

Swcan ECG Monitor

Version:V1.0.0.0

# User Manual

Registrant/Manufacturer: Nanjing Swcan Information Technology Co., Ltd

Post-Sales Support: Nanjing SWCAN Information Technology Co., Ltd

Attention: Please read the user manual carefully before using, maintaining or repairing the device. The manual is for instructional purposes only. Our company reserves the right to improve the design of the device.)

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### [Appendix A](#)

Thank you for purchasing the Swcan ECG Monitor.

Please read this manual carefully before using the product.

Please keep this manual for reference when using the product. In case of damage or loss of this manual, please contact us.

This product is suitable for patients who are intended operators .

This product consists of specialized hardware (Swcan ECG Monitor and relevant disposable parts), utilizes specialized software (single lead ECG monitoring APP) running on smartphones through 3G/ 4G / WIFI as a data reception; Bluetooth as a data transmission channel. All results produced by Swcan ECG Monitor are for references only. If abnormal conditions are detected, please seek professional medical help from a doctor or a hospital for further checks, diagnosis, and treatments.

If you have any questions during use, please contact: +86 25-58510219.


User manual revision date: November, 2017

Version Number: 20171117

Production date: See nameplate on the device

## 1. Safety warnings

All warning labels are designed to help you to use our product safely, preventing any possible damages to you or others.

Label	Warning
	May cause death or serious injuries if used improperly.
	Please refrain from disassembling, repairing or modifying the device as it may result in inaccurate measurements. Only disassemble when replacing the battery according to instructions.
	Please use high quality CR2032 batteries purchased through regular channels to avoid damage to the equipment or other hazards.
	Please avoid storing the device near water heaters, microwave ovens, boiling pots and/or high-pressure cooking pots to avoid possible fire caused by the device overheating.
	Please do not replace the battery with wet hands to avoid electric shock or injury.
	All results produced by the system are for references only. If abnormal conditions are detected, please seek medical help as soon as possible to conduct additional tests and confirm the diagnosis. Please do not rely on self-diagnosis and self-treatment, which could result in worsening of the condition.
	The system is designed for ECG monitoring only. Please do not use it for other purposes to avoid unexpected damages or accidents.
	Please do not store the device in very hot or very cold areas to avoid accidents.
	Please do not throw away the device as household trash, recycle it per medical device recycling standards instead.
	Prevent inhalation or swallowing of small parts, such as batteries. Do not use this device when doing X-ray, CT, magnetic resonance ultrasound, EEG, EMG, etc.



Please pay attention to the following precautions while using your ECG monitor:

1. Only single-use disposable ECG electrodes carrying medical device registration certificates are suitable to use with this product.
2. Please use CR2032 battery to avoid device damage and hazards.
3. Please do not apply excessive force onto the device to avoid malfunction.
4. Please do not use the device in conjunction with defibrillators to avoid damage to the device and personnel.
5. Please do not use the device in conjunction with pacemakers to avoid inaccurate measurements.
6. Please ensure the positive end of the electrode is attached correctly to prevent inaccurate measurements.
7. The electrode and other connecting parts should not get in contact with other conductors or the ground while in operation.
8. Please do not use the device on infants weighing less than 10kg.
9. The ECG monitor cannot be used directly on the heart.
10. Please stop using the device if severe itchiness develops around the area where the device is attached to skin.

11. Except the normal battery replacement, please do not disassemble or attempt to repair the device to avoid malfunction.
12. Please do not throw the device in fire since the battery can explode and cause injury or death.
13. Please do not dispose the device and its accessories as ordinary household garbage. Dispose them in accordance with the requirements of medical device standards.
14. Please be as far as possible from a strong magnetic field and high-power electrical apparatus to avoid interference with test data.



