Implement regular database integrity checks and automatic backup procedures with recovery mechanisms.
H11.6	Authentication failure: User session expiry during critical operations	Implement background session renewal, warning notifications before expiry, and secure task resumption after re-authentication.
H11.7	Data security: User credentials storage vulnerability	Use secure cryptographic methods for credential storage, secure keychain integration, and no plaintext password storage.
H11.8	Data integrity: Incomplete user profile creation	Implement mandatory field validation, profile completion progress indicators, and data entry validation feedback.
H11.9	Data storage: User profile data not persisted correctly	Implement transaction-based profile updates, data write verification checks, and recovery from incomplete saves.
H11.10	Connection failure: Unable to detect ECG device	Implement comprehensive device discovery troubleshooting, clear

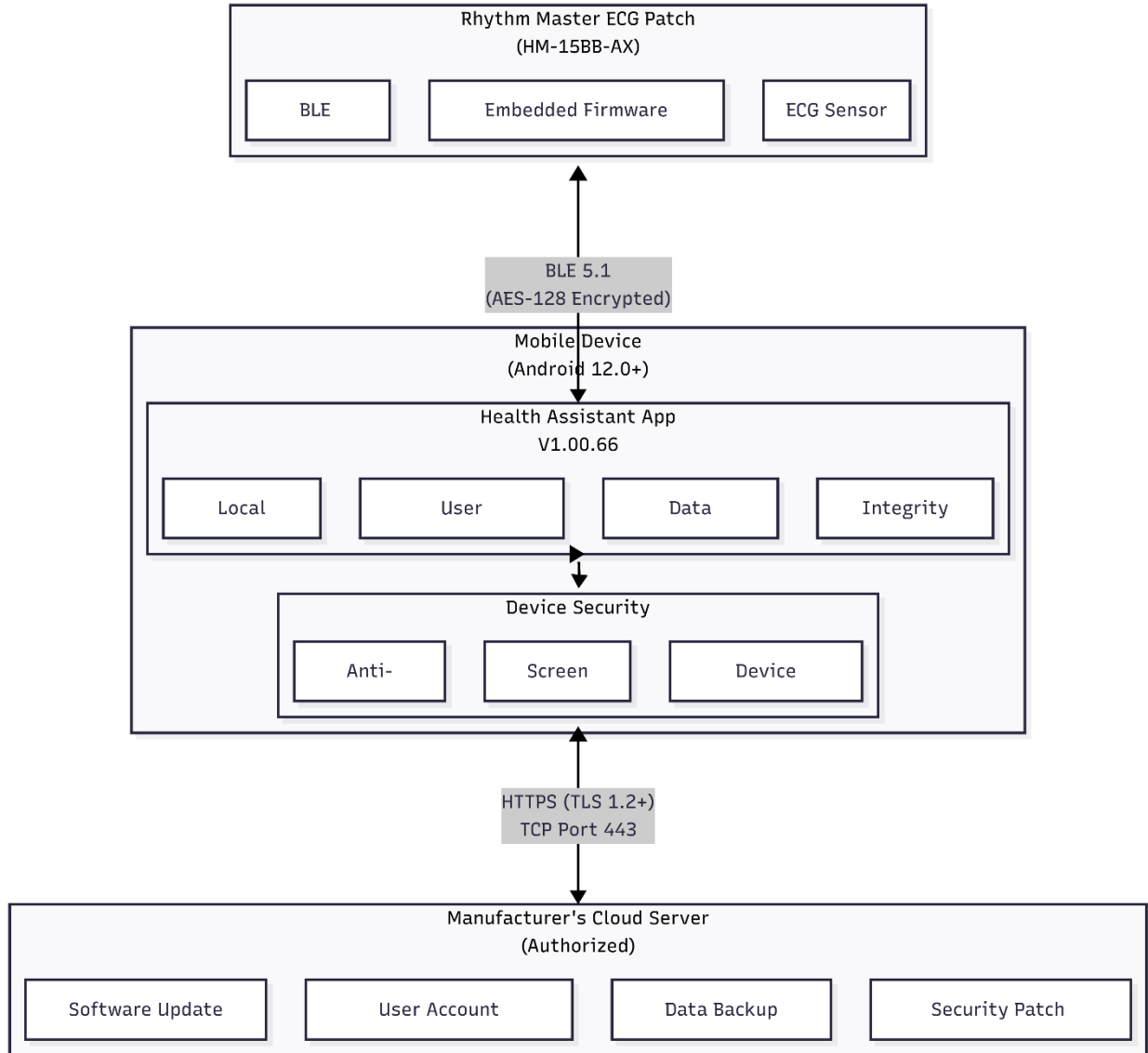
Hazard No.	Hazard	Risk control measures
		connection status indicators, and guided setup assistance.
H11.11	Data integrity: Corrupted ECG data during transmission	Implement checksums for all transmitted data packets, error detection protocols, and automatic re-transmission of corrupted segments.
H11.12	Display error: ECG waveform rendering inaccuracy	Implement standardized rendering algorithms, display calibration verification, and visual quality assurance testing. <a href="#">The software is added with a transient interference detection function of automatic low confidence flagging for affected ECG data segments and on-screen interference alert notifications.</a>
H11.13	Data transmission: Failed upload to web server	Implement queued upload system, automatic retry mechanism, and offline storage with sync when connectivity is restored.
H11.14	Device management: Unintended ECG Patch unbinding	Implement confirmation dialogs for device unbinding, clear warning of consequences, and simple re-binding workflow if done in error.
H11.15	Connection stability: Intermittent Bluetooth disconnections	Implement adaptive connection management, signal strength monitoring, and graceful reconnection with session persistence.
H11.16	Data transfer: Large ECG record upload failure	Implement chunked upload capability, resumable transfers, and upload progress indicators with status reporting.
<a href="#">H11.17</a>	<a href="#">Data processing:</a>	<a href="#">Implement reliable R-R interval based algorithm to calculate heart rate</a>

Hazard No.	Hazard	Risk control measures
	Inaccurate heart rate data	(validated per IEC 60601-2-47), display calibration verification, and visual quality assurance testing.
H11.18	Data processing: Inaccurate heart rate variability	Implement reliable R-R interval based algorithm to calculate HRV parameters (SDNN, RMSSD, pNN50) validated per IEC 60601-2-47 clause 201.12.1.101.2.3.3.2 HRV requirements, display calibration verification, and visual quality assurance testing.
H11.19	Data processing: Inaccurate ACC measurement	Implement reliable ADC conversion algorithm for ACC data (1g=16384), ensure accurate three-axis waveform display, and visual quality assurance testing.
H11.20	Software running: Incompatible operating system.	The mobile software is designed to support Android 12.0 or later operating system. And it detects low OS versions (Android) and displays a warning message prompting users to upgrade their system.

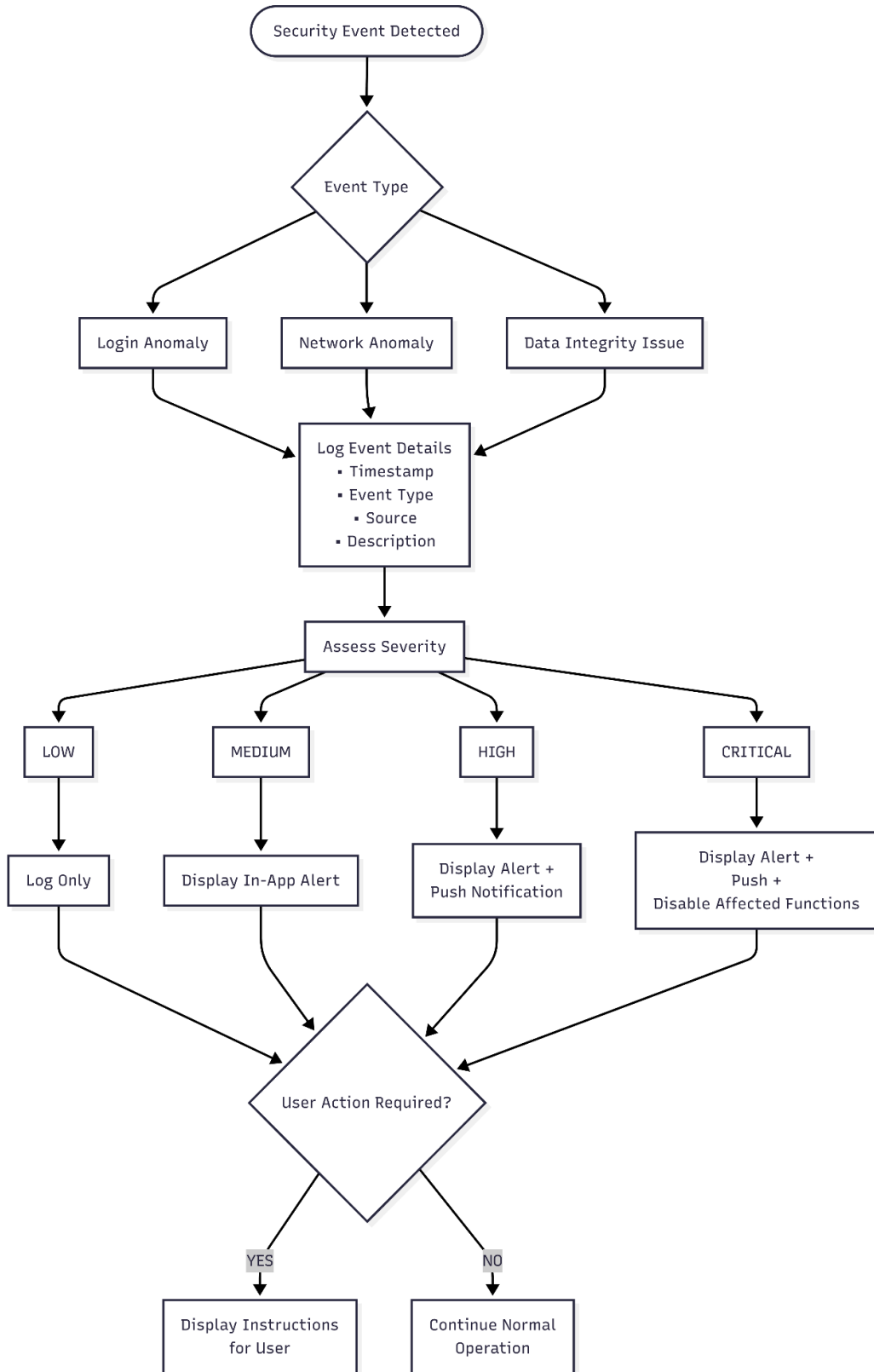
## Diagrams for users that allow recommended cybersecurity controls to be implemented

### System Architecture and Data Flow Diagram

The following diagram illustrates the overall cybersecurity control architecture of the Rhythm Master ECG Patch system, showing the security measures implemented at each level including data encryption, user authentication, and secure communication channels.



## Security Incident Response Flow



## Software bill of material

A complete Software Bill of Materials (SBOM) is provided as a separate document in machine-readable format to enable users to effectively manage their assets, understand the potential impact of identified vulnerabilities, and deploy appropriate countermeasures.

### SBOM Document Information:

#### SOFTWARE BILL OF MATERIALS (SBOM)

Health Assistant Mobile Application

Document Version: 2.0

Date: March 10, 2026

SBOM Author: Smwmed Inc.

Primary Component: Health Assistant Mobile Application v1.0.66

#### COMPONENT INVENTORY SUMMARY

#	Component Name	Version	Supplier	Relationship Type	Relationship	Relationship Assertion
1	ObjectBox Database	5.1.0	ObjectBox Ltd.	DEPENDS_ON	Included - Core DB Layer	Known
2	OkHttp Networking	5.3.2	Square Inc.	DEPENDS_ON	Included - HTTP Client Module	Known
3	Coil Image Loader	3.4.0	Instacart / Coil Contributors	DEPENDS_ON	Included - UI Image Caching	Known
4	Lottie Animation	6.7.1	Airbnb Inc.	DEPENDS_ON	Included - UI Animation Layer	Known
5	EasyBLE-X	1.5.5	Open Source Community	DEPENDS_ON	Included - Bluetooth Communication Module	Known

—	Android OS	12+	Google LLC (AOSP)	RUNS_ON	Platform Runtime Environment	Known
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### COMPONENT EOL SUMMARY TABLE

Component	Version	Current Support Status	End of Support	Post-EOL Plan
ObjectBox Database	5.1.0	Actively Maintained	No announced EOL	Migrate within 12 months or implement compensating controls
OkHttp	5.3.2	Actively Maintained	No announced EOL	Migrate to successor version
Coil	3.4.0	Actively Maintained	No announced EOL	Migrate if EOL announced; isolated from security-critical functions
Lottie	6.7.1	Actively Maintained	No announced EOL	Migrate if EOL announced; isolated from security-critical functions
EasyBLE-X	1.5.5	Actively Maintained	No announced EOL	Migrate if EOL announced; critical for device communication
Android OS	12+	Actively Maintained	Oct 2026	Update minimum OS to Android 13+ prior to EOL

### MACHINE-READABLE SBOM

A machine-readable version of this SBOM is provided in CycloneDX 1.6

JSON format: [health-assistant-mobile-sbom.cdx.json](#)

To request a complete copy of the SBOM, please contact: [support@smwmed.com](mailto:support@smwmed.com)

## Users to download version-identifiable manufacturer-authorized software and firmware

### Downloading Manufacturer-Authorized Software and Firmware

#### Mobile Application (Health Assistant) Updates

##### How to Know When Software is Available:

**In-App Notification:** When a new version is available, the Health Assistant app will display a pop-up notification informing users of the update. The notification includes the new version number and a summary of changes. Users can select "Update Now" to proceed with the update immediately, or "Remind Me Later" to postpone the update and receive a reminder at a later time.

