Rhythm Master ECG Patch User Guide

Model: HM-15BW-AX, HM-15BW-DX

Release date: 2026.02.05

Version: V1

Table of Contents

Chapter 1: Overview

Know Your Device

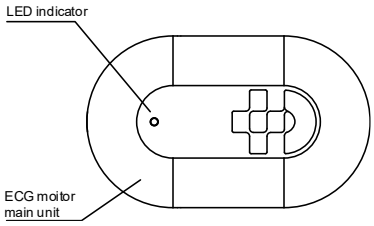
Thank you for choosing the SMW MED ECG (electrocardiogram) Monitor! This single-lead portable Rhythm Master ECG Patch is designed to help you track your heart health. By wearing the device properly and connecting it to the software on your computer via USB, you can continuously and conveniently record your ECG. When the Computer software is in the online mode, the recorded data will be sent to a cloud server for 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

Rhythm Master ECG Patch Main Unit

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

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

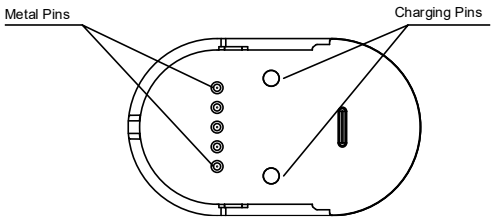


The meanings of different indicator light:

LED Indicator	What It Means
Blue ON	Battery is charging
Blue OFF	Battery charging is completed
White Flashing	Unsampled
White blinks six times	The device is connected to the charging dock

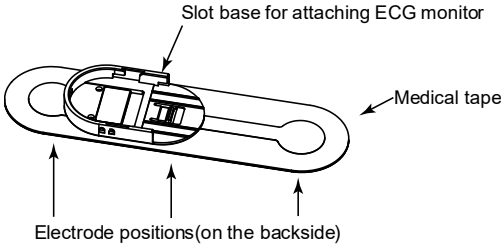
White Double blinking	The device is working (sampling)

- **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).

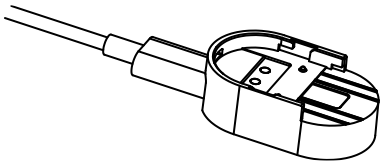


Charging Dock and Charging Cable

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).

The healthcare professionals is responsible for pasting the patch and confirming the patch position is appropriate for ECG monitoring. The HM-15BW-AX and HM-15BW-DX models are intended to be applied and initialized by healthcare professionals or trained personnel prior to the patient wearing period. These personnel are trained to follow the device placement instruction and to verify signal adequacy before the longer monitoring session begins.

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

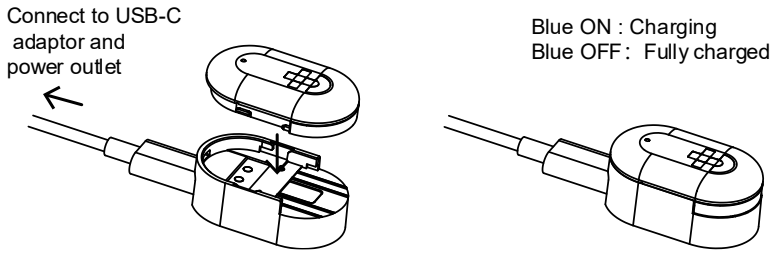
- Please remove the Rhythm Master ECG Patch from patient body before using external defibrillator. The device is contradicted for use during defibrillation since it's not defibrillation-proof.
- DO NOT use the device on infants or children. Do not let it be used by children or those with reduced physical 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 calculating the heart rate.
- The device cannot determining 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 software.



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 on the Devices page of the 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

- 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*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*0.8=2196 days, that is, 2196/365=6.02 years.

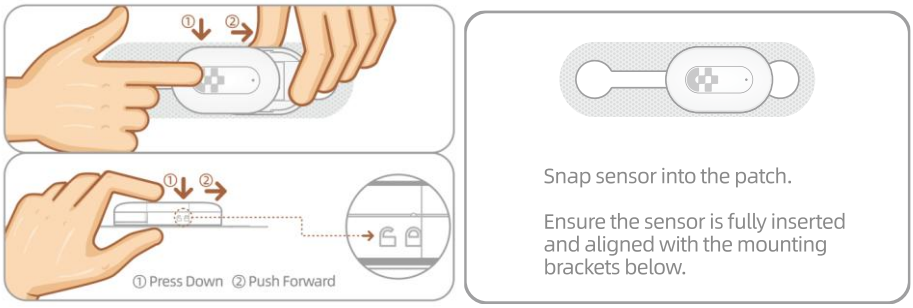
Install and Use Device

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.

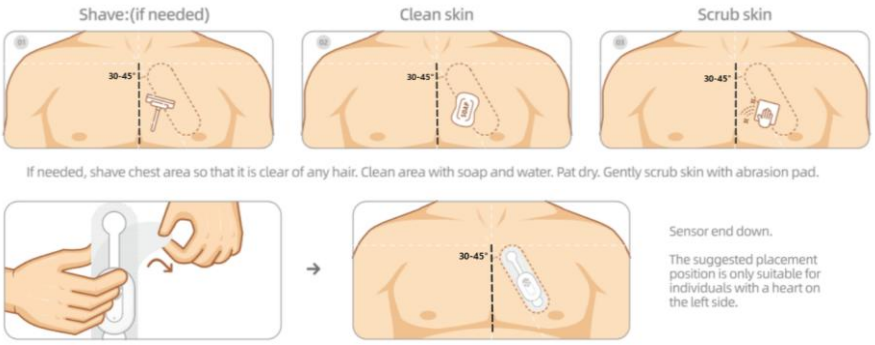
2. Slide the Rhythm Master ECG Patch along the notch into the slot on the base. Press downward while pushing forward.

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:

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.

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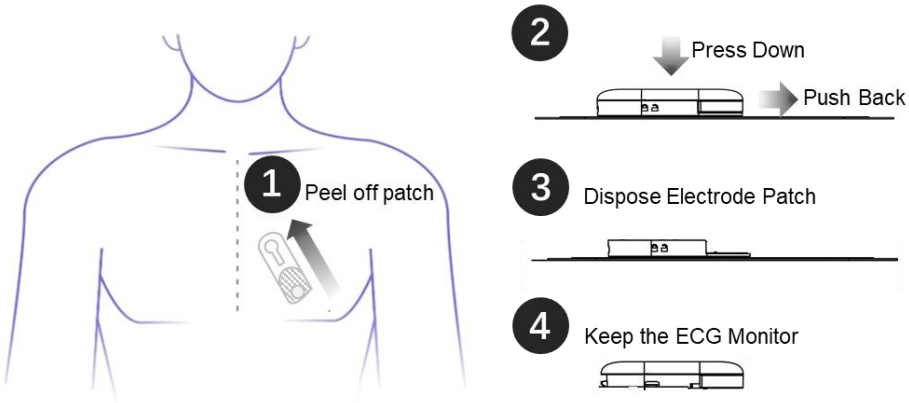
4. After the Patch has been collecting data for 30s, disassemble the sensor from the electrode patch without removing the patch from the chest. And connect the sensor to computer software Health Assistant with a USB cable. Upload the collected data to Health Assistant to verify whether the Patch is collecting data normally. If not, the physician shall adjust the attachment area and repeat the steps to verify the ECG adequacy.
5. If the collected ECG data is adequate, assemble the sensor back to the electrode patch and start ECG monitoring.

Remove the Rhythm Master ECG 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

Product name	Rhythm Master ECG Patch
Model	HM-15BW-AX, HM-15BW-DX
ECG Dynamic Range	-10mV to + 10mV
Applied Part Category	Type CF (cardiac floating)
Battery	LIR1654 3.6V 110mAh Rechargeable lithium-ion button battery
Data Stored and Transfer	Yes
Communication Protocol	USB2.0
Viewing Software Platform	APP on windows
Data Encryption	huffman Encoding encryption
Type of ECG Recorder	Patch
Number of ECG Channels	1
Recording Format	Continuous
Sensor Dimensions	37.0x22.5x7.7（H）mm
Sensor Weight	6.8 grams
Frequency Response	HM-15BW-AX: 0.5-40Hz HM-15BW-DX: 0.05-40Hz
Input Impedance	>10GOhms
Resolution	HM-15BW-AX: 15bit HM-15BW-DX: 20bit
Sampling rate	256Hz
Recording Standard	Holter

Patch Placement	Left chest, a finger's distance below the clavicle, tilted toward the left nipple at a 30-45° degree
Tolerance range for patch placement deviation from the target position	Upward offset (Y+): ⩽ 20mm Downward offset (Y–): ⩽ 20mm Outward offset (X+): ⩽ 40mm Inward offset (X–): ⩽ 30mm Clockwise rotation: ⩽ 45° Counterclockwise rotation: Not recommended
Recording Period	HM-15BW-AX: Up to 7 days HM-15BW-DX: Up to 4 days
Wear time	HM-15BW-AX: Up to 7 days HM-15BW-DX: Up to 4 days The patch has been tested to have a wear time (adhesive performance) of 7 days
Is it designed for simultaneously monitoring ECG and cardiac pacemaker signals	HM-15BW-AX: No HM-15BW-DX: Yes
Operation conditions	Temperature: 0°C to +45°C (32°F to 113°F) Humidity: 10% to 95% RH, non-condensing Atmosphere: 70 kPa to 106 kPa
Service Life	3 years
Hardware version	V1.0
PCB version	V1.62
Firmware version	V1.00.29
Computer software version	V1.0.30

Signal processing mode:

The GH3300 sensor offers two selectable signal processing modes: DC ECG channel (HM-15BW-DX) and AC ECG channel (HM-15BW-AX).