Please pay attention to the following when using the smartphone APP:

1. Only one user is allowed to use the device at the same time in the APP.
2. Please restart the APP if it crashes or terminates on its own. This does not affect the normal operations of the device or the quality of the measurements.
3. It is recommended to keep the APP connected to Bluetooth and Wifi networks on your smartphone, as this allows ECG recordings to upload to the cloud automatically in a timely manner.
4. Magnitude of the signal relative to the background grid is the same across all smartphones, with every grid cell representing 0.1mv
5. The software is free to use, provides free diagnoses and free upgrades. Please submit any feedback or suggestions to us directly, we will do our best to accommodate.
6. Please pay attention to the following when transporting or storing the ECG monitors:
  - 1) Please keep the devices dry, avoid high temperature and/or high humidity environments.
  - 2) Please avoid exposing the device to direct sunlight or ultraviolet light for prolonged periods of time, in order to prevent discoloration of the outer shell.
  - 3) Please keep any liquid or foreign matter from entering the ECG monitor to avoid damages to its internal electronics causing malfunction.
  - 4) Do not store the device in active gas or sterilizing gas environments to avoid damaging internal components, which could lead to malfunction.
  - 5) Secure product packages in relatively safe areas in transit to avoid damages caused by sudden impacts.

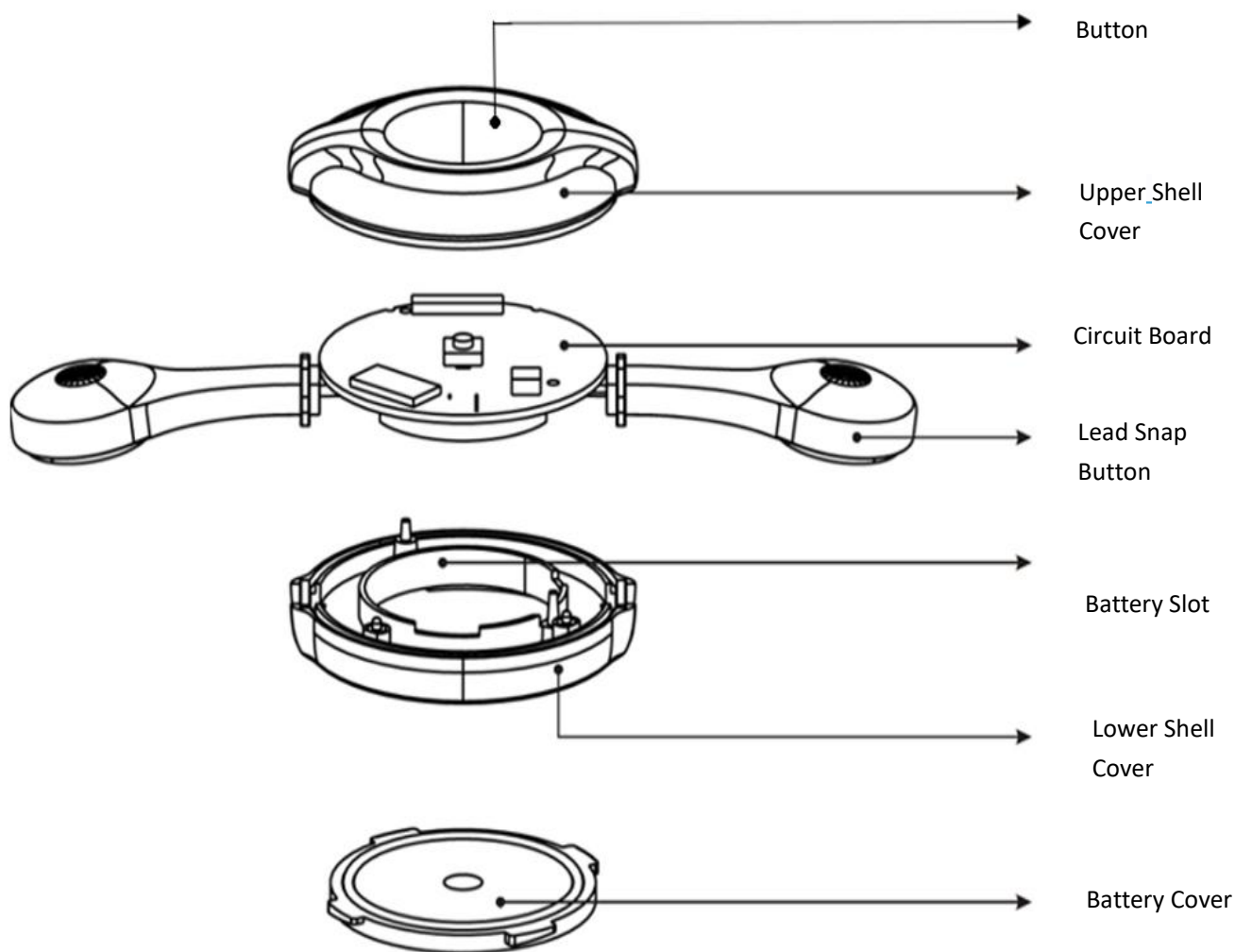
## 2. Product Information

### 2.1 Product usage

This product is used for 24 hours monitoring and recording of ECG signals.

### 2.2 Product components

The ECG Monitor is consisted of: Button, Upper Shell Cover, Circuit Board, Lead Snap Button, Battery compartment, Lower Shell Cover, Battery Cover.



## 2.3 Product Classifications

### 2.3.1 Electrical Shock Protection Classification

This product is classified as an internal powered device based on its protection classification

### 2.3.2 Degree of protection against electric shock

This product is classified as a CF type device based on its degree of protection