**Systematic Procedure for Downloading App Updates:** To download and install app updates, users should open the Health Assistant app and navigate to Profile > About > Check App for Updates. If an update is available, the app will display the new version number and release notes. Users can then follow the on-screen instructions to download and install the update from the official source provided by the manufacturer. After installation is complete, users should reopen the app and verify the updated version in Profile > About.

#### Embedded Firmware Updates (ECG Patch)

##### How to Know When Firmware is Available:

**In-App Notification:** When the Health Assistant app connects to the ECG Patch and detects that a newer firmware version is available, a pop-up notification will appear prompting the user to update the firmware.

**Systematic Procedure for Firmware Updates:** To update the ECG Patch firmware, users should first ensure the ECG Patch battery level is above 20%. Open the Health Assistant app and connect to the ECG Patch via Bluetooth, then navigate to Profile > About > Check FM for Updates. If an update is available, the firmware will be downloaded and installed automatically. Users should keep the mobile device close to the ECG Patch and do not disconnect or power off either device during the update process. The update typically takes 1-2 minutes to complete. Once finished, the ECG Patch will automatically restart, and users can verify the new firmware version in Profile > About.

#### Update Authorization

Software Component	Authorized Update Source	Verification Method
Health Assistant App	Official download channels provided by manufacturer (Smwmed Inc.) or through Health Assistant App	Digital signature verification
ECG Patch Firmware	OTA via Health Assistant App only	Cryptographic signature verification

**Warning:** Do not install software or firmware from unauthorized sources. Only download through official channels provided by the manufacturer (Smwmed Inc.) to ensure security and proper functionality.

## How the design enables the device to respond when anomalous conditions are detected

### Anomalous Condition Detection and Response

The device and mobile application are designed to detect and respond to the following anomalous conditions (security events):

Security Event Type	Detection Method	Device Response	User Notification
<b>Configuration Changes</b>			
Unauthorized settings modification	Hash verification of configuration files	Revert to last known good configuration, require app restart	Alert: "Configuration change detected. Please restart the app and re-enter your password to continue."
App permissions changed	Runtime permission monitoring	Request re-authorization, require app restart	Alert: "Please restart the app and log in again to verify permissions."
<b>Network Anomalies</b>			
Network connection failure	Network connectivity monitoring	Pause cloud synchronization, retry connection	Alert: "Network connection error. Please check your Wi-Fi connection, toggle network

			settings, or restart the app to retry."
Connection to unauthorized endpoints	Endpoint allowlist verification	Reject connection	Alert: "Connection failed. Please check your network settings or restart the app."
<b>Login Attempts</b>			
Failed login attempt	Password verification	Increment failed attempt counter	Alert: "Incorrect password. Please try again."
Multiple failed login attempts	Failed attempt counter (threshold: 5)	Account cooldown period activated	Alert: "Too many failed attempts. Please wait [X] minutes before trying again."
<b>Data Integrity</b>			
Malformed data packets	Packet structure validation	Discard packet, request retransmission	No user notification (event logged only)
Corrupted ECG data during transmission	Checksum verification	Discard corrupted data, request retransmission	No user notification (event logged only)

## A high-level description of the device features that protect critical functionality

### Device Features That Protect Critical Functionality

#### High-Level Security Features Overview

Feature	Description	Protection Provided
Fail-Safe Mode	Device continues basic ECG recording even if communication is compromised	Ensures patient monitoring continues during security events

Port Disabling	Bluetooth can be disabled via app settings or automatically upon threat detection	Prevents unauthorized data access
Communication Lockdown	Automatic suspension of cloud sync during detected security incidents	Protects data integrity and prevents data exfiltration
Secure Boot	Firmware integrity verification at device startup	Prevents execution of tampered firmware
Data Protection	All stored ECG data is compressed and does not contain user privacy information	Protects patient privacy; even if device is lost or stolen, no personally identifiable information is exposed
App Session Protection	When the app is moved to background or the device screen is locked, users are required to re-enter their password upon returning to the app	Prevents unauthorized access if mobile device is left unattended or accessed by others
Offline Operation	Full ECG recording capability without network connection	Ensures device functionality independent of network status

### Port/Communication Control

Communication Channel	Default State	User Control	Automatic Trigger	Disable
Bluetooth BLE	Enabled when app active	Can disable in Settings > Connectivity	Repeated connection from unauthorized device	
Wi-Fi (for cloud sync)	Enabled	Can disable in Settings > Connectivity	Detection of insecure network	
Cloud Data Sync	Enabled	Can disable in Settings > Privacy	Network anomaly detection	

## A description of backup and restore features and procedures to restore authenticated Configurations

### Offline Data Storage and Transfer

The ECG Patch does not have a dedicated backup mode. Instead, the device implements an offline-first data storage mechanism to ensure data integrity:

**Data Storage Mechanism:** During ECG recording, all collected data is stored locally in the device's flash memory. The data remains stored on the device until the recording session is complete and the data is successfully transferred to the mobile app.

**Data Transfer Process:** When the user connects the ECG Patch to the Health Assistant app, the stored ECG data is uploaded to the mobile device. If the transfer is interrupted due to Bluetooth disconnection or other issues, the data remains safely stored on the ECG Patch. Upon the next successful connection, the app will automatically resume the data transfer from where it was interrupted.

**Data Erasure Policy:** The ECG Patch will only erase the stored ECG data after the Health Assistant app confirms that all data has been successfully received. This ensures that no data is lost due to transmission failures or connection interruptions.

## A description of methods for retention and recovery of device configuration by an authenticated authorized user.

### Device Configuration Retention and Recovery

#### Methods for Configuration Retention

Configuration Type	Retention Method	Storage Duration	Access Control
User Preferences	Encrypted local database	Until app uninstall or user deletion	Authenticated user only

Device Pairing	Secure keystore	Until manual unbinding	Authenticated user only
ECG Data	Encrypted file storage	As per user preference (default: indefinite)	Authenticated user only
Security Settings	Encrypted configuration file	Until modified by user	Authenticated user only
Cloud Sync Preferences	Encrypted local + cloud	Synced across devices	Authenticated user only

### Recovery Methods for Authorized Users

**Method 1: Import Local Backup Data:** Users can import previously downloaded or backed-up ECG records through the app. To import data, navigate to Record > Import Record, then select the backup file to restore. The app will verify the file integrity and import the ECG data into the local database.

**Method 2: Sync from Cloud:** Users can synchronize ECG records stored on the cloud server to their mobile device. To sync data, navigate to **Record** and tap the download icon. Users can choose to sync: All Records, This Week, This Month, or Custom setting. The app will download the selected records and merge them with existing local data.

**User Authorization Verification:** Before any data recovery operation, users must be logged in with valid credentials. All recovery actions are logged in the security event log for audit purposes.

**A description of the secure configuration of shipped devices, instructions for user-configurable changes, and identification of user-configurable changes that could increase security risk for the medical device system.**

#### Secure Configuration of Shipped Devices

#### Default Security Configuration of Shipped ECG Patch

Configuration Item	Default Setting	Security Rationale
Bluetooth Pairing	Unpaired (requires user action)	Prevents unauthorized connections
Firmware	Latest stable version	Includes all security patches
Data Storage	Encrypted (AES-128)	Protects data at rest
Communication	BLE 5.1 with encryption enabled	Secure data transmission
Debug Mode	Disabled	Prevents unauthorized access
Firmware Update	Requires authenticated app	Prevents malicious firmware installation

### Default Security Configuration of Mobile App (Health Assistant)

Configuration Item	Default Setting	Security Rationale
User Account	None (requires registration)	Ensures user authentication
Password Requirements	Enforced ( $\geq 6$ chars, uppercase + number)	Strong authentication
Auto-Lock	Enabled	When the app is moved to background or the device screen is locked, users are required to re-enter password upon returning
Biometric Login	Disabled (optional enablement)	User choice for convenience vs. security
Cloud Sync	Enabled (can be disabled)	Default data backup
Security Event Logging	Enabled	Audit trail maintenance

Notification Alerts	Enabled for security events	User awareness
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### User-Configurable Changes

The following settings can be modified by users:

Setting	Options	Location	Default
Cloud Sync	Enable/Disable	Settings	Enabled
Update Notifications	Enable/Disable	Settings	Enabled

Where appropriate for the intended use environment, a description of how forensic evidence is captured, including but not limited to any log files kept for a security event.

### Forensic Evidence Capture

The ECG Patch system maintains comprehensive log files to support security event investigation and forensic analysis. All log data is managed on a per-account basis through a centralized server infrastructure.

### Log File Specifications

Attribute	Description
File Format	Plain text log files (.log)
Naming Convention	HMAApp_app_YYYYMMDD.log
Storage Location	Centralized cloud server
Management Structure	Account-based segregation
File Size Range	Typically 0.05 MB to 16.38 MB per daily log

### Log Information Captured

Each log entry contains the following metadata:

Date: Calendar date of log generation (YYYYMMDD format)

Log ID: Unique identifier for each log file

File Size: Size of the log file in megabytes

Update Time: Timestamp of last modification (YYYY-MM-DD HH:MM:SS)

Source: Originating platform (e.g., Android)

### Data Retention Policy

Log files are retained on the server for a defined period. After the retention period expires, log files are automatically purged from the system to manage storage resources.

### Access and Retrieval

Log files are accessible through the account management interface. Authorized users can view the log list with pagination (configurable records per page) and download individual log files in their original format.

### Analysis Capabilities

Currently, log analysis is performed manually. No automated analysis software is integrated into the system. Users or administrators must download and review log files using external tools for forensic investigation purposes.

## Information, if known or anticipated, concerning device cybersecurity (including components) end of support and end of life

### End of Support and End of Life Information

#### Product Lifecycle Overview

Product Component	Current Version	Support Period	End of Life
Rhythm Master ECG Patch (HM-15BB-AX)	Hardware Rev 1.0	3 years from date of purchase	3 years from date of purchase

Embedded Firmware	V1.00.29	Continuous updates until hardware EOL	Same as hardware
Health Assistant Mobile App	V1.00.66	Continuous updates until hardware EOL	Same as hardware

Note: The product service life is 3 years from the date of purchase. Cybersecurity support, including security patches and software updates, will be provided throughout the service life.

Phase	Duration	Coverage	Response Time
Full Support	Years 1 from date of purchase	Feature updates, security patches, bug fixes, full technical support	Critical security issues within 72 hours
Extended Support	Year 3 from date of purchase	Security patches and critical bug fixes only	Critical security issues within 7 days
End of Life	After Year 3	No further updates or patches provided	Technical support limited to decommissioning assistance

## Post-Support Risk Management

Important Notice for Users Operating Device After End of Support:

When the product reaches end of life (3 years from date of purchase), the manufacturer may no longer provide security patches or software updates. Users should be aware of the following:

Increased Cybersecurity Risk:

After the support period ends, new vulnerabilities may not be patched, and the risk of security incidents may increase over time. Continued use of the device beyond the support period is at the user's own risk.

Recommended Actions:

Plan for device replacement before the end of the 3-year service life

Contact the manufacturer for information on newer device models

If continued use is necessary, implement additional security controls on the mobile device (e.g., ensure latest OS security patches, use secured networks only)

Risk Acknowledgment:

Users who continue to use the device after the end of support period acknowledge that cybersecurity risks may increase and accept responsibility for any associated risks. The manufacturer recommends replacing the device with a currently supported model to maintain optimal security protection.

Notification Timeline:

6 months before end of support: Notification sent to registered users via app and email

3 months before end of support: Reminder with replacement options

At end of support: Final notice with decommissioning guidance

**Information on securely decommissioning devices by sanitizing the product of sensitive, confidential, and proprietary data and software.**

**Secure Device Decommissioning**

**Overview**

When retiring or disposing of the Rhythm Master ECG Patch and/or the Health Assistant mobile app, users must follow secure decommissioning procedures to protect sensitive, confidential, and proprietary data.