1) The DC ECG channel (Models: HM-15BW-DX) features ultra-low noise and a lower gain of 1 times, primarily to ensure that input signals are maintained within an appropriate range. In this mode, the ECG signal is converted from analog to digital through a high-resolution delta-sigma analog-to-digital converter (LNADC), preserving the integrity and original characteristics of the signal, making it suitable for scenarios requiring observation of baseline signal changes. This mode is designed to preserve the very low-frequency and direct current (DC) components of the electrocardiogram (ECG) signal. Its primary clinical utility is to monitor baseline drift that may contain clinically relevant information, and to provide data requiring the full signal frequency content. While the nominal input range remains ± 10mV, this mode maintains a wider effective dynamic range in the low-frequency domain by avoiding baseline suppression, thereby capturing subtle DC and near-DC variations.
2) The AC ECG channel (Models: HM-15BW-AX) 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.

The main difference between DX and AX mode is the cut-off frequency.

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.

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 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: How can I do if the computer software prompt "Signal disturbance"?

The computer 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".

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.

Q8: 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.

Q9: How to choose the appropriate model?

The HM-15BW-DX is designed for simultaneously monitoring ECG and cardiac pacemaker signals, making it suitable for patients with implanted cardiac pacemakers.

The HM-15BW-AX is intended for the general population and does not support pacemaker signal detection functionality.

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: ≤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
LOT	Batch Code	SN	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
	Prescription only		MR unsafe symbol is a medical device which poses unacceptable risks to the patient. medical staff or other persons within the MR environment.

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

Web: www.smwmed.com

Chapter 8: Cybersecurity instruction

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

Operating environment requirements

Software type	Hardware Configuration	Software Environment	Network conditions
Computer software	Processor: Intel Core i3-2120 2.0GHz or above; Memory: 8GB or above; Hard disk: 128GB or above;	Windows 11 or above	no request

Note: The computer software can only be operated under the specified operating environment. When it detects that the operating environment is outdated, the computer 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.

Firewall Requirements

Users are recommended to enable the built-in Windows Firewall or equivalent third-party firewall software on their computer. The firewall should be configured to allow only necessary network communications for the Health Assistant software and block unauthorized incoming connections.

Password Requirements

The Health Assistant computer software requires user authentication with password protection to ensure secure access to device functions and patient data. 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 "User Access Control Mechanism" of this chapter.

Data and equipment interface

Rhythm Master ECG Patch follows the USB protocol to realize the communication between the embedded device and the Health Assistant software.

Network Ports and Interfaces

ECG Patch (HM-15BW-AX, HM-15BW-DX) Interface:

Interface Type	Port/Protocol	Direction	Functionality	Approved Endpoints
USB	USB 2.0 (Type-C)	Bidirectional (Incoming/Outgoing)	ECG data transmission and device charging	Health Assistant Computer Software only

USB Interface Specifications:

Specification	Details
Protocol Standard	USB 2.0
Maximum Communication Rate	480 Mbps (protocol specification)
Actual Data Throughput	200 KB/s
Interface Type	Type-C
Direction	Bidirectional
Purpose	Data transmission with computer software and charging

Note: The Rhythm Master ECG Patch communicates with the computer exclusively via USB 2.0. No wireless network interfaces (such as Wi-Fi) are available on this device model.

Computer Software (Health Assistant) Network Interfaces:

Interface Type	Port/Protocol	Direction	Functionality	Approved Endpoints
HTTPS	TCP 443	Outgoing	Cloud data upload (online mode only)	https://ctrl.healthassistant.app
HTTPS	TCP 443	Incoming	Cloud data download (online mode only)	https://ctrl.healthassistant.app

Note: Network connectivity is optional. The Health Assistant computer software can operate in offline mode without any internet connection. Cloud synchronization is only available when the user manually enables online mode.

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.

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
USB	Computer	Windows 11 or above	USB2.0	Data transmission with computer software Charging	200KB/s

Note: 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
Xiaomi air13 - Intel(R) Core(TM) i5-8250U CPU @ 1.60GHz 1.80 GHz Win11 Lenovo - Intel(R) Core(TM) i5-10210U CPU @ 1.60GHz 2.11 GHz Windows 11 Pro Intel(R) Core(TM) i7-7600U CPU @ 2.80GHz 2.90 GHz Lenovo - AMD Ryzen 7 5800H with Radeon Graphics 3.20 GHz Windows 11	uart	Connection test between Rhythm Master ECG Patch and Health Assistant software; The Health Assistant software controls the Rhythm Master ECG Patch to conduct function test.

Supporting Infrastructure Requirements

Minimum System Requirements

Requirement	Specification
Processor	Intel Core i3-2120 2.0GHz or above
Memory	8GB or above
Hard Disk	128GB or above
Operating System	Windows 11 or above
USB Port	USB 2.0 Type-C (or Type-A with adapter)
Network (for online mode)	Wi-Fi or Ethernet connection

Technical Instructions for Secure Network Deployment

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

Secure Configuration: For optimal security, users should enable Windows BitLocker or equivalent disk encryption on their computer and configure screen lock protection using password or PIN to prevent unauthorized access. Antivirus software should be installed and kept running in the background at all times.

Network Security (for online mode): When using online mode for cloud synchronization, users should connect to secured networks that use WPA2 or WPA3 encryption protocols. Public or unsecured networks should be avoided for transmitting sensitive health data. For users who must access the system via public networks, enabling a VPN is recommended as an additional layer of protection.

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.

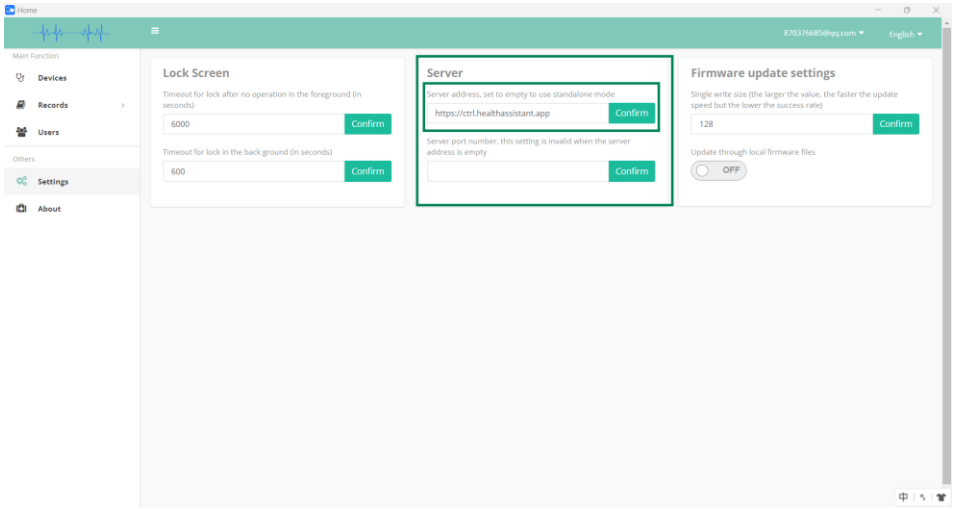
4) Agent/after-sales engineer's return visit: Agent/after-sales engineer will assist customers to complete the installation and update during the product after-sales service process.

Network use of the device

The Health Assistant computer software supports both offline and online modes:

Offline Mode: When using this software in offline mode, the use of application does not require network connection for basic functions. All ECG data can be collected, viewed, and stored locally without internet access.

Online Mode: If users want to switch to the online mode, they need to follow these steps: Enter the "Settings" page, find the "Server" tab, select the "Server address" input box within this tab as shown in the figure below, enter " https://ctrl.healthassistant.app ", then click the "confirm" button and restart the software. After that, they can enter the online mode. When using this software in the online mode and there is a network connection at this time, if there is data that has been transmitted to the Computer software, this data will be automatically uploaded to the server.



Cybersecurity detection and user notification

Users need to install anti-virus software on the PC terminal, such as Kaspersky, McAfee, Norton. The antivirus software must be permanently running in the background of the system. When the antivirus software detects a cybersecurity threat (such as a Trojan or worm virus), it will notify the user through the pop-up window.

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: Computer Software (Health Assistant), Version number: V1.0.30

The purpose of the device's connection to an IT-NETWORK	The Rhythm Master ECG Patch is designed for high-resolution ECG measurements. The Computer Software (Health Assistant) is connected to the main unit of the Rhythm Master ECG Patch (Model:HM-15BW-AX, HM-15BW-DX) through USB cable, and collects human dynamic ECG signals,amplifies, transforms and transmits the signals
The required characteristics of the IT-NETWORK incorporating the device	Please refer to section "Operating environment requirements" of Chapter 8: Cybersecurity instruction in User Manual.
The required configuration of the IT-NETWORK incorporating the device	Support USB2.0 protocol. (1) The maximum communication rate shall be 480Mbps, (2) the interface type shall be TYPE-C
The technical specifications of the network connection of the device including security specifications	Support USB2.0 protocol. (1) The maximum communication rate shall be 480Mbps, (2) the interface type shall be TYPE-C
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	Not applicable.