### 2.3.3 Waterproof Classification

This product is classified as a common device based on its with waterproof classification of IP22

### 2.3.4 Operation Classification

This product is classified as a continuous operation device.

### 2.3.5 Management type classification

This product is classified as a 6821 electronic medical device, a Class II medical device.

## 2.4 Transportation, storage and operating environments

### 2.4.1 Transportation and storage environment

The device should be transported and stored under the following conditions:

Temperature range:  $-20^{\circ}\text{C} \sim 55^{\circ}\text{C}$

Relative humidity range: 10% ~ 80%

Atmospheric pressure range: 50Kpa~106Kpa

#### 2.4.2 Operating Environment

Temperature: 5~450℃

Relative Humidity: ≤9580%

Atmospheric pressure range: 86Kpa ~106Kpa

**The device must not be used with flammable anesthetic gas mixed with air or nitrogen oxide mixed with flammable anesthetic gas.**

#### 2.5 For people

This product is suitable for infants weighing over 10kg, children, adults and the elderly.

#### 2.6. Target users:

The target users of this product are medical institutions and individuals.

#### 2.7. Requirements for personnel operating Swcan ECG Monitor:

Adults with proper training.

Persons with medical doctor qualifications or other medical personnel.

**Attention: Please read the manual carefully before use. Users should understand the correct usage and are able to follow instructions in the manual.**

#### 2.8. Product description:

Swcan ECG Monitor is a re-useable product, not a single-use disposable product.

The disposable ECG electrodes are single-use disposable parts of the device.

#### 2.9. Products intended to be used in combination:

The Swcan ECG Monitor is intended to be used in conjunction with single-use disposable ECG electrodes (Single-use disposable ECG electrodes are disposable medical products; users can choose to either self-purchase electrodes with valid medical device registration certificate or contact us directly for purchase).

#### 2.10. Place of use:

This product is suitable for medical institutions and family use.