**Data to Be Sanitized**

Data Category	Location	Sanitization Required

ECG Recordings	ECG Patch local memory, Mobile app storage, Cloud storage	Yes - All locations
User Account Information	Mobile app, Cloud servers	Yes - All locations
Device Pairing Information	ECG Patch, Mobile app	Yes - Both devices
Login Credentials	Mobile app secure storage	Yes
Security Event Logs	Mobile app storage, Cloud	Yes - Per retention policy
Configuration Settings	ECG Patch, Mobile app	Yes

### Cloud Data Deletion

If cloud synchronization was enabled:

1. Cloud data deletion is initiated automatically when the user account is deleted
2. Data is marked for deletion immediately
3. Actual deletion occurs within 30 days
4. Confirmation email sent when cloud data deletion is complete
5. To request immediate deletion: Contact [support@smwmed.com](mailto:support@smwmed.com)

### Certificate of Data Destruction

For enterprise or healthcare facility users requiring documentation:

1. Request Certificate of Data Destruction from the manufacturer
2. Provide device serial number(s) and account information
3. Manufacturer will verify deletion and issue certificate
4. Certificate includes:

- Date of decommissioning
- Device identifiers
- Data categories deleted
- Sanitization method used
- Authorized signature

Contact for Certificate: [support@smwmed.com](mailto:support@smwmed.com)

### Physical Disposal

After data sanitization:

- ECG Patch contains electronic components and battery
- Dispose according to local e-waste regulations
- Do not dispose in regular household waste
- Contact local recycling center for proper disposal locations

### Software update information

Refer to section Downloading Manufacturer-Authorized Software and Firmware of this chapter.

### Instructions for when the device is unavailable in the cloud or the Internet

Instructions for Operation Without Internet/Cloud Access

Function	Internet Required	Network Type	Alternative Without Internet
Initial app download	Yes	Wi-Fi or Mobile Data (4G/5G LTE)	N/A - Must have internet for initial download

User registration (first time)	Yes	Wi-Fi or Mobile Data	N/A - Required for account creation
User login (first time on device)	Yes	Wi-Fi or Mobile Data	N/A - Required for initial authentication
Subsequent logins	No*	None	Cached credentials allow offline login
ECG recording	No	Bluetooth only (BLE 5.1)	Full functionality available
Viewing ECG data	No	None	Full functionality available
Cloud data backup	Yes	Wi-Fi or Mobile Data	Data stored locally until connectivity restored
Software updates	Yes	Wi-Fi or Mobile Data (recommended)	Update when connectivity available
Sharing data with healthcare provider	Yes**	Wi-Fi or Mobile Data	Export locally, transfer via other means

\*After initial authentication, users can operate offline for up to 30 days before re-authentication is required.

### Offline Operation Procedures

**Before Going Offline:** Before using the device in an offline environment, users should ensure the Health Assistant app is installed and have logged in at least once while connected to the internet. Users should also verify that the ECG Patch is properly paired with their mobile device. Once logged in, cached credentials remain valid for 30 days without internet connection.

**During Offline Operation:** During offline operation, users can open the Health Assistant app normally and perform ECG recordings as usual. If prompted for login, users can use their cached credentials. All recorded data is stored securely on the local device until internet connectivity is restored.

**When Internet is Restored:** When internet connectivity is restored, the app automatically detects the connection and begins background synchronization. Once synchronization is complete, a green icon will appear on the right side of each recording in the Record list, indicating that the record has been successfully synced to the cloud.

## Data Integrity During Offline Operation

Concern	Mitigation
Data loss during offline period	All data encrypted and stored locally with automatic backup
Data corruption	Integrity checks performed on each read/write operation
Storage full	Warning at 80% capacity; oldest synced records can be removed
Extended offline period	Maximum 30-day offline operation; re-authentication required after

## Troubleshooting Connectivity Issues

If app shows "No Internet Connection" but device has connectivity:

1. Check if app has network permissions enabled
2. Verify no VPN is blocking app traffic
3. Check if firewall is blocking app endpoints
4. Try switching between Wi-Fi and Mobile Data
5. Restart the app
6. Contact support if issue persists

## Chapter 9: Electromagnetic compatibility instructions

### Parameter description

Name	Working frequency	Modulation type	Maximum Tune-up power(dBm)
Bluetooth	2402MHz – 2480 MHz	Bluetooth Low Energy	0dBm

**Note:** Even if other equipment meets the emission requirements of the corresponding national standards, the equipment or system may still be interfered by other equipment.

### EMC statement

The intended environment of use: In the clinic, doctors' office or hospital under the direction of physician, Don't be near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Essential performance:

The Rhythm Master ECG Patch is a lightweight, compact cardiac monitoring device designed for continuous ECG recording for up to 3 days. This Type CF cardiac floating device features high-precision ECG monitoring with a dynamic range of  $\pm 10\text{mV}$  and excellent signal quality with a frequency response of 0.5-40Hz.

The device weighs only 6.8 grams and measures 37.0x22.5x7.7mm, making it comfortable for extended wear. It is powered by a rechargeable 3.6V lithium-ion battery and utilizes Bluetooth Low Energy technology for seamless data transmission to smartphones.

The device delivers single-channel continuous ECG recording with high-resolution 15-bit data acquisition, ensuring precise cardiac monitoring. Data security is maintained through Huffman encoding encryption, while the companion smartphone app provides convenient monitoring capabilities. The recorder can be easily applied to the sternum or appropriate torso position and maintains reliable performance in operating temperatures ranging from 0°C to 45°C. The device meets professional Holter recording standards and offers reliable performance with an input impedance of  $>10\text{GOhms}$ , ensuring accurate cardiac monitoring for medical applications..

- 1) The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying document;
- 2) Portable and mobile RF communications equipment can affect the device.

#### Warning:

- 1) Use of accessories, transducers and cables other than those specified or provided by the manufacturer, it could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- 2) Use of the device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 3) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 4) Precautions regarding sources of EM energy that:
  - emit levels of EM energy that exceed the immunity test levels of the referenced EMC standards used, or
  - have other emission characteristics to which the medical device has not been tested for immunity.
- 5) Avoid using around RF emitters with wireless power transfer (WPT) and 5G cellular.
- 6) RFID equipment may interfere with the device and lead to performance degradation, caution should be paid when use the device around RFID equipment.
- 7) Do not use the device when in an environment with security systems like Electronic Article Surveillance (EAS) or metal detectors.
- 8) Do not use the equipment around MRI, diathermy and electrocautery. Otherwise, degradation of the performance of this equipment could result.

## FCC declaration

FCC ID: 2BQF2-SMW-ECG2025

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two 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 equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

NOTE: "Harmful interference" is defined in 47 CFR §2.122 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

FCC Caution:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

## Declaration of conformity

Table 1

<b>Guidance and manufacturer's declaration – electromagnetic emission</b>		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Table 2

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 8$ kV contact; $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	$\pm 8$ kV contact; $\pm 2$ kV, $\pm 4$ kV, $\pm 8$ kV, $\pm 15$ kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m 80 MHz to 2.7 GHz	
Electrostatic transient / burst IEC 61000-4-4	$\pm 2$ kV for power supply lines $\pm 1$ kV for input/output lines	$\pm 2$ kV for power supply lines Not apply	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1$ kV Line-to-line $\pm 2$ kV Line-to-ground	$\pm 1$ kV Line-to-line Not apply	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % $U_T$ ; 0,5 cycle g) At $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ and $315^\circ$ 0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single phase: at $0^\circ$ 0 % $U_T$ ; 250/300 cycle	0 % $U_T$ ; 0,5 cycle g) At $0^\circ$ , $45^\circ$ , $90^\circ$ , $135^\circ$ , $180^\circ$ , $225^\circ$ , $270^\circ$ and $315^\circ$ 0 % $U_T$ ; 1 cycle and 70 % $U_T$ ; 25/30 cycles Single phase: at $0^\circ$ 0 % $U_T$ ; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE $U_r$ is the a. c. mains voltage prior to application of the test level.			

Table 3

Guidance and Manufacturer's Declaration					
– IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m

	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
<p>Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.</p> <p>Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.</p>					

Table 4

<b>Guidance and Manufacturer's Declaration</b>		
<b>- IMMUNITY to proximity magnetic fields</b>		
<b>Test frequency</b>	<b>Modulation</b>	<b>Immunity level (A/m)</b>
30 kHz	CW	8
134.2 kHz	*Pulse Modulation 2.1 kHz	**65
13.56 MHz	*Pulse Modulation 50 kHz	**7.5
<p>Note* - The carrier shall be modulated using a 50 % duty cycle square wave signal.</p> <p>Note** - r.m.s., before modulation is applied.</p>		

## Annex 1: Software Description

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# 1. Install Health Assistant and Register

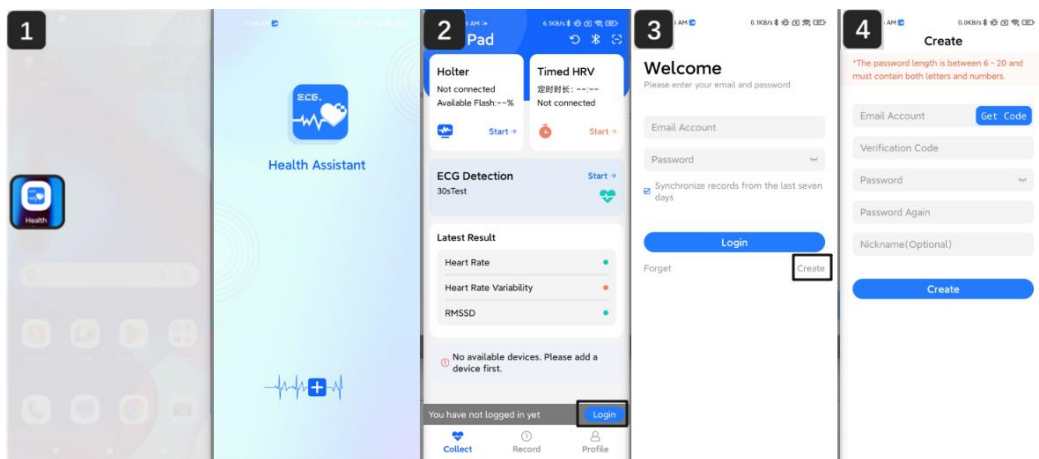
## 1.1. Install Health Assistant

Health Assistant is used for controlling the Rhythm Master ECG Patch and managing data. Scan the QR code or search “Health Assistant” in the APP store to download the app and follow the instructions to install it. For Android devices, ensure you allow all necessary permissions.



## 1.2. Register

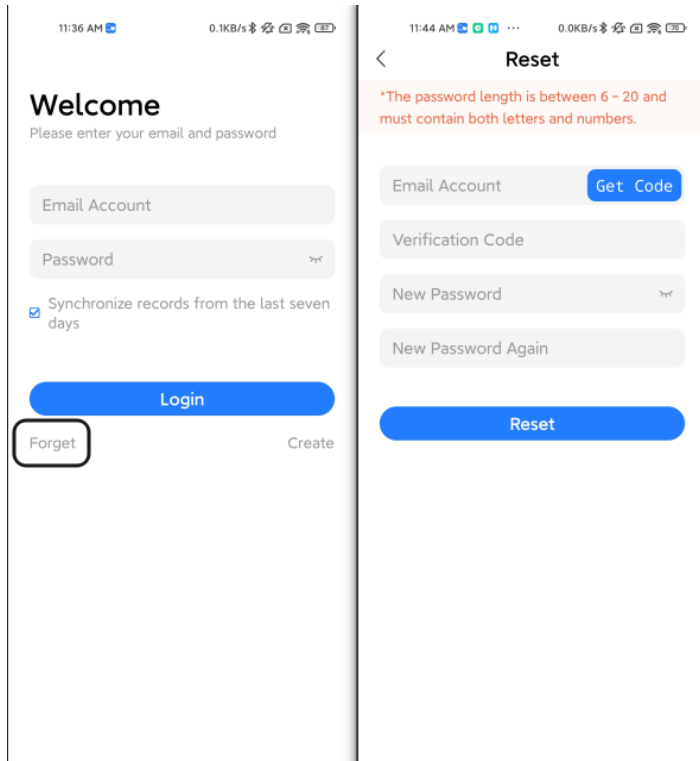
For the first time, register your personal account by following these steps:



1. Tap the **Health Assistant** icon.
2. Tap **Login**
3. Tap **Create** to register for the first time
4. Enter your email address and tap **Get Code**. Once you receive the verification code in your email inbox, enter it along with your desired password and password confirmation. Then tap **Create** to complete registration. (The password must have English capitalization and numbers, and the length should not be less than 6 digits.)

Notes:

a. If you forgot the password, you could tap "Forget" and enter your email address in the reset interface, then request a verification code.