IT-network connection-related risks

Hazard No.	Hazard	Risk control measures
H12.1	Computer software function failure on computer: USB data transmission error	Implement data verification protocols and automatic retransmission of data with user notification on failed transfers.
H12.2	Computer software function failure on computer: Application memory overflow	Implement memory usage monitoring with automatic data saving mechanisms and controlled application restart when thresholds are exceeded.
H12.3	Authentication failure: User session expiry during critical operations	Implement background session renewal, warning notifications before expiry, and secure task resumption after re-authentication.
H12.4	Connection failure: Unable to detect ECG device	Implement comprehensive device discovery troubleshooting, clear connection status indicators, and guided setup assistance.
H12.5	Data integrity: Corrupted ECG data during transmission	Implement checksums for all transmitted data packets, error detection protocols, and automatic re-transmission of corrupted segments.
H12.6	Display error: ECG waveform rendering inaccuracy	Implement standardized rendering algorithms, display calibration verification, and visual quality assurance testing. 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.
H12.7	Data transfer: slow data transfer rate for some devices on certain systems	Make asynchronous calls without blocking the serial port data.
H12.8	Data security: User credentials storage vulnerability	Use secure cryptographic methods for credential storage, secure keychain integration, and no plaintext password storage.

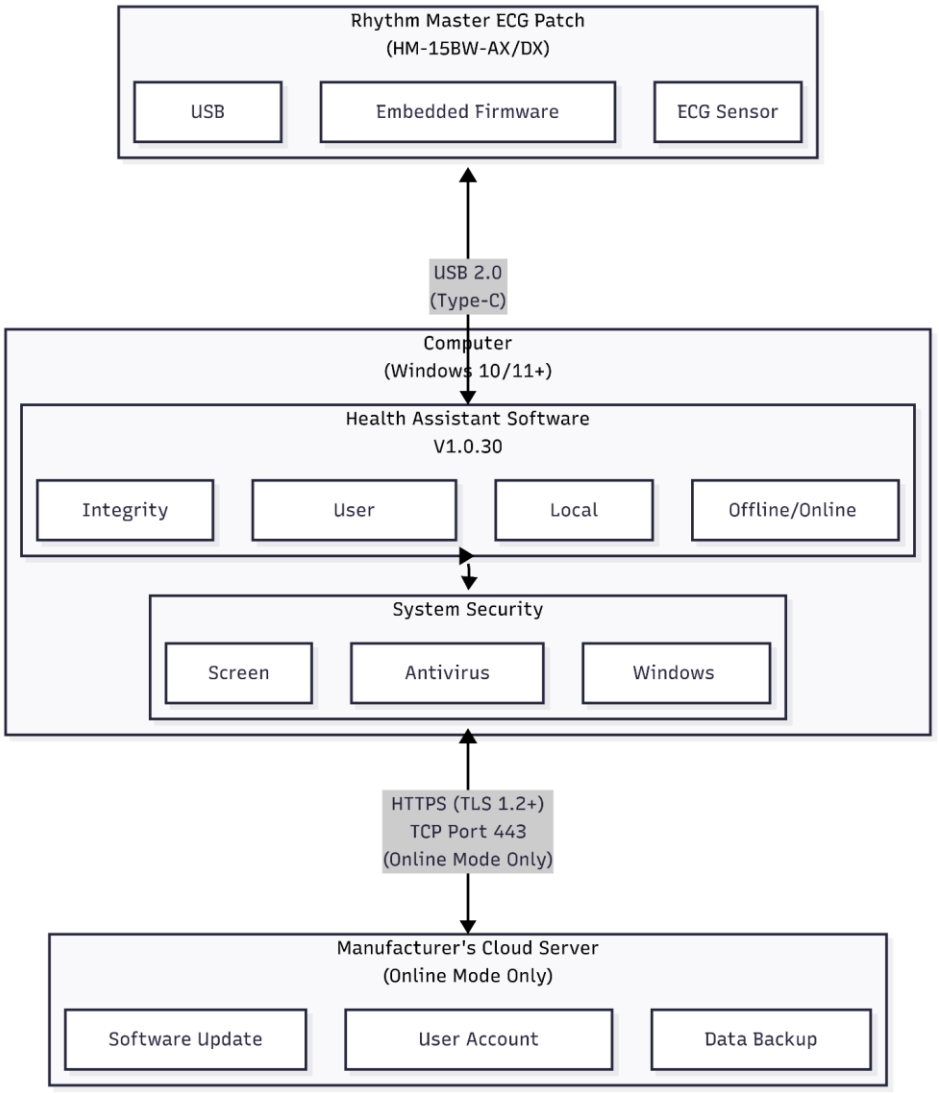
Hazard No.	Hazard	Risk control measures
H12.9	Data transfer: The abnormal device status	When the device is in an abnormal state, stop data transmission or related operations.
H12.10	Data integrity: Incomplete test user information	Check the integrity and accuracy of the test user information.
H12.11	Data security: Test user information storage vulnerability	Add an account isolation mechanism so that different accounts can only access the content under their own accounts.
H12.12	Data security: The risk of information leakage	Add an automatic screen - locking mechanism.
H12.13	Data integrity: The risk of data loss, isolation and damage.	Add a software application mode switching function. The offline mode can be switched to the online mode to upload data to the cloud.
H12.14	Data processing: Pacemaker signal detection error	Implement reliable algorithm for pacemaker signal decompression and parsing, ensure correct red marker display per IEC 60601-2-47 201.12.4.4.109, and visual quality assurance testing.
H12.15	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.
H12.16	Software running: Incompatible operating system.	The computer software is designed to support Windows 11 or later operating system. And it detects low OS versions (Windows) and displays a warning message prompting users to upgrade their system.

Diagrams for users that allow recommended cybersecurity controls to be implemented

Diagrams for Cybersecurity Controls Implementation

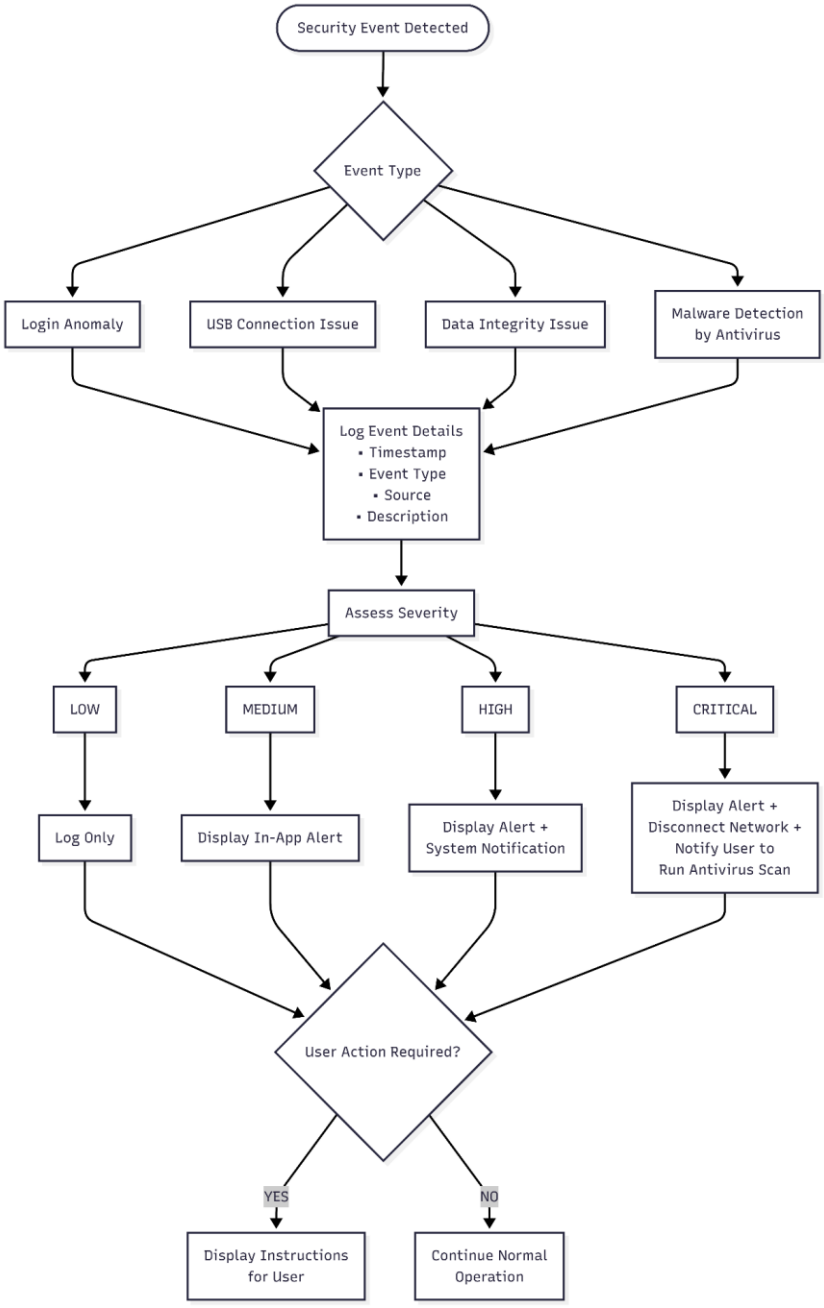
System Architecture and Data Flow Diagram

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

The following diagram illustrates how the system responds when security events are detected, including the classification of event severity and corresponding user notifications.