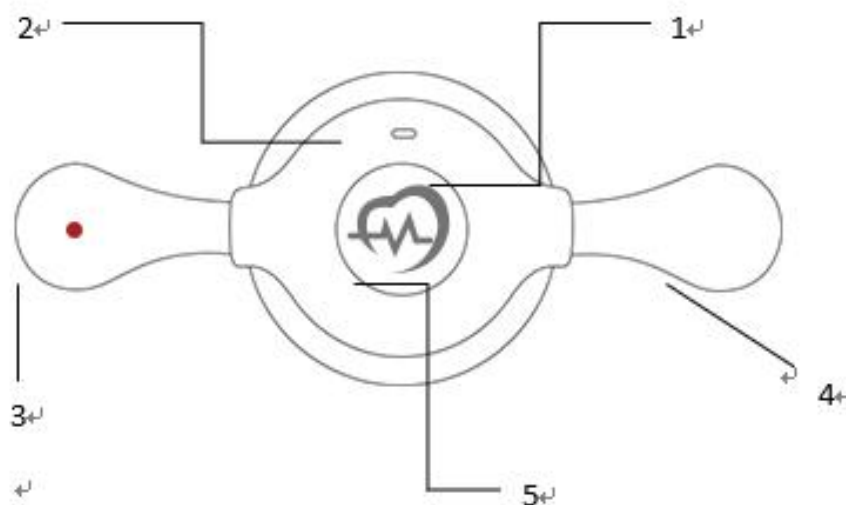
#### 2.11. Contraindications

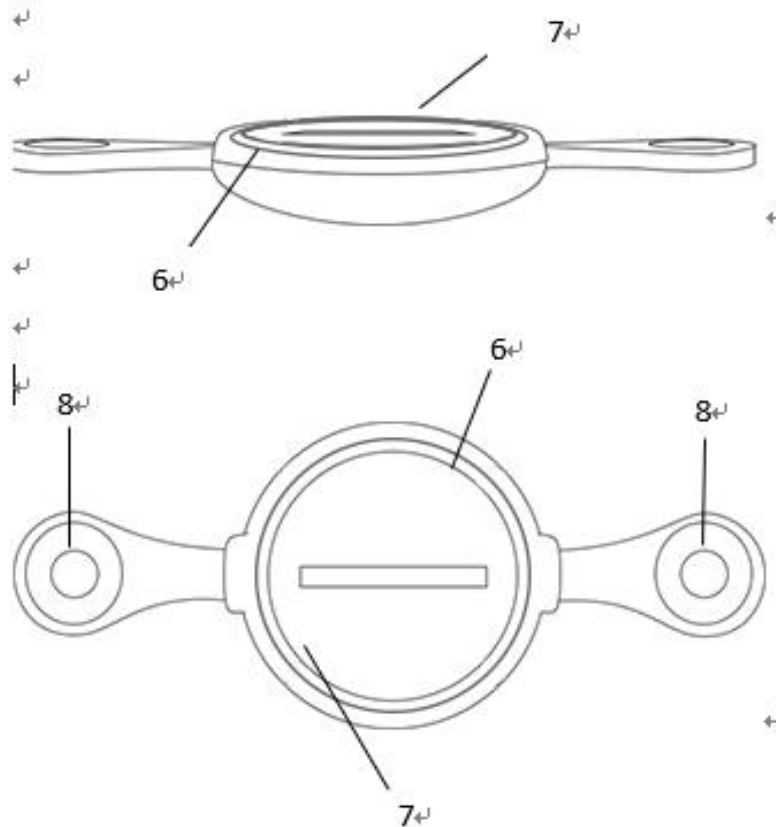
This product must not be used in conjunction with a pacemaker.

This product must not be used if your skin is allergic to single-use disposable ECG electrodes.

#### 2.12 Product overall structural diagram

##### 2.12.1 SWK801 Swcan ECG Monitor Overall Structural Diagram

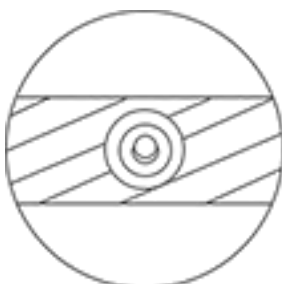




1:Central Processor	2:Indicator light	3:Upper electrode lead	4:Lower electrode lead	5:Button
6:Metal ring	7: Back cover (Battery compartment)	8: Electrode snap button		

#### 2.12.1.1 Single-use Disposable ECG Electrodes

The SWK801 ECG Monitor is intended to be used in conjunction with single-use disposable ECG electrodes (Single-use disposable ECG electrodes are disposable medical products, users can choose to either self-purchase electrodes with valid medical device registration certificates or contact us directly for purchase).