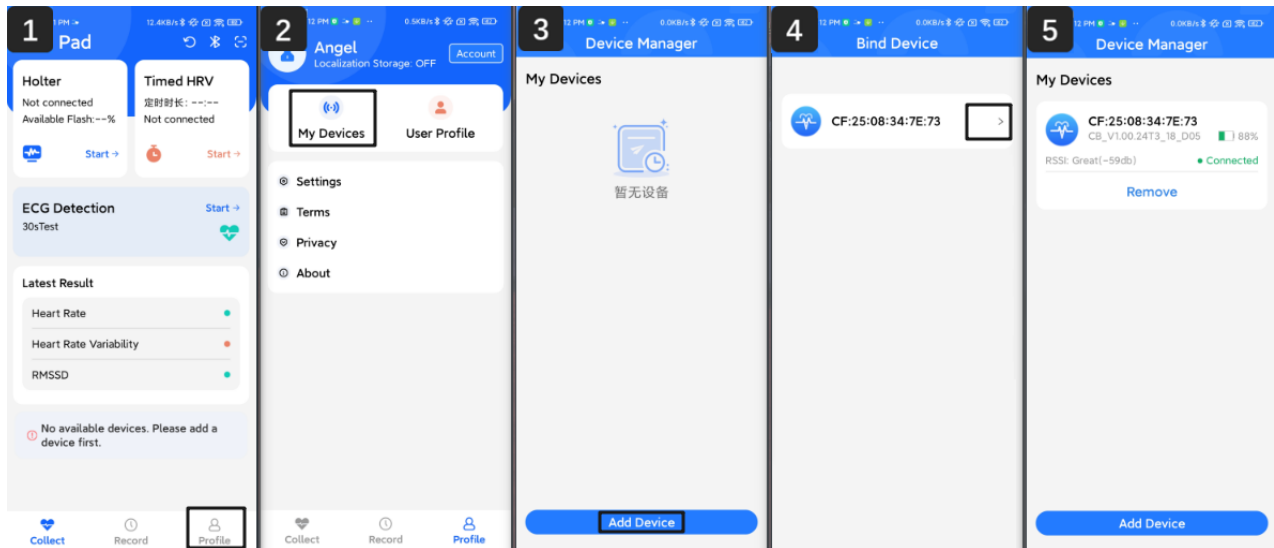
b. You need to log in following the instructions above every time you open this APP.

## 2. Connect the Device to Your Smartphone

To connect and use the Rhythm Master ECG Patch, turn on Bluetooth on your smartphone and ensure the Rhythm Master ECG Patch is within 16 feet.

### Connect Rhythm Master ECG Patch to smartphone

Open Health Assistant and follow below instruction.

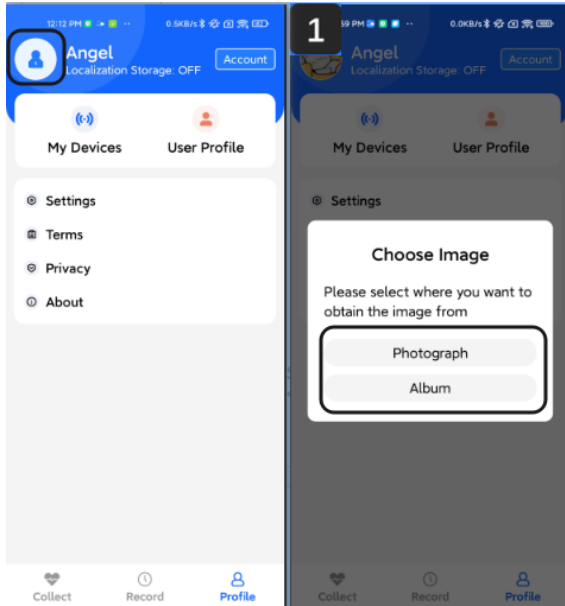


1. Tap **Profile**.
2. Tap **My Devices**.
3. Tap **Add Devices** to add your new Rhythm Master ECG Patch.
4. Wait for about 3s your smartphone to detect the Rhythm Master ECG Patch nearby. Once detected, the available monitors will be listed. Select the Rhythm Master ECG Patch to connect. If multiple devices are detected, note that only one device can be connected at a time. The MAC address of each device is displayed on the device itself to help you identify the correct one.
5. The Rhythm Master ECG Patch is now connected. In this interface, you can check the connection status and remaining battery power.

## 3. Information of “Profile”

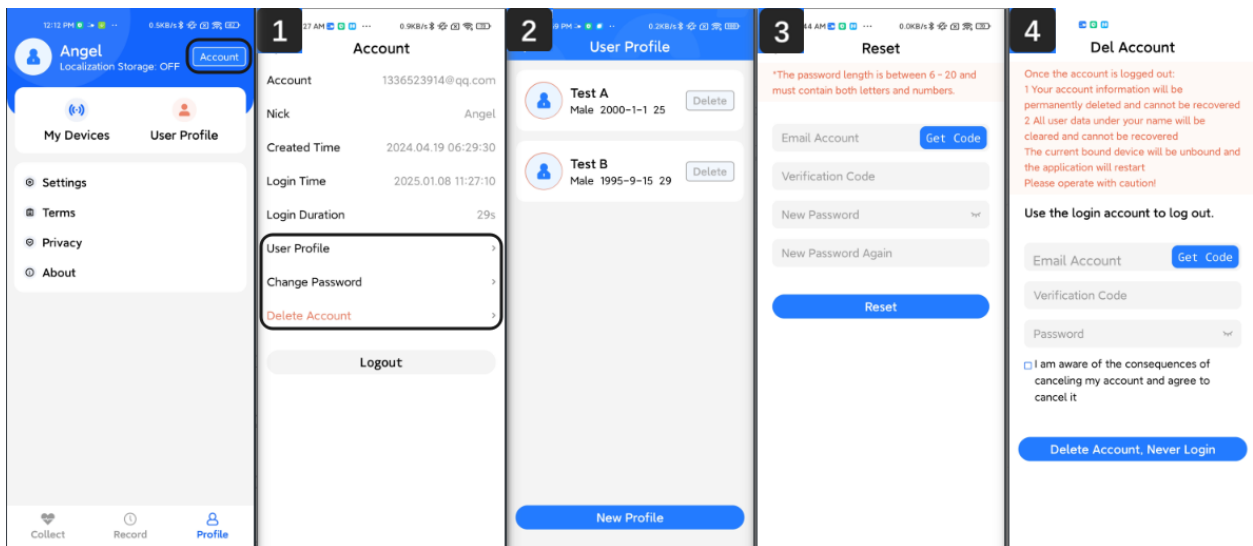
### 3.1. Avatar

Tap to choose the portrait icon and update your profile image.



## 3.2. Account Information

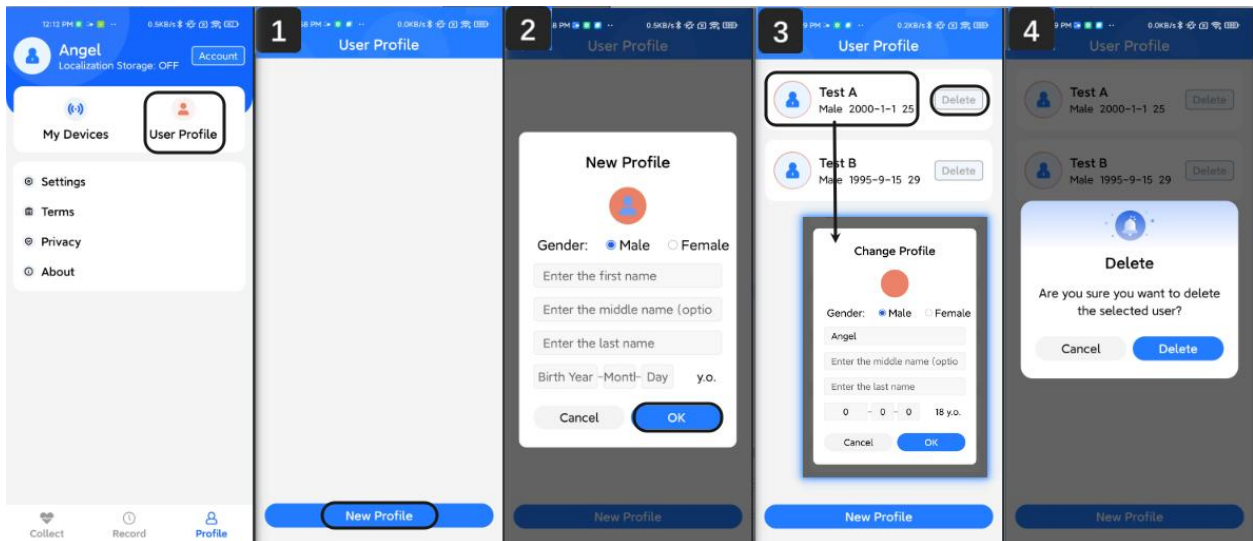
Tap the **Account** to change the individual information.



1. Account: Displays current login account information. Users can manage their profile settings, change password and delete account in this interface.
2. User Profile: Tap **User Profile**, showing information about currently connected or previously connected devices. Users can view device details and remove paired devices in this interface.( Annex 1: 2 connect)
3. Reset password: Tap **Change Password** to enter the reset interface, where you can reset the password after getting the email verification code.

4. Delete Account: Tap **Delete Account**, enter the verification code and current password, then tap **Delete Account, Never Login**, all information of your account would be permanently deleted.

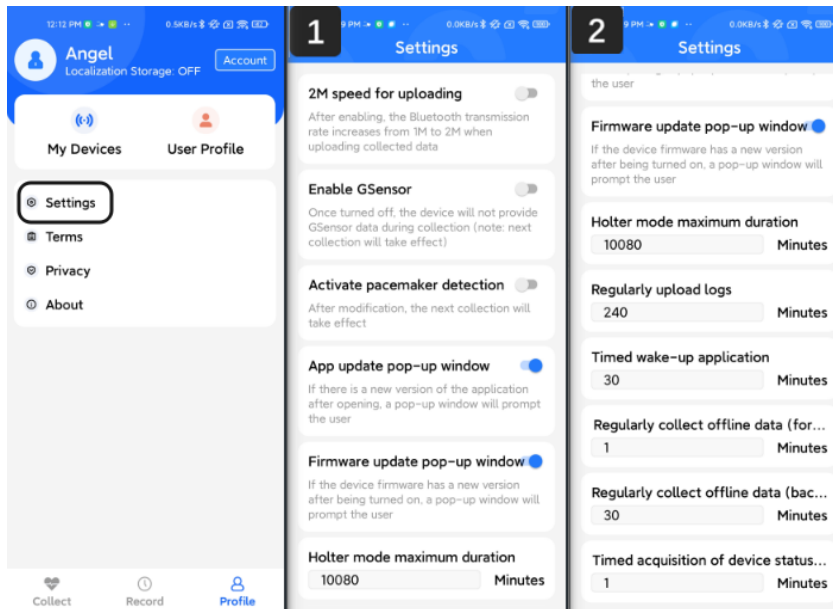
### 3.3. User Profile.



1. User Profile: This interface will display a list of all monitored records.
2. To add a new profile, you need to tap the **New Profile** option and fill in necessary information such as gender, name and birthday
3. Modify existing information: tap the user's name to open the profile settings interface to update their personal information.
4. Click the **Delete** button at the right side of the record to delete user profiles in this interface.

### 3.4. Settings

Settings: Allows users to modify data collection configurations and parameters.