Security Event Detected
Event Type
Login Anomaly
USB Connection Issue
Data Integrity Issue
Malware Detection by Antivirus
Log Event Details
• Timestamp
• Event Type
• Source
• Description
Assess Severity
LOW
MEDIUM
HIGH
CRITICAL
Log Only
Display In-App Alert
Display Alert + System Notification
Display Alert + Disconnect Network + Notify User to Run Antivirus Scan
User Action Required?
YES
NO
Display Instructions for User
Continue Normal Operation

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 PC Application

Document Version: V2.0
Date: March 10, 2026

Field	Value
Document Name	Health Assistant Desktop Application SBOM
SBOM Author	Smwmed Inc.
Author Contact	support@smwmed.com
Author Website	https://www.smwmed.com
SBOM Format	NTIA Minimum Elements Compliant / CycloneDX 1.6
SBOM Version	2.0
Primary Component	Health Assistant Desktop Application v1.0.30

COMPONENT INVENTORY SUMMARY

#	Component Name	Version	Supplier	Relationship Type	Relationship	Relationship Assertion
1	adm-zip	0.5.16	Open Source Community (NPM)	DEPENDS_ON	Included - File Compression Lib	Known

2	axios	1.13.6	Axios Org / Open Source Community	DEPENDS_ON	Included - HTTP Client Stack	Known
3	electron-dl	4.0.0	Open Source Community	DEPENDS_ON	Included - Downloader Module	Known
4	electron-store	11.0.2	Open Source Community	DEPENDS_ON	Included - Local Persistence Storage	Known
5	jspdf	3.0.0	Open Source Community (jsPDF Project)	DEPENDS_ON	Included - PDF Export Component	Known
6	moment.js	2.30.1	Open Source Community (Moment Team)	DEPENDS_ON	Included - Time Formatting Library	Known
7	react-day-picker	9.4.4	Open Source Community (GitHub Project)	DEPENDS_ON	Included - Calendar UI Module	Known
8	react-i18next	15.0.2	i18next Community	DEPENDS_ON	Included - Localization Framework	Known
9	serialport	12.0.0	Open Source Community	DEPENDS_ON	Included - Hardware Interface Layer	Known

			(SerialPort JS)			
—	Windows OS	11	Microsoft Corp.	RUNS_ON	Host Platform Runtime	Known

COMPONENT EOL SUMMARY TABLE

Component	Version	Current Support Status	End of Support	Post-EOL Plan
adm-zip	0.5.16	Actively Maintained	No EOL posted; ⩾ 2027	Migrate to archiver or yazl if unmaintained
axios	1.13.6	Actively Maintained	~2027	Upgrade to v2.x or migrate to fetch API
electron-dl	4.0.0	Maintained	No immediate concern	Monitor for v5.x; use Electron native APIs if discontinued
electron-store	11.0.2	Actively Maintained	~Q1 2028	Upgrade with Electron; alternative: electron-json-storage
jspdf	3.0.0	Actively Maintained	v4 mid-2026	Upgrade to v4.x upon release
moment.js	2.30.1	Maintenance Mode (v2.30.1 released 2024)	No formal EOL announced	Migration to Day.js by Dec 2026 for optimization
react-day-picker	9.4.4	Actively Maintained	No EOL published	Monitor; alternative: react-datepicker

react-i18next	15.0.2	Actively Maintained	Aug 2026	Upgrade to v16.x by Q2 2026
serialport	12.0.0	Actively Maintained	Node 22 EOL Apr 2027	Upgrade with Node.js LTS migration
Windows 11	11	LTS Support	Oct 2031	COMPLETED: Windows 10 no longer supported

MACHINE-READABLE SBOM

A machine-readable version of this SBOM is provided in CycloneDX 1.6 JSON format: health-assistant-PC-sbom.cdx.json

To request a complete copy of the SBOM, please contact: support@smwmed.com

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

Downloading Manufacturer-Authorized Software and Firmware

Computer Software (Health Assistant) Updates

1. **In-App Notification:** When a new version is available, the Health Assistant software 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.
2. **Manufacturer Website:** Software updates and release notes are published on the manufacturer's official website. Users can visit the website to view available versions and download updates through official channels

Embedded Firmware Updates (ECG Patch)

In-Software Notification: When the Health Assistant software connects to the ECG Patch via USB and detects that a newer firmware version is available, a notification will appear prompting the user to update the firmware.

Version Identification

Users can verify current software and firmware versions at any time:

Component	Location	Version Format
Computer Software Version	About	V1.0.30
Firmware Version	Device (when ECG Patch connected)	V1.00.29

Update Authorization

Software Component	Authorized Update Source	Verification Method
Health Assistant Computer Software	Official download channels provided by manufacturer (Smwmed Inc.)	Digital signature verification
ECG Patch Firmware	Via Health Assistant Computer Software 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

Security Event Detection

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

Security Event Type	Detection Method	Device Response	User Notification

Configuration Changes			
Unauthorized settings modification	Hash verification of configuration files	Revert to last known good configuration, require software restart	Alert: "Configuration change detected. Please restart the software and re-enter your password to continue."
Connection Issues			
USB connection failure	USB connectivity monitoring	Pause data transmission, retry connection	Alert: "USB connection error. Please check the USB cable connection, try a different USB port, or restart the software."
Unable to detect ECG device	Device discovery monitoring	Display troubleshooting guidance	Alert: "ECG device not detected. Please ensure the device is connected via USB and powered on."
Login Attempts			
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."
Data Integrity			
Corrupted ECG data during transmission	Checksum verification	Discard corrupted data, request retransmission	No user notification (event logged only)
USB data transmission error	Data verification protocols	Automatic retransmission	Alert: "Data transmission error. Retrying..."

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
Offline Operation Mode	Software operates fully without internet connection	Ensures device functionality independent of network status; reduces attack surface
USB-Only Communication	ECG Patch communicates only via USB, no wireless interfaces	Eliminates wireless attack vectors
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
Account Isolation	Different user accounts can only access content under their own accounts	Prevents unauthorized access to other users' data
Auto Screen Lock	Automatic screen-locking mechanism	Prevents unauthorized access if computer is left unattended
Mode Switching	Ability to switch between offline and online modes	Allows data backup to cloud while maintaining offline capability

Offline Data Storage and Transfer

The ECG Patch 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 computer software.

Data Transfer Process: When the user connects the ECG Patch to the Health Assistant software via USB, the stored ECG data is uploaded to the computer. If the transfer is interrupted due to USB disconnection or other issues, the data remains safely stored on the ECG Patch. Upon the next successful connection, the software 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 software 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 backup and restore features and procedures to restore authenticated Configurations

Backup and Restore Features

Backup Features

Local Backup:

Data Type	Backup Method	Storage Location
ECG Recordings	Manual export	User-specified local folder
User Settings	Automatic on change	Application data folder
Database	Manual export	User-specified local folder

Cloud Backup (Online Mode):

When online mode is enabled, ECG data can be automatically synchronized to the cloud server at https://ctrl.healthassistant.app for backup purposes.

Restore Procedures

Restore from Local Backup:

To restore data from a local backup, navigate to File > Import Data, then select the backup file to restore. The software will verify the file integrity and import the data into the local database.

Restore from Cloud (Online Mode):

When using online mode, users can download previously uploaded ECG records from the cloud server. Navigate to Data > Download from Cloud and select the records to restore.

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 Location	Access Control
User Preferences	Encrypted local storage	Application data folder	Authenticated user only
Device Settings	Configuration file	Application data folder	Authenticated user only
ECG Data	Local database	User-specified folder	Authenticated user only

Recovery Methods for Authorized Users

Method 1: Import Local Backup Data

Users can import previously exported ECG records through the software. To import data, navigate to Record > Import Data, then select the backup file to restore. The software will verify the file integrity and import the ECG data into the local database.

Method 2: Sync from Cloud (Online Mode)

Users can synchronize ECG records stored on the cloud server to their computer. To sync data, enable online mode and navigate to Record > Download from Cloud. Users can choose to sync: All Records, This Week, This Month, or Custom setting. The software 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
USB Connection	Requires software authentication	Prevents unauthorized data access
Firmware	Latest stable version	Includes all security patches
Data Storage	Flash memory with integrity checks	Protects data integrity
Firmware Update	Requires authenticated software connection	Prevents malicious firmware installation

User-Configurable Changes

The following settings can be modified by users within the Health Assistant software:

Setting	Options	Location	Default
Operating Mode	Offline/Online	Settings > Server	Offline
Cloud Server Address	User input	Settings > Server	Not configured
Update Notifications	Enable/Disable	Settings	Enabled

Other security-related settings, such as screen lock timeout, are managed through the Windows operating system settings and are not configurable within the Health Assistant software.

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. Log files are stored locally on the user's computer in the following directory:

Default Path: {Installation Drive}:\Health Assistant\file\log\

Attribute	Description
File Format	Plain text log files (.log)
Naming Convention	hm_YYYYMMDD.log
Storage Location	Local storage
File Size Range	Typically 5 KB to 500KB per daily log

Log Information Captured

Each log entry contains the following metadata:

File Name: Log file identifier with date (hm_YYYYMMDD.log)

Date Modified: Timestamp of last modification

Type: Text document

Size: Size of the log file in kilobytes

Data Retention Policy

Log files are retained locally on the user's computer. Users are responsible for managing storage and manually deleting log files when no longer needed.

Access and Retrieval

Log files are stored in the local file system and can be accessed directly through the operating system's file explorer. No additional authentication is required beyond local system access.

Analysis Capabilities

The system does not include automated log analysis tools. Log files can be opened and reviewed using standard text editors (e.g., Notepad, Notepad++) 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-15BW-AX/DX)	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 Computer Software	V1.0.30	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.

Support Phases

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 (e.g., ensure latest OS security patches, maintain updated antivirus software, 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
- 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 computer software, 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 flash memory, Computer local storage, Cloud storage (if online mode used)	Yes - All locations
User Account Information	Computer software, Cloud servers (if online mode used)	Yes - All locations
Login Credentials	Computer software secure storage	Yes
Security Event Logs	Computer software logs folder	Yes - Per retention policy
Configuration Settings	ECG Patch, Computer software	Yes

Cloud Data Deletion

If cloud synchronization (online mode) 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

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**

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

Internet/Network Requirements Summary

Function	Internet Required	Alternative Without Internet
Initial software installation	Yes (for download)	Can install from provided installation media
User registration (first time)	Optional	Can use offline mode without registration
ECG recording	No	Full functionality available
Viewing ECG data	No	Full functionality available
Local data storage	No	Full functionality available
Cloud data backup	Yes	Data stored locally only
Software updates	Yes	Update when connectivity available or via installation media

Operating Without Internet

The Health Assistant computer software is designed to operate fully in offline mode without any internet connection:

Offline Mode (Default): The software operates in offline mode by default. All basic functions including ECG data collection, viewing, analysis, and local storage are fully available without internet access. No user account registration is required for offline operation.

When Internet is Not Available: If the facility does not provide or allow internet access, users can operate the software entirely in offline mode. ECG data will be stored locally on the computer. Software updates can be obtained through installation media provided by the manufacturer or authorized distributors.

Switching to Online Mode

If users wish to enable cloud synchronization and have internet access available, they can switch to online mode by following these steps: Enter the Settings page, find the Server tab, enter the server address "https://ctrl.healthassistant.app" in the Server address input box, click the Confirm button, and restart the software. After restarting, the software will operate in online mode and automatically synchronize data to the cloud when connected to the internet.

Data Integrity During Offline Operation

Concern	Mitigation
Data loss during offline period	All data stored locally with automatic backup
Data corruption	Integrity checks performed on each read/write operation
Storage full	Warning displayed when disk space is low
Extended offline period	No limitation on offline operation duration

Chapter 9: Electromagnetic compatibility instructions

Parameter description

Name	Cable length (m)	Whether to block	Remark
USB Cable	0.5	Yes	/

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, the HM-15BW-AX can record for 7 days, and the HM-15BW-DX can record for 4 days. This Type CF cardiac floating device features high-precision ECG monitoring with a dynamic range of ±10mV and excellent signal quality, the HM-15BW-AX has a frequency response range of 0.5-40Hz, and the HM-15BW-DX has a frequency response range of 0.05-40Hz.

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 USB2.0 technology for seamless data transmission to computer.

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 computer 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 >10GOhms, 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.

Declaration of conformity

Table 1

Guidance and manufacturer´s declaration – electromagnetic emission		
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 uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The 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.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer´s declaration – electromagnetic immunity			
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	± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact; ± 2 kV, ± 4 kV, ± 8 kV, ± 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	± 2 kV for power supply lines ±1 kV for input/output lines	± 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	± 1 kV Line-to-line ± 2 kV Line-to-ground	± 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°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % UT; 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_T 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
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. Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.					

Table 4

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

Annex 1: Software Description

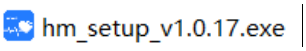
1. Install Health Assistant

1.1. Install

Health Assistant is used for controlling the Rhythm Master ECG Patch and managing data. Scan the QR code to download the app and follow the instructions to install it. For computer devices, please allow all necessary operations.

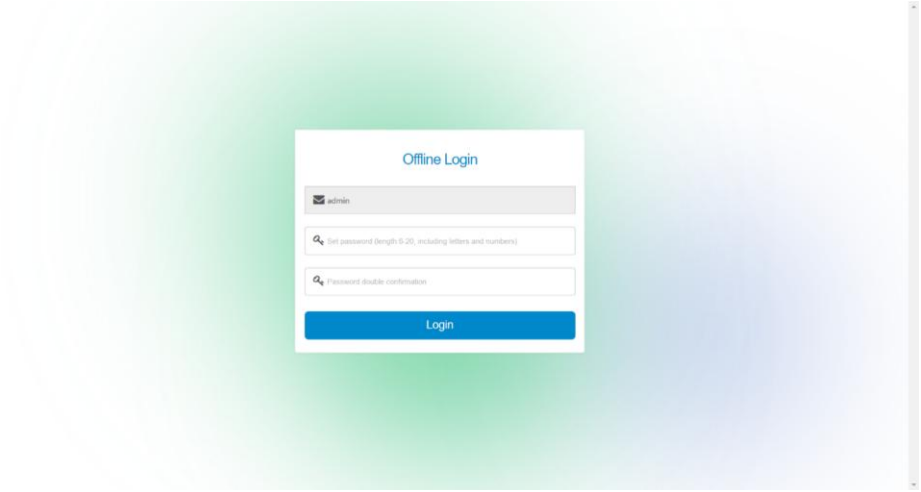
In order to better guide customers to use this product, the following describes a complete installation and opening process on the Windows operating system

1) Obtain the computer software of the Rhythm Master ECG Patch through technical support, as follows:



2) In the Windows operating system, double-click the exe installation program and complete the software installation according to the prompts. After the installation is successful, the software will start the shortcut icon on the desktop, as follows:

3) When the program is opened, the software has a power-on self-check function of the running environment. If the hardware environment of the running software is not supported, the software will prompt the related reasons (such as “connection failed, please check software service status”). If it supports, enter the login interface, and enter the account password, as follows:



1.2. Application Modes

- Standalone Mode: No account registration is required, and the application runs without an internet connection needed. All data will be stored locally on the device.

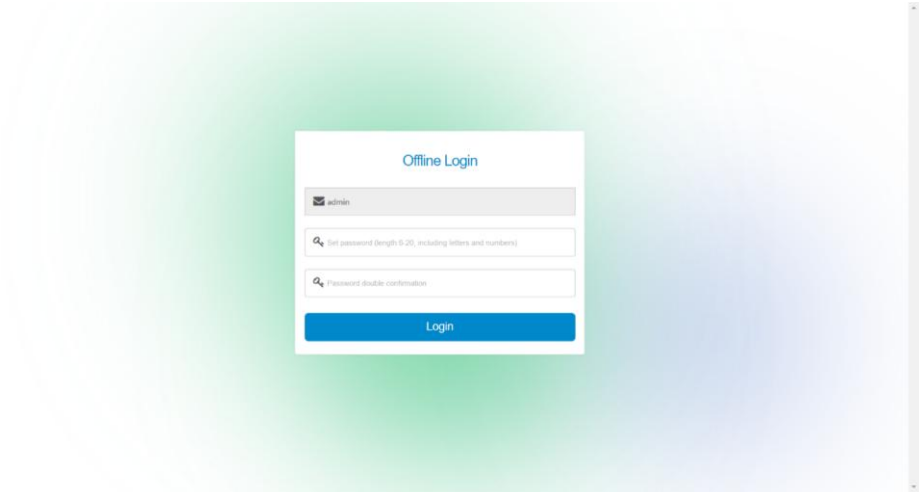
- Online Mode: Requires account registration via email. All data will be synchronized to the cloud server, enabling seamless data sharing for multiple devices associated with a same account.

If the application has been previously accessed in online mode on the current device, it remains functional even if the network is temporarily unavailable. Users can still log in and use the account normally, although cloud synchronization will pause. Data synchronization will automatically resume once the network is restored.

2. Getting Started

2.1. First-Time Installation

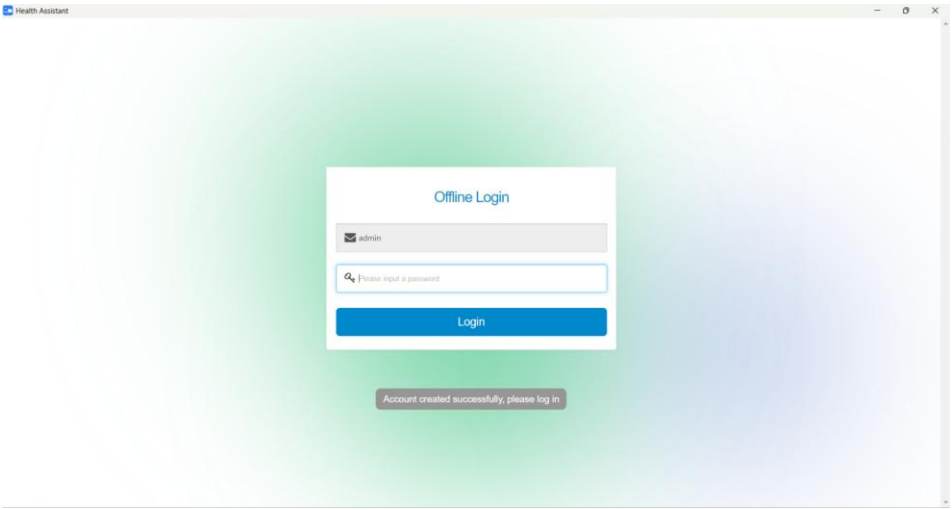
Upon initial installation, the application defaults to standalone mode. Users must set a password during the first launch. After entering the password, the application proceeds to the main interface.