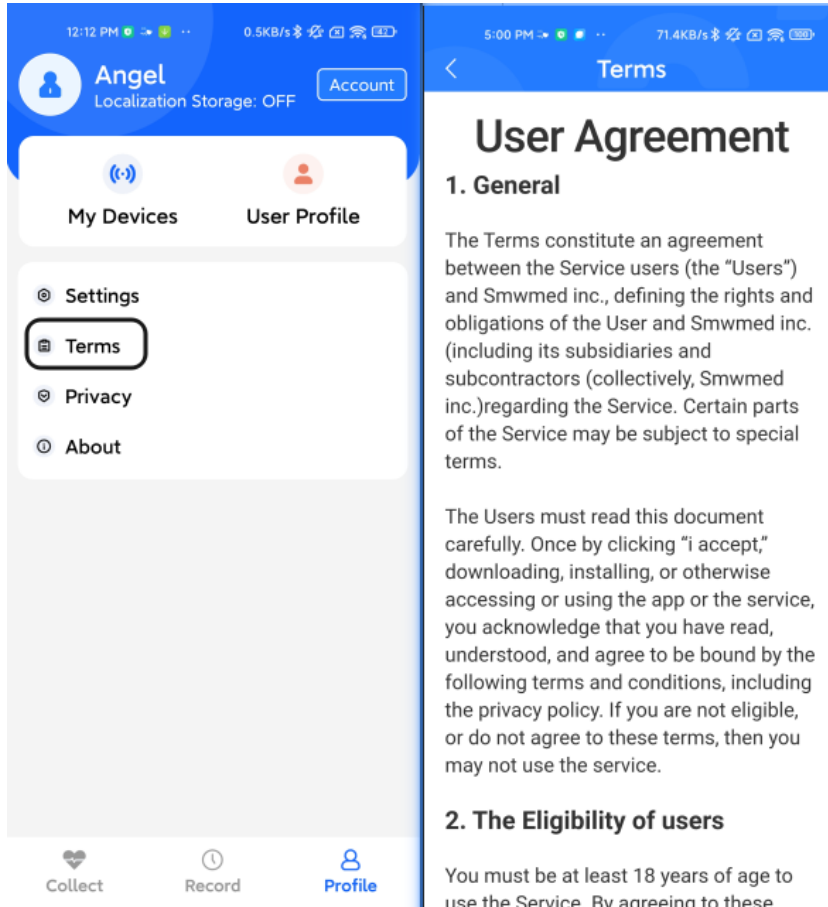


- **2M Speed for Uploading:** When enabled, Bluetooth transmission rate switches from 1M to 2M. Please note that some device models may not support 2M Bluetooth communication, which could result in reduced transmission speed when enabled.
- **Enable Gsensor:** When activated, the device will collect motion data (Gsensor data) alongside ECG data, facilitating subsequent data analysis. Please note this may reduce battery life. When disabled, only ECG data will be collected without motion information.
- **Activate pacemaker detection:** Data collection operates with pace detection enabled.
- **APP Update Pop-up Window:** Enables push notifications when new app versions are available.
- **Firmware Update Pop-up Window:** Enables push notifications when new firmware versions are available for connected devices.
- **Holter Mode Maximum Duration:** Sets the automatic stop time for Holter mode operation. The maximum duration can be set up to 7 days (168 hours).
- **Regularly Upload Logs:** Defines the time interval for system log uploads. (range 1 - 65536 minutes)
- **Timed Wake-up Application:** Sets the interval for app wake-up operations. (range 1 - 65536 minutes)
- **Regularly Collect Offline Data (Foreground):** Specifies the time interval for collecting offline data when the app is running in the foreground. (range 1 - 65536 minutes)
- **Regularly Collect Offline Data (Background):** Specifies the time interval for collecting offline data when the app is running in the background. (range 1 - 65536 minutes)

- Timed Acquisition of Device Status (Foreground): Sets the interval for updating device status when the app is running in the foreground.(range 1 - 65536 minutes)

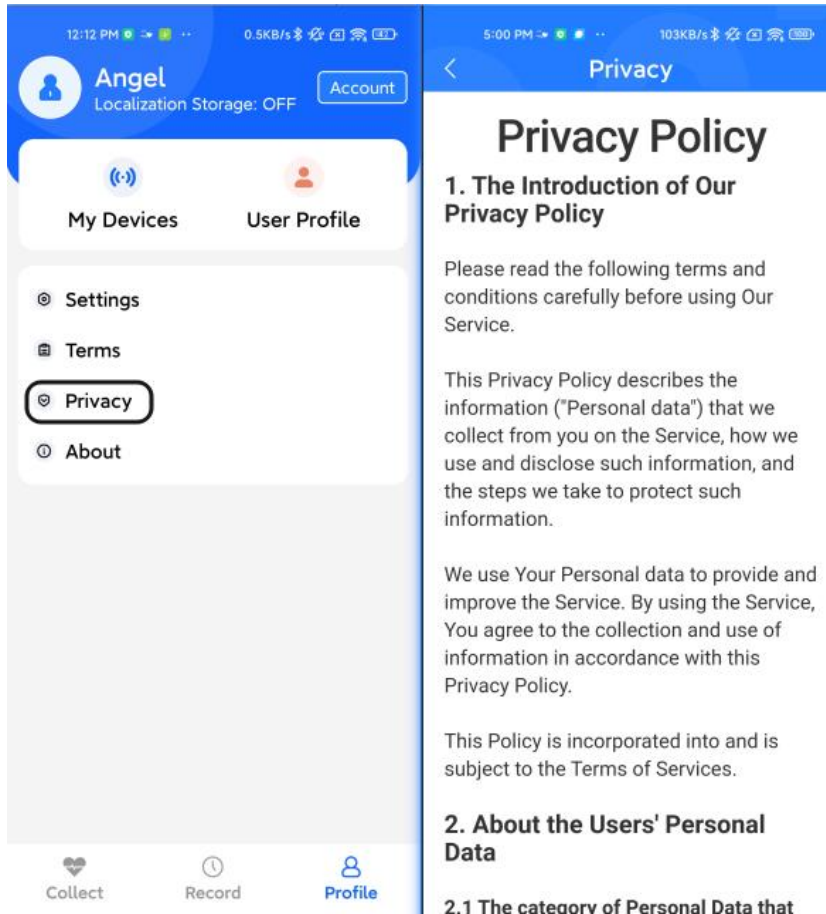
### 3.5. Terms

Terms: Access to view the Terms of Service.



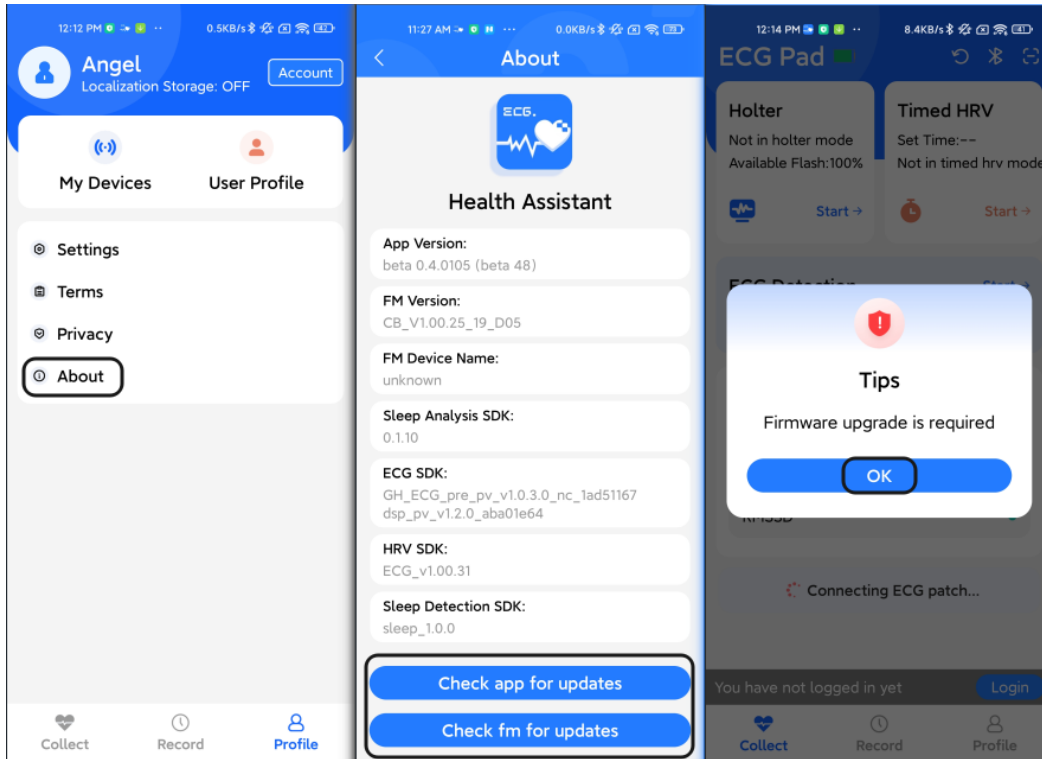
### 3.6. Privacy

Privacy: Access to view the Privacy Policy.



### 3.7. About

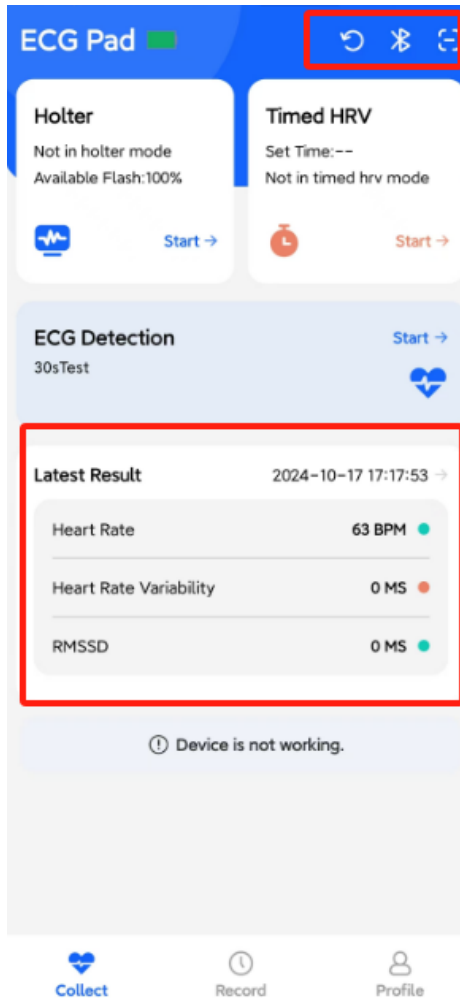
About: Displays version information for both the app and connected devices. Users can perform app updates and firmware upgrades through this interface.



In the 'About' interface, you can view version information and perform update checks for both the app and firmware. Also, pop-up notifications appear when launching the app, allowing you to choose to proceed with the update.

#### 4. Information of "Collect"

In **Collect** interface, you can check the following information:



Top-right buttons (from left to right):

- Refresh: Synchronizes and updates device status
- Bluetooth: Manages Bluetooth connection
- QR Code Scanner: Connect to devices by scanning their QR codes

Latest Result: Displays the most recent measurement results from the last test session. The measurement provides three key indicators: heart rate (HR), Heart Rate Variability (HRV), and Root Mean Square of Successive Differences (RMSSD).

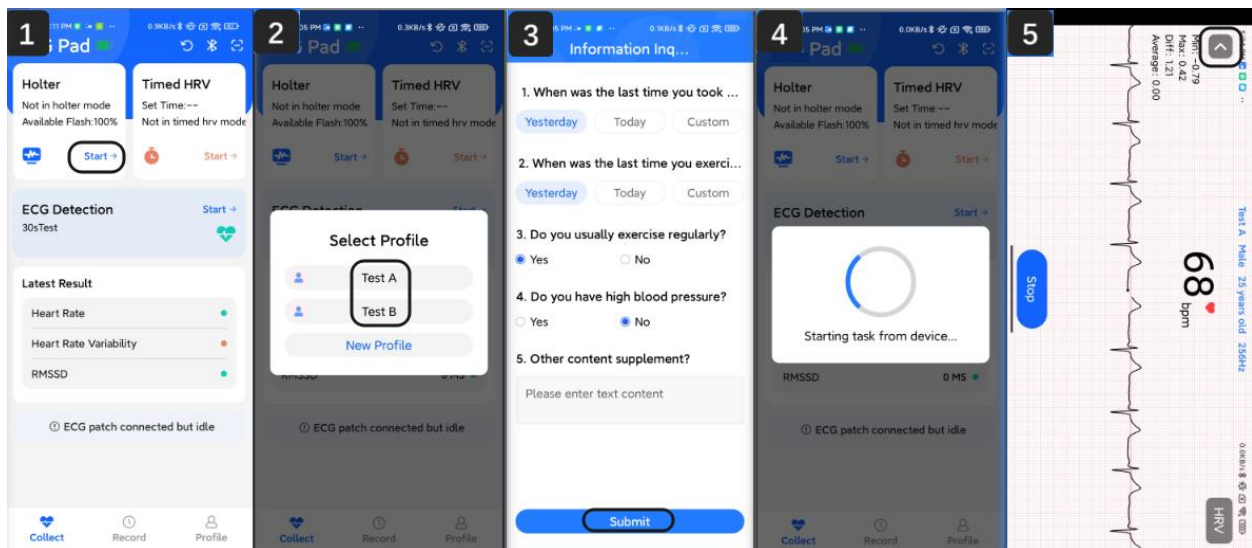
## 5. Basic Functions of software operation

### 5.1. Holter Mode

Holter mode is for continuous Rhythm Master ECG Patching, allowing you to monitor your ECG patterns for up to 3 days (default 24 hours). You can stop the monitoring at any time. When monitoring stops, a report including the ECG signal from the entire monitoring session will be generated and recorded.

## Start Holter Mode

1. On the Collect page, tap **Start** in the Holter Mode tab after reading the tips
2. Select your individual profile.
3. Input check-in information by answering the questions. Scroll down and tap **Submit**.
4. Select the ECG sampling rate and then tap **OK**.
5. Once Holter mode monitoring starts, you can leave the page as it will keep monitoring in the background.



## Tips during Holter Monitoring

1. You can check the live ECG at any time by clicking **Check** in the Holter Mode tab.
2. Holter monitoring will automatically stop when the set time ends if not manually stopped.
3. If the Rhythm Master ECG Patch disconnects from your smartphone during Holter mode, monitoring will continue until the set time ends with data stored offline in the monitor. When reconnected, the system will ask if you want to upload the offline data.