3. Device Operation and Data Collection

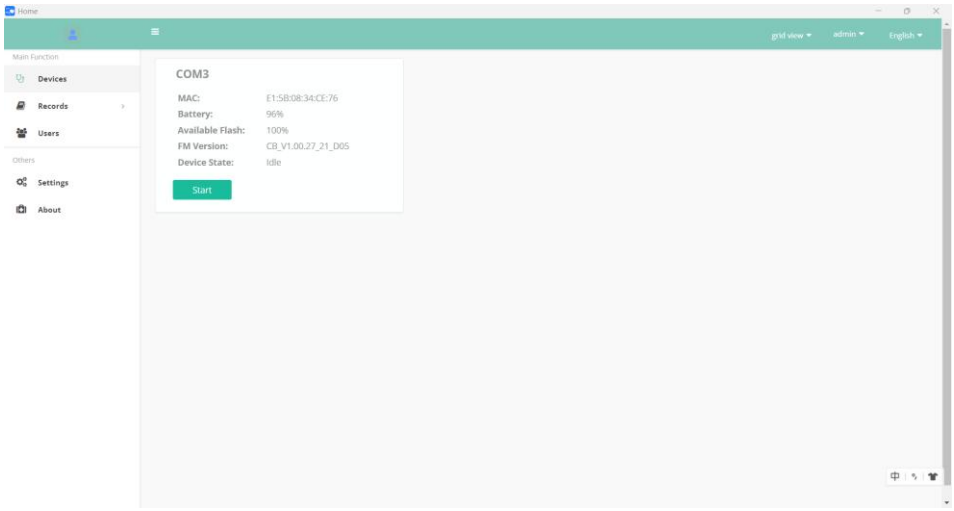
3.1. Log In

After successfully creating a local account, log in to access the program.



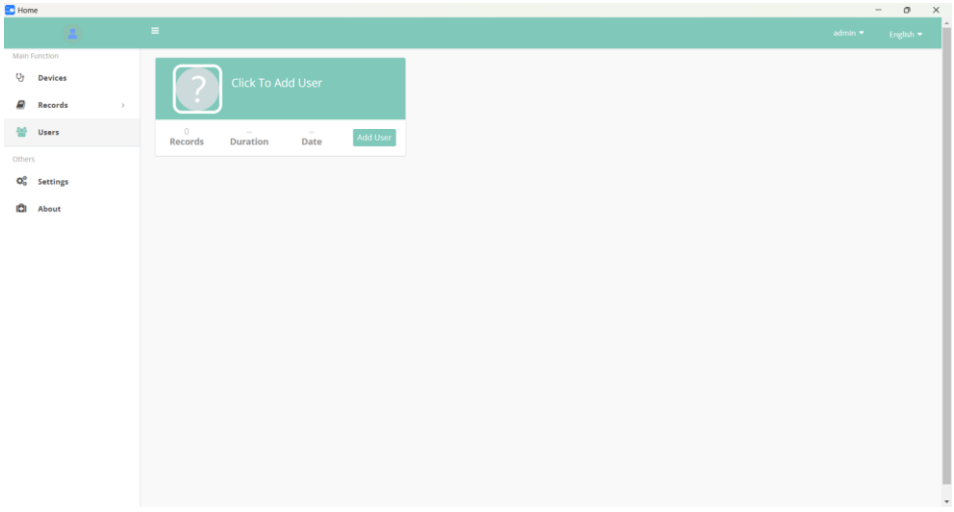
3.2. Connect Devices

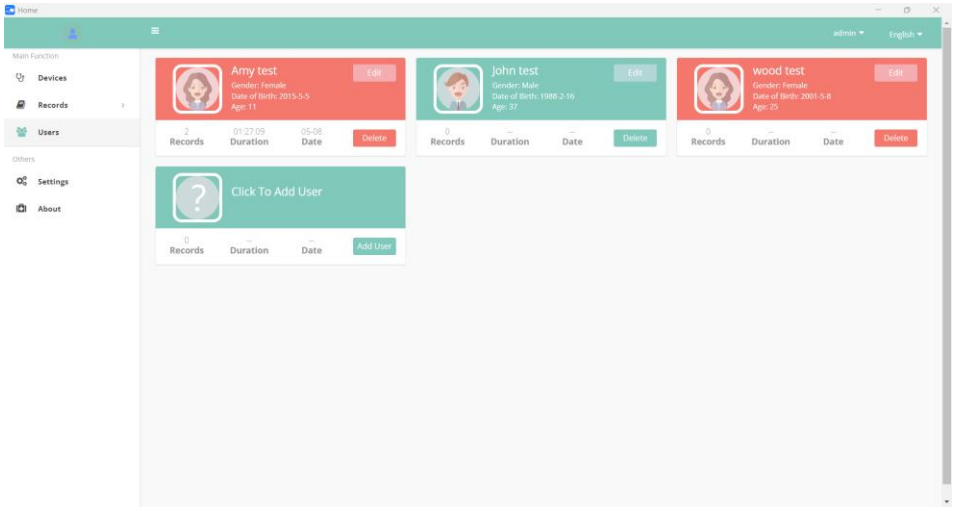
Use a Type-C cable to connect the charging dock to the computer. Place the device into the charging dock. The software will detect the connected device and display it.



3.3. Add Patient Information

Go to the **"Users"** page on the left panel to input patient information.





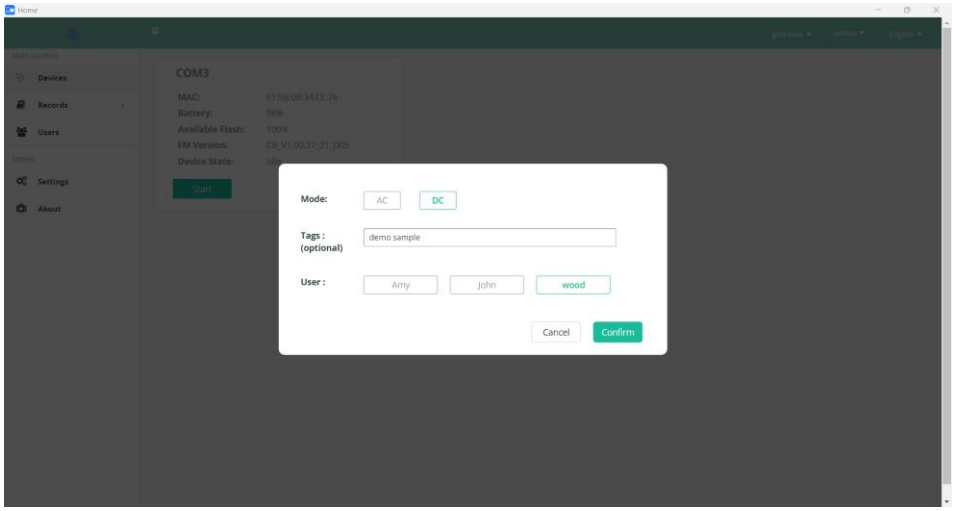
3.4. Start Data Collection

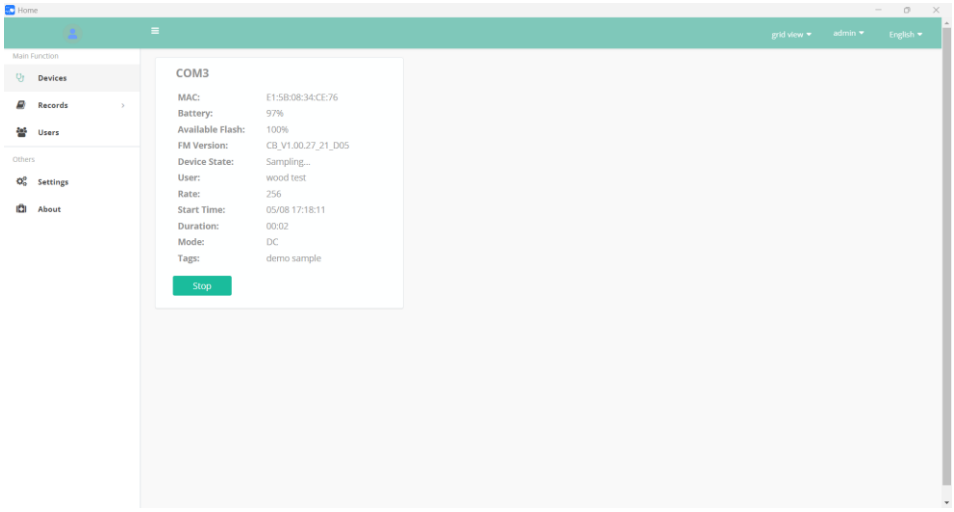
Navigate to the **"Devices"** interface and click the **"START"** button on the device to initiate data collection. A settings dialog box will appear.

Configure Settings: Set the sampling mode, assign tags, and link the patient information.

- Tags help categorize the collected data for easier filtering. Tags are separated by space. In below example, two tags, demo and sampling, are added for this session.

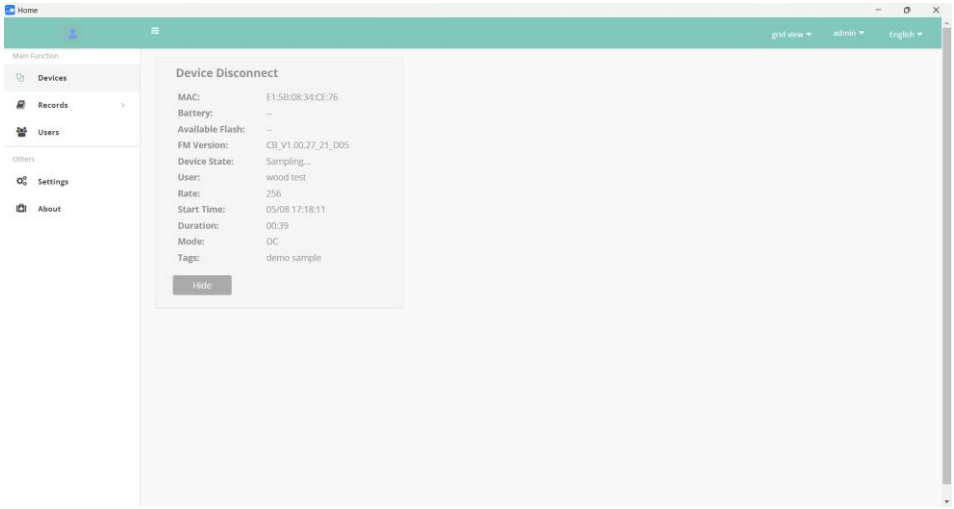
Confirm Settings: After settings configuration click **"Confirm"** to begin data collection.





3.5. Attach Device to Patient

Remove the device from the charging dock and adhere it to the patient's body using the specialized ECG adhesive patches for data collection. Please refer to and follow the ECG user guide for the wearable ECG devices to put the device onto patient's body properly.

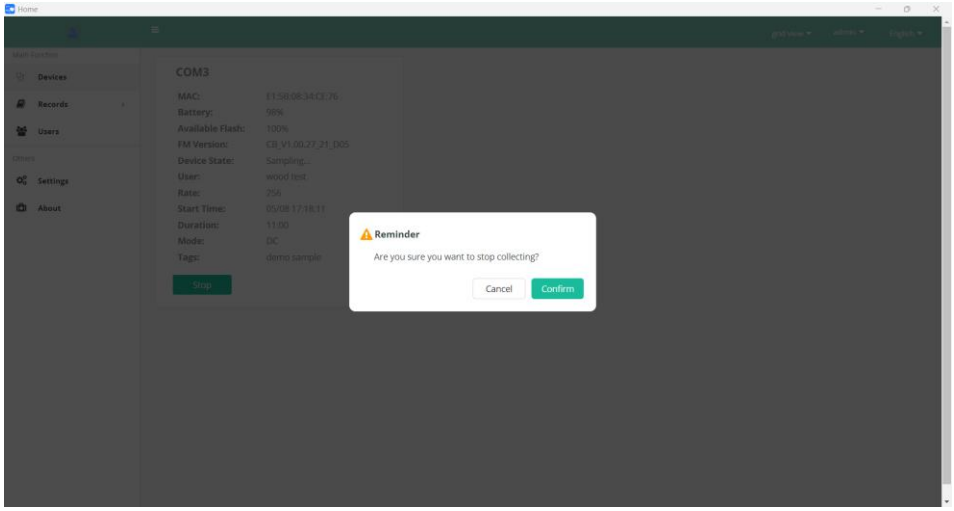

Home
grid view
admin
English
Main Function
Devices
Records
Users
Others
Settings
About
Device Disconnect
MAC: E1:5B:08:34:CE:76
Battery: --
Available Flash: --
FM Version: CB_V1.00.27_21_D05
Device State: Sampling...
User: wood test
Rate: 256
Start Time: 05/08 17:18:11
Duration: 00:39
Mode: DC
Tags: demo sample
Hide

3.6. Complete Data Collection

After data collection, please follow below procedures:

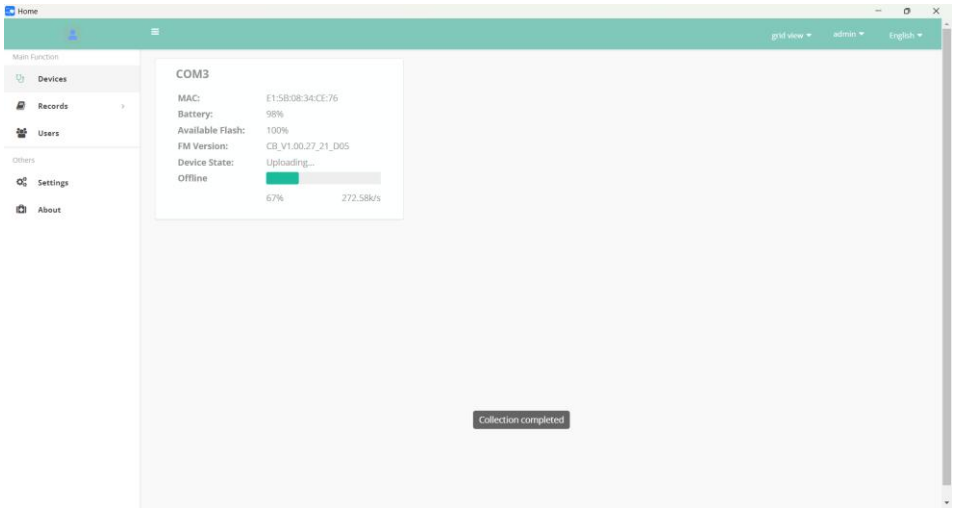
- Remove the device from the patient.
- Place it back into the charging dock connected to the computer.
- Click the **"Stop"** button in the software to end data collection.

If the device has already stopped data collection, placing it in the charging dock will automatically start data transfer.



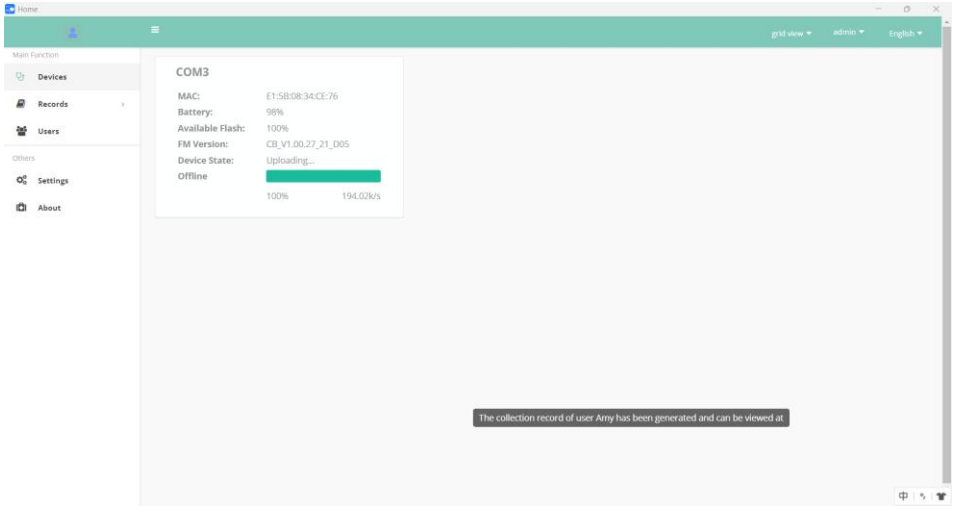
3.7. Transfer Data

Click **"Confirm"** to begin transferring data to the software.



3.8. Complete Transfer

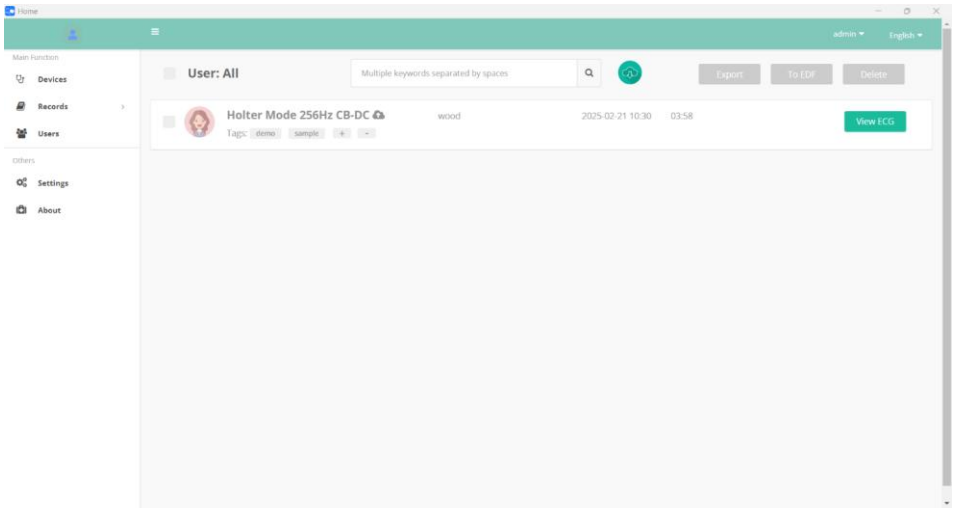
Once the transfer is finished, the process is complete.



4. Data Display and Analysis

4.1. Access Waveform Data

Navigate to the **"Records"** page to view the collected waveform. Select the records of interest to display. Click the **"View ECG"** button to display the waveform on the interface.



4.2. Export PDF file

Click the **"Export PDF"** button to generate the PDF file of this record.

4.3. Navigate Waveforms

Use the controls to browse through different time segments of the waveform:

- Drag the progress bar at the bottom with the mouse to move to a specific time.
- Use the left and right arrow buttons on the progress bar for precise navigation:
  - **>S:** Advances the waveform by 1 second with each click.
  - **>P:** Advances an entire page of data.
  - **>|:** Jumps directly to the end of the waveform graph.

Note on ACC, viewing of ECG and pacemaker signal detection:

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

- **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.