## Check Holter Mode Monitoring

During Holter mode recording, you can return to check your ECG diagram and HRV status at any time. If you have questions about your ECG diagram or HRV metrics, please consult your therapist or doctor for interpretation and guidance.



1. On the **Collect** page, tap the **Holter Mode** tab.
2. On this page, you can monitor your live ECG recording. Tap **HRV** to check extracted HRV metrics.
3. The HRV page will show the major HRV metrics (IHR, RMSSD, ACC).

### Note on IHR, RMSSD, ACC, [viewing of ECG](#):

This information is for basic user knowledge. Please consult your therapist or doctor to properly interpret the metrics.

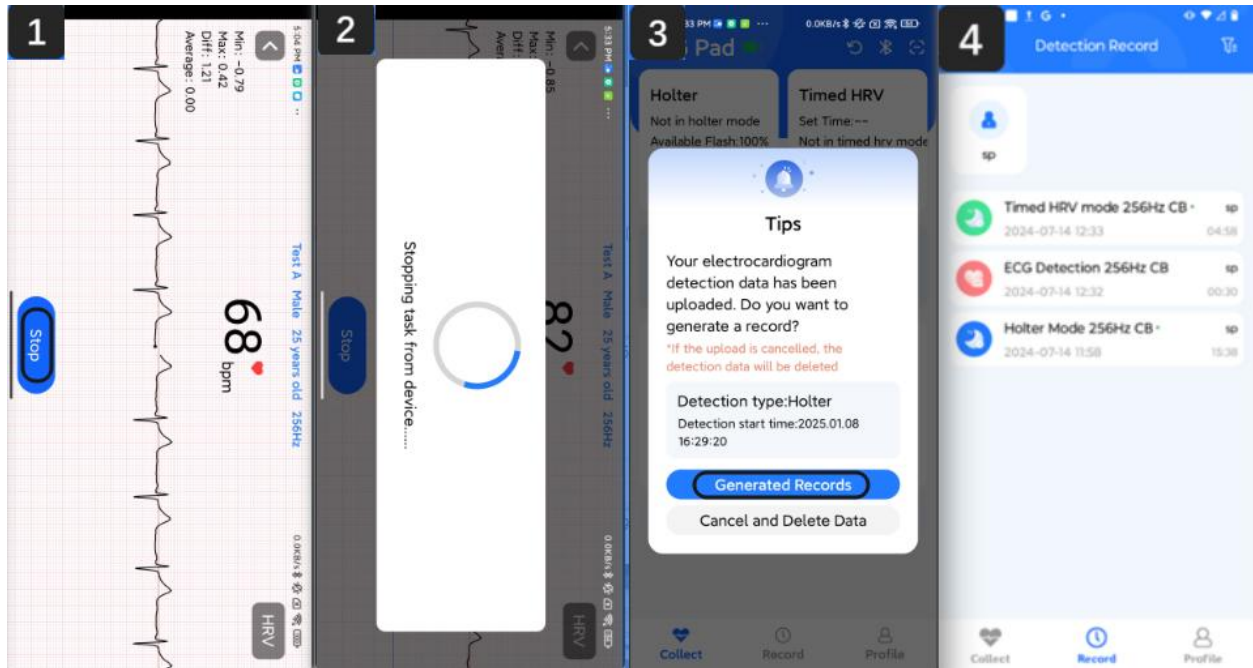
- **IHR (Instantaneous Hear Rate):** IHR refers to the heart rate calculated at each beat-to-beat interval, often derived from the time between successive R-wave peaks in an

ECG. It is intended solely for general reference and long-term trend observation, offering a summary indication of average heart rate over the recording period.

- **RMSSD:** RMSSD is a time-domain measure of HRV that calculates the square root of the mean of the squared differences between successive R-R intervals (the time between successive R-wave peaks on the ECG. As considered as a reliable marker of parasympathetic (vagal) activity, RMSSD has been used for stress, recovery and other mental health assessment purpose. It provides a quantitative indication of variations in heart rate over time and is displayed for general reference and trend observation only. The HRV value does not have diagnostic or interpretive intent.
- **ACC (Accelerometer):** Accelerometer measures the heart's ability to accelerate and decelerate over short time periods. It is often derived from analyzing the changes in R-R intervals and can provide insights into the dynamic responsiveness of the heart to various stimuli. ACC (Accelerometer) represents the three-axis motion signals (X/Y/Z) of the device. It allows users and physicians to understand whether the patient is in motion or at rest for reference to signal quality; it is not intended for diagnosis or autonomic function assessment.
- **Viewing of ECG:** The device allows for the viewing of recorded ECG waveforms. It's displayed for reference and is the primary functionality that enables a qualified healthcare professional to perform diagnostic interpretation.

## Stop Holter Mode

Holter monitoring will automatically stop when the set time ends. Or, you can manually stop recording according to the following steps:



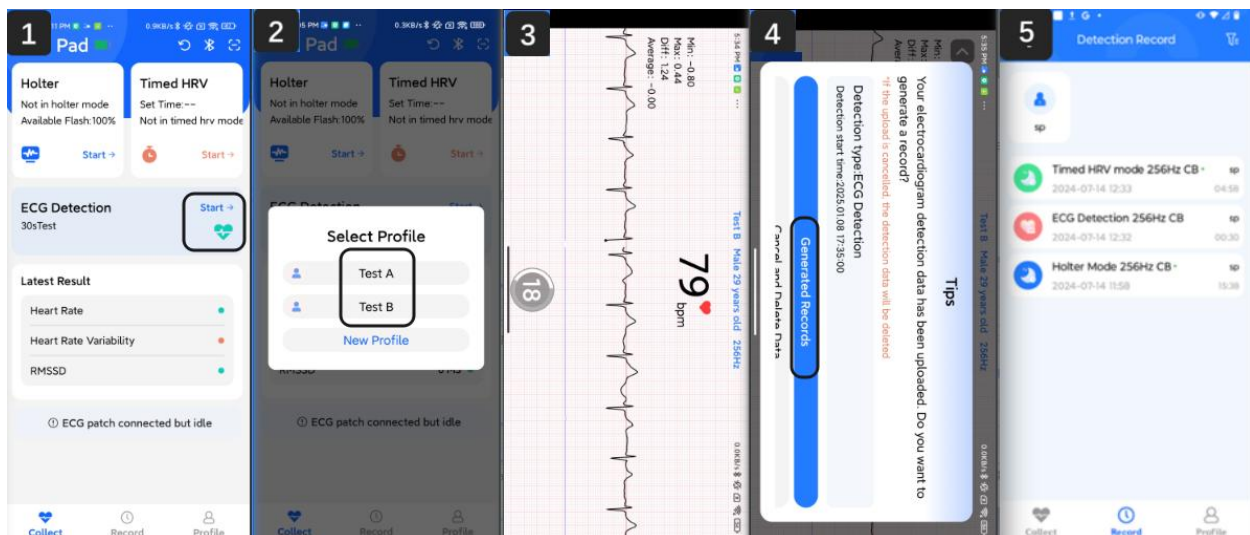
1. Tap **Stop** on the live Rhythm Master ECG Patching page to end Holter monitoring.
2. The system will automatically start uploading offline data to your smartphone. Please wait until it completes.
3. Tap **Generated Records** to save the data locally on your smartphone. If you don't want to save the data, select **Cancel and Delete Data**.
4. After clicking **Generated Records** and a short wait, wait for offline data saving to be completed. The system will then return to the **Record** page. Your Holter monitoring data is now saved and accessible by clicking the records listed on this page. When your smartphone is connected to the internet, records will automatically upload to the cloud platform (showed in Annex 2). A **green dot** will appear next to the data entry once the upload is completed.

## 5.2. ECG Detection

ECG Detection mode captures a 30-second waveform snapshot to evaluate signal quality and electrode connection. The displayed waveform is for clinician review only and not for diagnostic interpretation. Stay still during detection to minimize motion interference with the true ECG signal. The interpretation of the ECG pattern requires medical professionals; please consult your healthcare provider if you have any concerns about the captured ECG data.

### Use ECG Detection Mode

1. On the **Collect** page, tap **Start** in the **ECG Detection** tab.
2. Follow the instruction to select your individual profile.
3. ECG detection starts and will last for 30 seconds. **Do NOT leave this page or turn off your display during the detection.**
4. After the 30-second timer stops, ECG detection will automatically stop. A prompt for data record saving will appear. Select **Generate Records** to proceed to the **Record** page.
5. After clicking **Generated Records** and a short wait, wait for data saving to be completed.

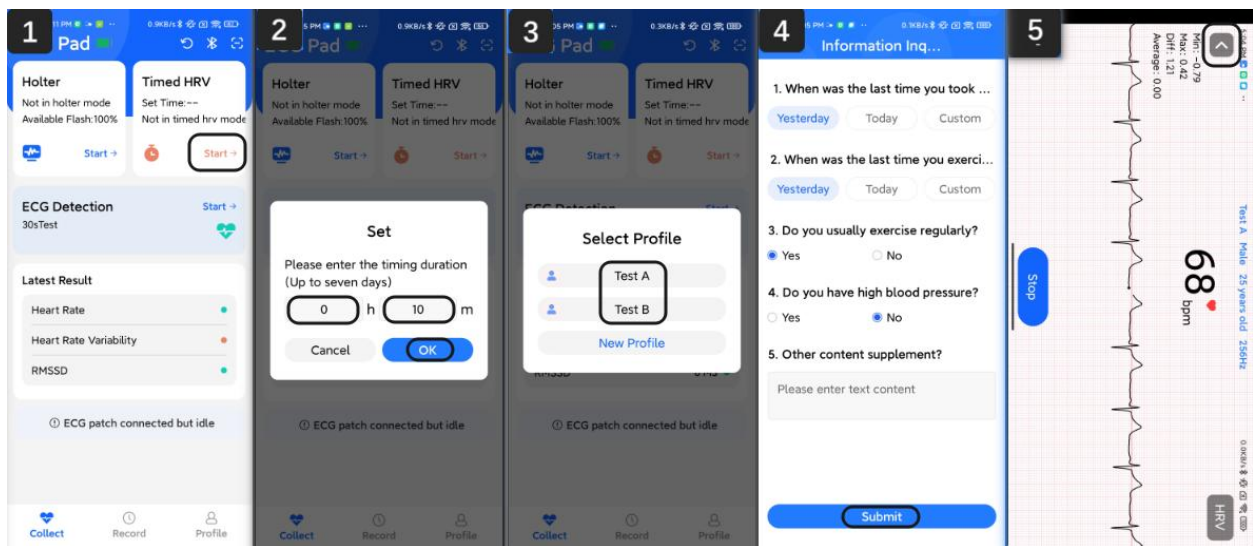


## 5.3. Timed HRV Mode

Timed HRV Mode enables you to set a timer (from 1 to 120 minutes) for your ECG/HRV recording. The recording will automatically end when the timer expires.

### Use Timed HRV Mode

1. On the **Collect** page, tap **Start** in the **Timed HRV Mode** tab.
2. Set the period of time for ECG recording.
3. Follow the instruction to select your individual profile.
4. Input your basic medical condition and then click **Submit**.
5. HRV mode recording starts and will last until the timer ends. You can also stop it early by clicking **Stop**. Follow the notification to save or delete the new data recorded.



## 6. Access Your Data and Analysis

### Access Your Data on the Phone:

The ECG data acquired by the Rhythm Master ECG Patch will be stored on your smartphone. You can access this data using the Health Assistant app. All your recent records from Holter Mode, ECG Detection, and Timed HRV Mode will be listed on the **Record** page.

#### 1) Holter Mode:

A continuous monitoring mode for all-day detection. The device will collect data offline until manually stopped or reaching the preset maximum duration. After collection is completed, users can view ECG waveforms and HRV statistical results.

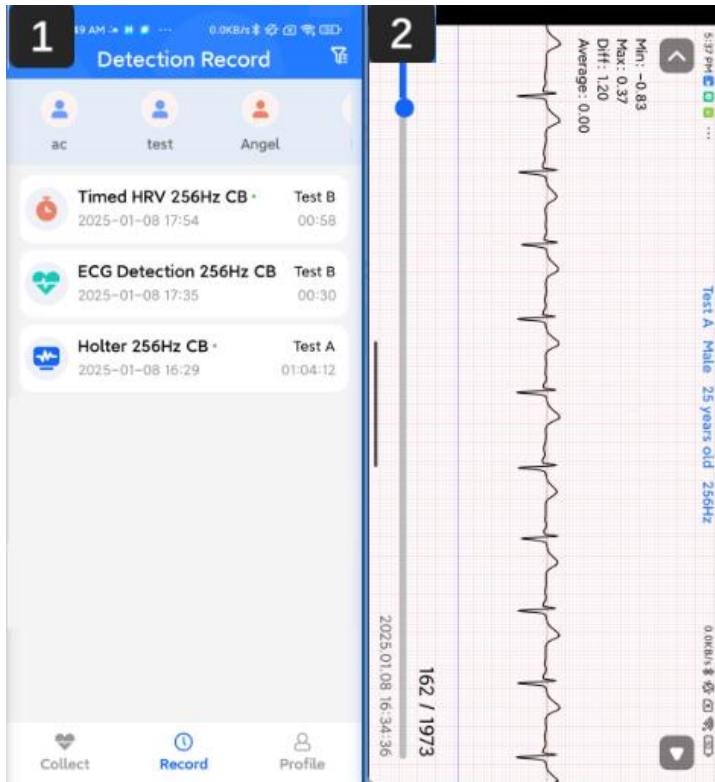
#### 2) ECG Detection:

A real-time monitoring mode designed for short-term ECG waveform observation. Data collected in this mode will not be uploaded to the cloud server.