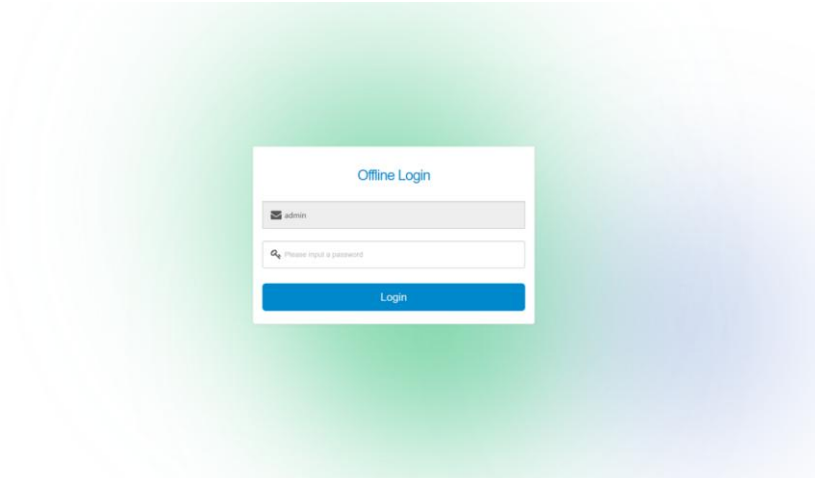
- **Pacemaker signal detection (only for model HM-15BW-DX)**: The pacemaker signal detection function is designed to identify pacing pulses with amplitude ranging from ±2mV to ±700mV and pulse width ranging from 0.1ms to 2.0 ms. The system is capable of detecting pacing pulses with a rise time of ⩽100μs and supports pacing rate detection within the range of 30 to 200ppm. These parameters are configured and verified in accordance with IEC 60601-2-47 requirements. It's only displayed for reference.

5. Setting

5.1. Automatic Locking

The application will lock under the following conditions:

- No activity for 1 minute while in the foreground.
- Switched to the background for more than 6 seconds.
  To continue using the application, re-enter your password to unlock it.

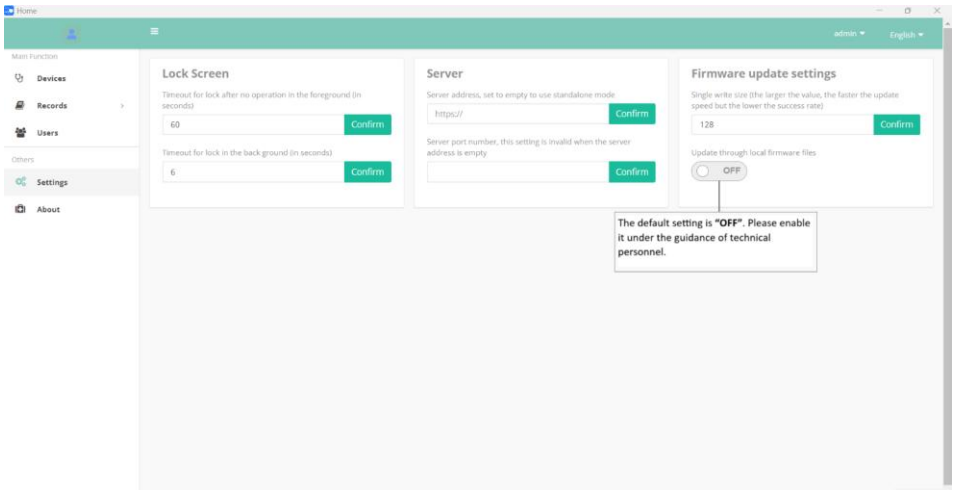


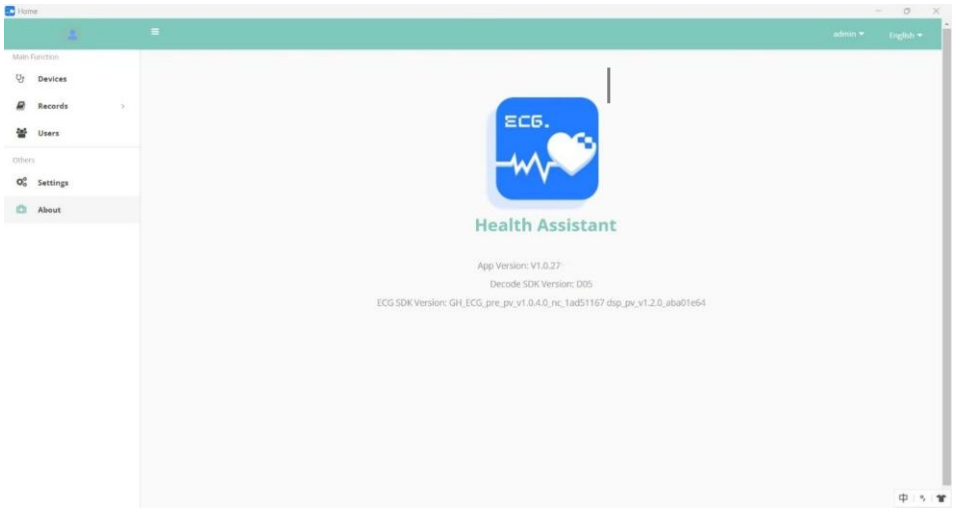
You can modify the lock screen timeout in the Settings interface.

- The timeout is specified in seconds.
- After making changes, click "Confirm" to apply the new setting.

5.2. Tips for Current Application Version

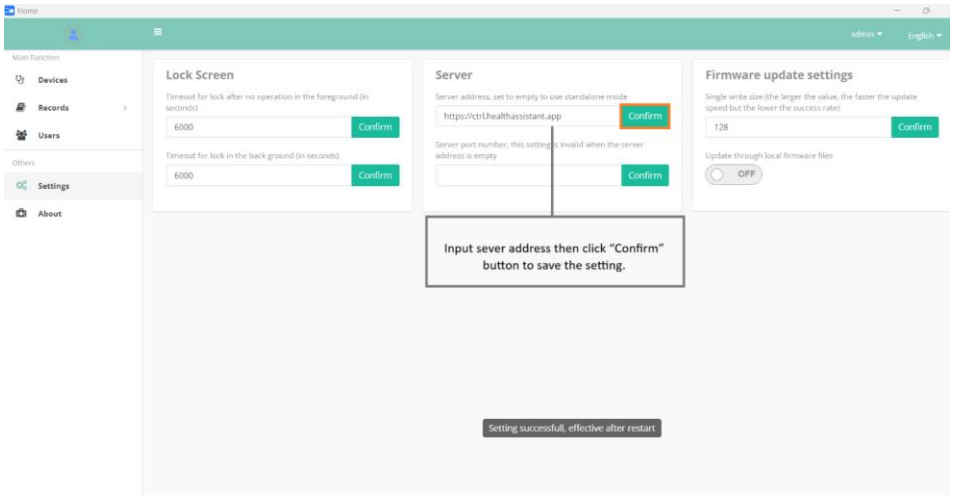
Please make sure using below settings for current application version to avoid version conflict.



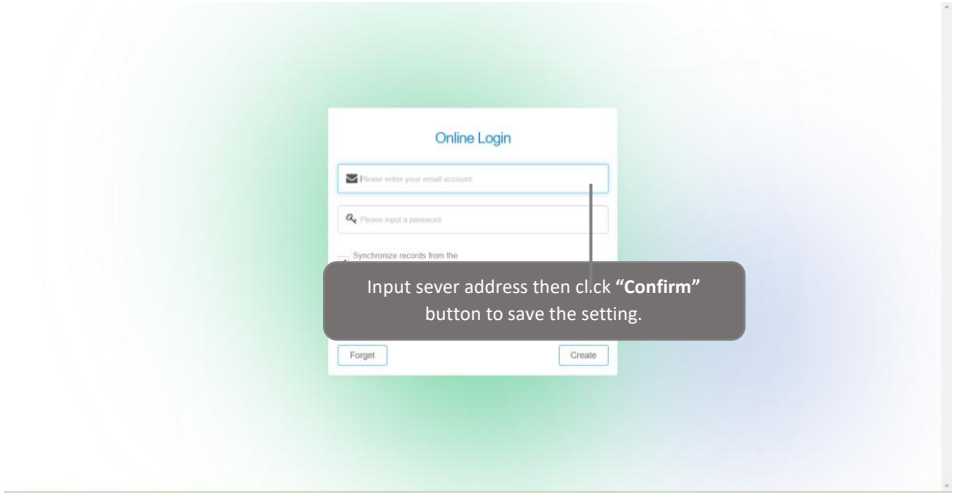


5.3. Settings for Online Mode

Please navigate to **“Settings”** page and input the provided server address to link to the cloud server for enabling Online Mode. The server address is https://ctrl.healthassistant.app .

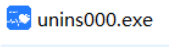


Restarting the Application is needed to activate the setting. After closing and reopening the application, you will return to the login interface for Online Mode.

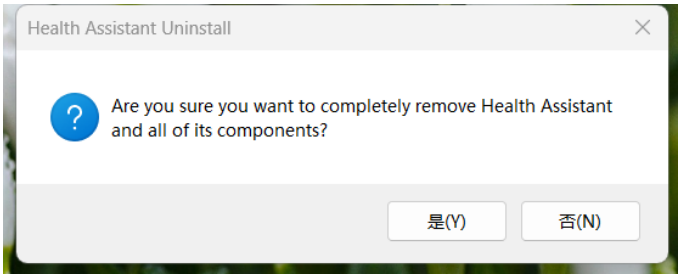


6. Software uninstallation procedures

1) Open the directory where the software is located and double-click unins000.exe



2) The uninstall dialog box pops up, select the “Y” button to complete the deletion.



7. 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 Computer Software via UART connection. And the data only will be transmitted to the Computer Software 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

If the Computer Software being used is in the online mode, when the user log in to the Health Assistant account and transmit the Rhythm Master ECG Patching data to this Computer Software, 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 dearly 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.

8. Maintenance and precautions

8.1. Overview

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

8.2. Routine maintenance method

Such as occurs when the software failed to start, run-time error, etc., should stop using, and contact Smwmed Inc., or local agents.

8.3. 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.

8.4. Quality control

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

9. Failure analysis and treatment

9.1. 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 and more detailed information, please contact SMW Med 's after-sales service department.

9.2. 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 or cause other problems now like, please do not resolve itself, please contact with us.

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