#### 3) Timed HRV Mode:

A scheduled monitoring mode where users input a specific duration before starting. The device automatically stops data collection when the preset duration is reached. Similar to Holter Mode, users can view ECG waveforms and HRV statistical results after collection is completed.

### Review your ECG Detection data:



1. Tap **Record** on the homepage. Scroll through the list to find earlier records and select the record you want to review.

2. Once a record is selected, the screen will display the ECG signal along the time axis. Move the blue button on the progress bar to view the ECG signal at different times.

Note: Before transmitting the data to mobile application, please make sure the device is correctly connected to the mobile application. If not, please connect them according to the Section 2- Connect the Device to Your Smartphone.

## Review your Holter Mode or Timed HRV Mode data:

These records include ECG diagrams and allow you to check analyzed HRV metrics.

1. On the **Record** page, select any Holter Mode or Timed HRV Mode data from the list.
2. You will be prompted to select the analysis you want to access. Choose the desired mode:

**A. Electrocardiogram:** Displays the recorded ECG signal. You can scroll through the button to view different times within the record. You can click the "PDF" button to generate the PDF file of this record, and click the "10mm/mV" button to switch gain.

**B. Heart Rate Variability:** Shows the analyzed HRV metrics from the recorded ECG. You can scroll through the button at the bottom to view different times within the record.

The three graphs in the HRV interface show:

- 1) IHR (Instantaneous Heart Rate) Graph:

Displays real-time heart rate variations of the subject over time, showing immediate changes in heart rate at each moment.

- 2) HRV (Heart Rate Variability) Graph, it includes three key metric:

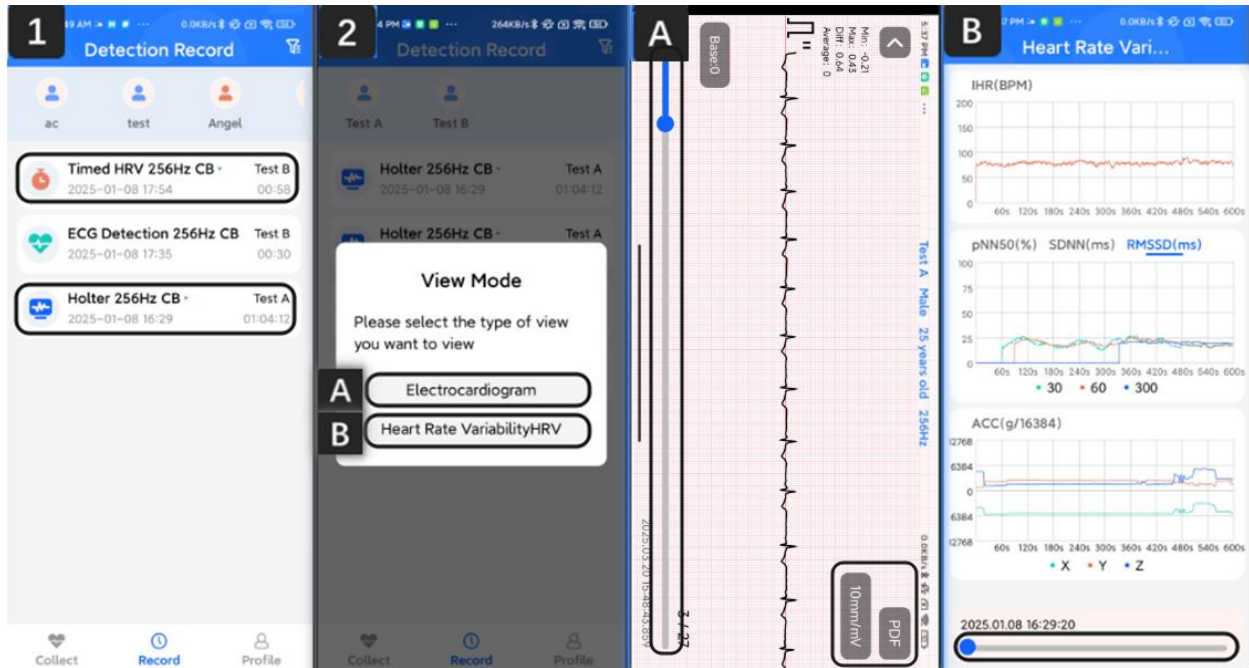
pNN50: Percentage of successive RR intervals that differ by more than 50ms. Indicates parasympathetic activity and stress levels.

SDNN: Standard deviation of NN intervals. Reflects overall heart rate variability and cardiac health status.

RMSSD: Root Mean Square of Successive Differences. Measures short-term heart rate variability and is associated with vagal tone and stress response.

- 3) ACC (Accelerometer) Real-time Data Graph:

Displays movement data across three axes (X, Y, Z), helping to monitor physical activity levels and correlate movement patterns with heart rate changes during the measurement period.



## 7. Software uninstallation procedures

For Android devices (using Samsung as an example):

- 1) On the home screen or app drawer, press and hold the app icon
- 2) When the pop-up menu appears, tap "Uninstall" or the trash bin icon
- 3) Confirm the uninstallation by tapping "OK" when prompted
- 4) The app will be completely removed from your smartphone



## 8. Security Information

**Privacy:** This product requires online user registration for device usage and data transmission. Uploaded ECG and other information will be analyzed on a cloud server. We are committed to maintaining and protecting your personal privacy information.

### Information storing

Only the Rhythm Master ECG Patching data of the user is collected via the bio-processor. None of personal information nor sensitive data of the user is collected from the Rhythm Master ECG Patch device and mobile application. In each recording session, ECG data will be stored in the device. Once the data is transmitted to the mobile application, the Rhythm Master ECG Patch will delete this storage data. Before writing data to the mobile application, the raw data will be encrypted by Huffman algorithm.

### **Information transmission**

User can view the Rhythm Master ECG Patching data and device's battery status in the mobile application via BLE secure connection. And the data only will be transmitted to the mobile application when the user log in to the account and connect to the device. Huffman coding will be applied to ensure the security and the integrity of data during transmission.

### **Cloud server**

When the user log in to the Health Assistant account and transmit the Rhythm Master ECG Patching data to this mobile application, the data will be automatically uploaded to a cloud server(DigitalOcean, LLC.), which is a qualified and safe cloud server and you can see the "Terms of Service Agreement" and "Privacy Policy" in their website([DigitalOcean | Cloud Infrastructure for Developers](#)).

### **End of Support**

The Rhythm Master ECG Patch and customer support includes a call center, vendor web portals, and service support personnel. The information that flows through this support infrastructure will be processed and analyzed for security concerns at the legal manufacturer, The type of information may include, but is not limited to: customer complaints, feedback or issues, reports from organizations within the Rhythm Master ECG Patch system (e.g., manufacturing, logistics partners), and adverse event reports from quality management teams. These, and other relevant logs, will be monitored to identify and detect post-production security concerns. The final phase of a medical device life cycle is decommissioning when device was discontinued and no longer supported. The below points were considered when decommissioning the Rhythm Master ECG Patch device. Notifying customers, the end of life or end of support date as soon as possible with the reason so that customers can take any necessary action including removal of network connectivity,

transition to a supported product, and implementation of compensating controls. Customer data and information stored in Rhythm Master ECG Patch devices should be erased or removed by the person responsible for the information before a Rhythm Master ECG Patch device is decommissioned.

The data stored on the cloud of the device needs to be either deleted. The destruction of data must be clearly documented and follow any local regulatory or legal procedures.

Consideration for end of support includes when third-party products and components are no longer supported by their manufacturer or developer and when known common vulnerabilities and exposures are identified but not remediated by the third-party component manufacturer or developer. Provide anticipated end of life and end of support dates to customers as part of customer security documentation.

## **9. Maintenance and precautions**

### **9.1. Overview**

In order to give full play to the performance of this software, ensure its reliability, and prolong its service life, please maintain it strictly in accordance with the requirements of this chapter.

### **9.2. Routine maintenance method**

For example, when the software fails to start or experiences a run-time error, etc., users should stop using the device, and contact Smwmed Inc., or local agents.

### **9.3. Daily use precautions**

- Do not copy the software to other machines for installation and use without the written authorization of the manufacturer or its sales representative.
- Before using the software, please read the "user manual" of this product carefully, and use it by trained and qualified personnel.

### **9.4. Quality control**

It is only used by authorized personnel trained by Smwmed Inc., or its agents, otherwise the test results may be adversely affected.

## 10. Failure analysis and treatment

### 10.1. Overview

This chapter introduces the handling methods and steps of common software failures. If you still cannot eliminate the failure according to the work instructions in this chapter or need more detailed information, please contact SMW Med's after-sales service department(support@smwmed.com).

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### 10.2. Simple troubleshooting

After the following malfunctions occur in the software, the troubleshooting methods in the following table should be used to solve them. If you cannot solve them or even cause other problems, please contact us instead of resolving by yourself.

Summary of daily software failure analysis and handling

Failure phenomenon	Cause Analysis	Method of exclusion
The software does not start normally	Operating environment hardware does not support	Replace the hardware environment
No response after software button is clicked	The software is abnormal or the program file is damaged	Contact after-sales service personnel for maintenance
Other failures	When other failures occur	Please contact the after-sales service

## Annex 2: Cloud Platform Description

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### 1. Accessing the Platform

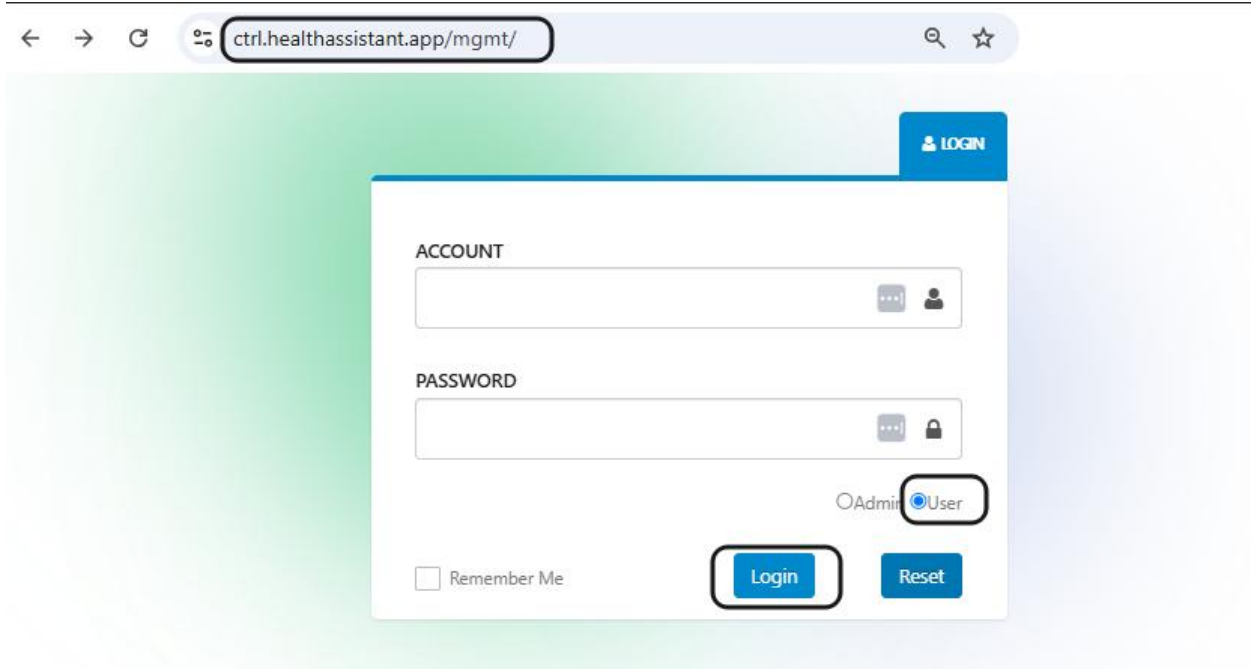
Open your web browser and navigate to <https://ctrl.healthassistant.app/mgmt/>

### 2. Login Process

Enter your account credentials

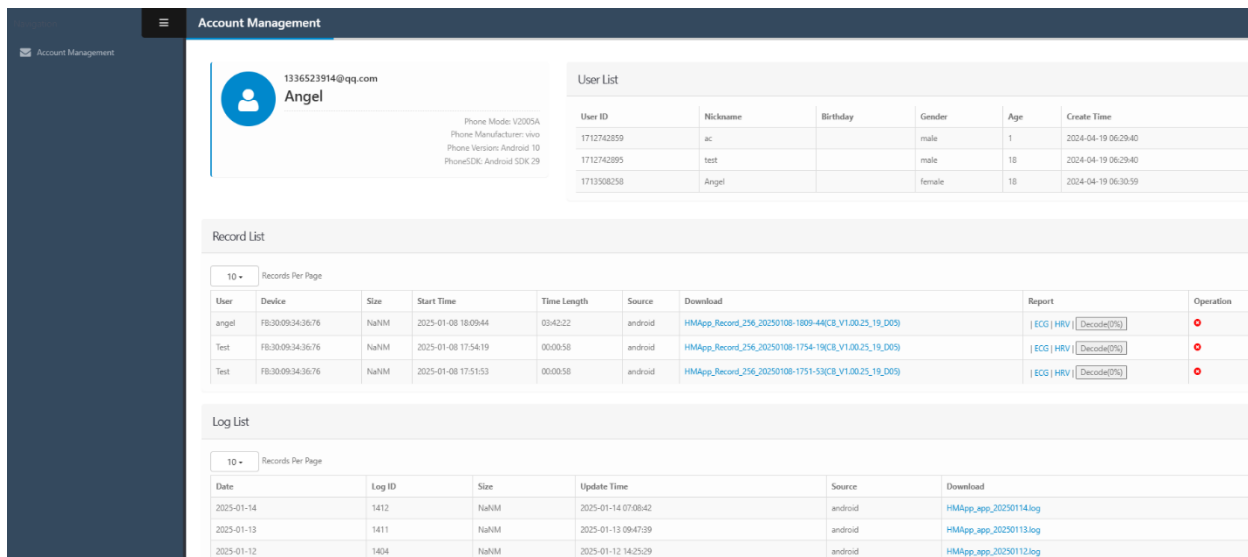
Select "**User**" mode from the dropdown menu

Click the "**Login**" button to access the platform. If you need to clear your account credentials, click the "**Reset**" button, or you can click "Remember me" to store you account data so that you don't need to input your account credentials next time.



### 3. Navigating the Main Interface

After successful login, you will see three main sections in the navigation menu: **User List**, **Record List** and **Log List**.



**Account Management**

Account Management

1336523914@qq.com  
Angel

Phone Model: V2005A  
Phone Manufacturer: vivo  
Phone Version: Android 10  
PhoneSDK: Android SDK 29

**User List**

User ID	Nickname	Birthday	Gender	Age	Create Time
1712742859	ac		male	1	2024-04-19 06:29:40
1712742895	test		male	18	2024-04-19 06:29:40
1713508258	Angel		female	18	2024-04-19 06:30:59

**Record List**

10 Records Per Page

User	Device	Size	Start Time	Time Length	Source	Download	Report	Operation
angel	FB3009343676	NaNM	2025-01-08 16:09:44	03:42:22	android	HMAApp_Record_256_20250108-1809-44(CB_V1.00.25_19_009)	ECG   HRV   [Decode(2%)]	●
Test	FB3009343676	NaNM	2025-01-08 17:54:19	00:00:58	android	HMAApp_Record_256_20250108-1754-19(CB_V1.00.25_19_009)	ECG   HRV   [Decode(2%)]	●
Test	FB3009343676	NaNM	2025-01-08 17:51:53	00:00:58	android	HMAApp_Record_256_20250108-1751-53(CB_V1.00.25_19_009)	ECG   HRV   [Decode(2%)]	●

**Log List**

10 Records Per Page

Date	Log ID	Size	Update Time	Source	Download
2025-01-14	1412	NaNM	2025-01-14 07:08:42	android	HMAApp_app_20250114.log
2025-01-13	1411	NaNM	2025-01-13 09:47:39	android	HMAApp_app_20250113.log
2025-01-12	1404	NaNM	2025-01-12 14:25:29	android	HMAApp_app_20250112.log

#### 3.1 User List Section

The User List displays detailed user profile information with view-only access to user details and profiles linked to the account. Please note that any profile modifications can only be made through the mobile app's **profile** interface.

### 3.2 Record List Section

The Record List manages all ECG recording data, offering both viewing and downloading capabilities. Users can view data in two viewing modes: ECG View and HRV View, and can also download both raw data and decoded CSV files.

Record List								
10 Records Per Page								
User	Device	Size	Start Time	Time Length	Source	Download	Report	Operation
angel	FB:30:09:34:36:76	NaNM	2025-01-08 18:09:44	03:42:22	android	<a href="#">HMAApp_Record_256_20250108-1809-44(CB_V1.00.25_19_D05)</a>	ECG   HRV   CSV	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:54:19	00:00:58	android	<a href="#">HMAApp_Record_256_20250108-1754-19(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:51:53	00:00:58	android	<a href="#">HMAApp_Record_256_20250108-1751-53(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:50:21	00:01:00	android	<a href="#">HMAApp_Record_256_20250108-1750-21(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	⊘

For ECG viewing, navigate to the "**Records**" page, select the desired record, and click the "ECG" button to display the waveform.

Record List

10 Records Per Page

User	Device	Size	Start Time	Time Length	Source	Download	Report	Operation
angel	FB:30:09:34:36:76	NaNM	2025-01-08 18:09:44	03:42:22	android	<a href="#">HMApp_Record_256_20250108-1809-44(CB_V1.00.25_19_D05)</a>	ECG   HRV   CSV	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:54:19	00:00:58	android	<a href="#">HMApp_Record_256_20250108-1754-19(CB_V1.00.25_19_D05)</a>	ECG   HRV   Decode(0%)	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:51:53	00:00:58	android	<a href="#">HMApp_Record_256_20250108-1751-53(CB_V1.00.25_19_D05)</a>	ECG   HRV   Decode(0%)	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:50:21	00:01:00	android	<a href="#">HMApp_Record_256_20250108-1750-21(CB_V1.00.25_19_D05)</a>	ECG   HRV   Decode(0%)	⊘

**User Info**

Nickname: angel

Terminal Type: PC Terminal

**Device Info**

MAC: FB:30:09:34:36:76

Firmware Type: CB

**Data Info**

Size: 4.10M

Start Time: 2025-01-08 18:09:44

Time Length: 03:42:22

Sample Rate: 256

URL: 080110011a107f985957e6aebfd3d83aa3d96ad3b77b20e5cee9c09cc0f7e242

**Block Info**

Block Count: 6832

First Block ID: 0

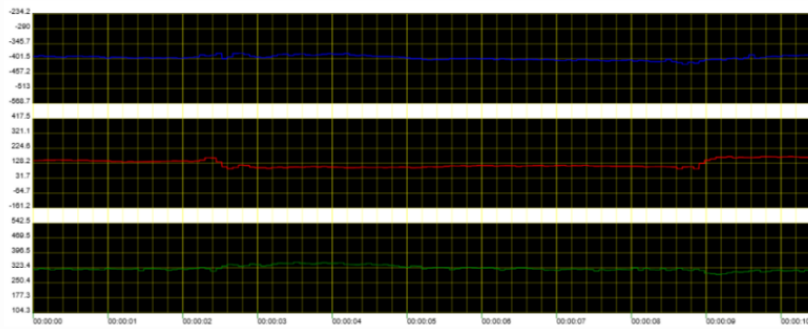

Last Block ID: 6831

Lack Blocks: None

Invalid Blocks: None

Leave Block Count: 0

GSensor Data: None

Navigation controls: 1 ZoomX 1

Progress bar: 0s 1334s 2668s 4003s 5337s 6671s 8006s 9340s 10675s 12009s 13343s

The interface provides intuitive navigation controls, including a draggable progress bar and control buttons:

- >S: Single-second advancement
- >P: Page-by-page navigation
- >|: Jump to end of recording

For HRV analysis, select a record and click "HRV" to view heart rate variability metrics and trends. Users can drag the progress bar to view waveforms from different time periods and adjust the display scale by selecting different ranges such as "50", "40", or "30".

### Record List

10 Records Per Page

User	Device	Size	Start Time	Time Length	Source	Download	Report	Operation
angel	FB:30:09:34:36:76	NaNM	2025-01-08 18:09:44	03:42:22	android	<a href="#">HMApp_Record_256_20250108-1809-44(CB_V1.00.25_19_D05)</a>	ECG   <b>HRV</b>   CSV	🔴
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:54:19	00:00:58	android	<a href="#">HMApp_Record_256_20250108-1754-19(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	🔴
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:51:53	00:00:58	android	<a href="#">HMApp_Record_256_20250108-1751-53(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	🔴
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:50:21	00:01:00	android	<a href="#">HMApp_Record_256_20250108-1750-21(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	🔴



For file downloading, click the "**Download**" button below the corresponding record to download the raw data file.

Record List

10 Records Per Page

User	Device	Size	Start Time	Time Length	Source	Download	Report	Operation
angel	FB:30:09:34:36:76	NaNM	2025-01-08 18:09:44	03:42:22	android	<a href="#">HMAApp_Record_256_20250108-1809-44(CB_V1.00.25_19_D05)</a>	ECG   HRV   CSV	
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:54:19	00:00:58	android	<a href="#">HMAApp_Record_256_20250108-1754-19(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:51:53	00:00:58	android	<a href="#">HMAApp_Record_256_20250108-1751-53(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:50:21	00:01:00	android	<a href="#">HMAApp_Record_256_20250108-1750-21(CB_V1.00.25_19_D05)</a>	ECG   HRV   <input type="button" value="Decode(0%)"/>	

Account Management

Record List

10 Records Per Page

angel FB:30:09:34:36:76 NaNM 2025-01-08 18:09:44 03:42:22 android [HMAApp\\_Record\\_256\\_20250108-1809-44\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV | CSV

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:54:19 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1754-19\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:51:53 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1751-53\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:50:21 00:01:00 android [HMAApp\\_Record\\_256\\_20250108-1750-21\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:47:53 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1747-53\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:45:21 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1745-21\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:42:50 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1742-50\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:40:18 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1740-18\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:37:46 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1737-46\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test FB:30:09:34:36:76 NaNM 2025-01-08 17:35:14 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1735-14\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Test E2:35:07:34:36:76 NaNM 2025-01-08 17:32:42 00:00:58 android [HMAApp\\_Record\\_256\\_20250108-1732-42\(CB\\_V1.00.25\\_19\\_D05\)](#) | ECG | HRV |

Total Pages: 74, Record Count: 735

1 2 3 4 5 6 7 8 9 10

https://ctrl.healthassistant.app/mgmt/function\_URL?%7B%20%22netive\_code%22%3A%22%7D%2Fdownload.do?apikey=1F192D3A136F4DAF986A4E3E07893E2D&url=080110011a107985957e6ebfd3d82ea3096ad3b77b20e5cee9c09cc07e242

Alternatively, click "**Decode**" under the report column of the corresponding data list, wait briefly for the decoding process to complete, then click the "**CSV**" button to download the decoded data as a CSV file.

Record List

10 Records Per Page

User	Device	Size	Start Time	Time Length	Source	Download	Report	Operation
angel	FB:30:09:34:36:76	NaNM	2025-01-08 18:09:44	03:42:22	android	<a href="#">HMAApp_Record_256_20250108-1809-44(CB_V1.00.25_19_D05)</a>	ECG   HRV   <b>CSV</b>	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:54:19	00:00:58	android	<a href="#">HMAApp_Record_256_20250108-1754-19(CB_V1.00.25_19_D05)</a>	ECG   HRV   [Decode(0%)]	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:51:53	00:00:58	android	<a href="#">HMAApp_Record_256_20250108-1751-53(CB_V1.00.25_19_D05)</a>	ECG   HRV   [Decode(0%)]	⊘
Test	FB:30:09:34:36:76	NaNM	2025-01-08 17:50:21	00:01:00	android	<a href="#">HMAApp_Record_256_20250108-1750-21(CB_V1.00.25_19_D05)</a>	ECG   HRV   [Decode(0%)]	⊘

OCTOPUS Admin English Angel Admin

Account Management

10 Records Per Page

Save As

Downloads

File name: HMAApp\_Record\_256\_20250108-1809-44(CB\_V1.00.25\_19\_D05).csv

Save as type: Microsoft Excel Comma Separated Values File (\*.csv)

Save Cancel

Log List

<https://ctrl.healthassistant.app/admin/ecg/080110011a107f985957e6aebfd3d82ea3d96ad3b77b20e5cee9c09cc0f7e242.csv>

### 3.3 Log List Section

The Log List maintains a comprehensive record of system events and data collection processes, serving as a valuable resource for technical support, problem diagnosis, and activity tracking.