#### 2.12.1.2 Cell Battery

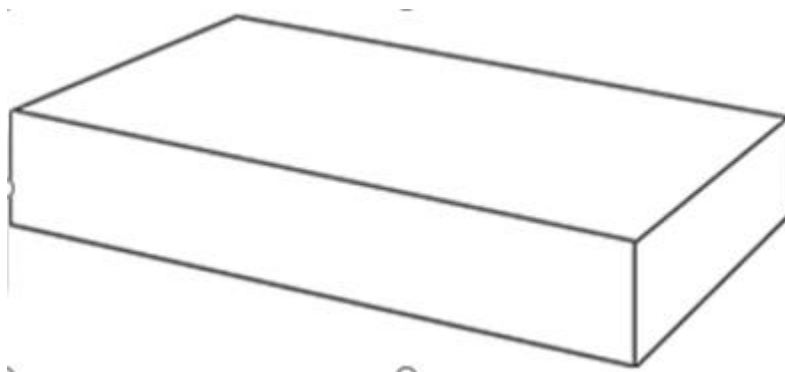
The SWK801 ECG Monitor requires a single non-rechargeable CR2032 cell battery. Please purchase high quality batteries from certified sales channels.



#### 2.12.1.3 Smartphone APP

Download free from the designated website and install it on your (Bluetooth enabled) smartphone

#### 2.12.1.4 Accessory (Outer box)



### 2.13 The Swcan ECG Monitor software

#### 2.13.1 Name: Swcan ECG Monitor software

#### 2.13.2 Model number: SWK801

#### 2.13.3 Version naming convention:

Naming convention: X.Y.Z.B;

X represents major updates to the software;

Y represents minor updates to the software;

Z represents bug fix updates to the software;

B represents build;

App release version: V1.9;

App full version: V1.9.1.1;

Software component release version: V2.2;

a) Software component full release version: V2.2.2.2.

#### 2.13.4 Software Environment

##### 2.13.4.1 System software

##### 2.13.4.1.1 App software, see appendix A

##### 2.13.4.1.2 Software components (Embedded software)

##### 2.13.4.1.2.1 Hardware Configuration

Processor: ARM Cortex-M3

Clock: 48MHz

RAM:128KB

Data storage: 128MB

ADS: 16-bit dual-channel low-energy analog-to-digital converter.

Battery: CR2032 cell battery

Network: 2.4G Bluetooth Low Energy

## 3、Operating Guide

### 3.1 Smartphone APP installation guide

This APP supports bluetooth enabled smartphones with at least 50M free storage available.




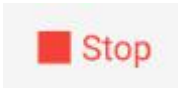


Confirm the smartphone can get onto the internet;

Scan the QR code found on the product packaging or search in App Store for the SWCAN app, download the APP;

Tap install after downloading to install the APP onto your smartphone;

The APP icon will appear on-screen once the installation is successful.

### 3.2 Smartphone APP feature list

Number	Icon	Function	State
Icon 1		Start electrocardiogram measurements	Start new ECG measurements.
Icon 2		Manage connections to devices	Tap the button to search for all nearby devices. You can also choose to disconnect from the current device or switch to other devices. Sometimes disconnection could occur when there's weak signal between your smartphone and the device, you can reconnect the device here. Please make sure Bluetooth is enabled on your smartphone before using this functionality.
Icon 3		View the 30 second real-time ECG	Tap the button to see a live stream of your ECG measurements for up to 30 seconds. Bluetooth connection is required prior to using this functionality.
Icon 4		Stop electrocardiogram measurements	Stop the ECG measurements.
Icon 5		View measurement results	Tap the button to see all measurement results.
Icon 6		Discard data	Tap the button to discard the data and start a new measurement.

Icon 7



ECG Results  
History

Tap the icon to access ECG results history.

### 3.3 How to use the Swcan ECG Monitor

#### 3.3.1 Battery installation

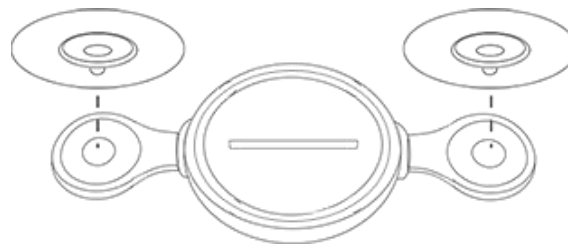
Please rotate and open the back cover (a coin can be used in the slot to assist), place a new CR2032 battery inside the battery compartment with the positive (+) side up, then replace the cover and rotate to tighten. A steady green light indicates the device is ready.



Warning: Poor quality batteries or batteries with insufficient charge may result in device startup failures.

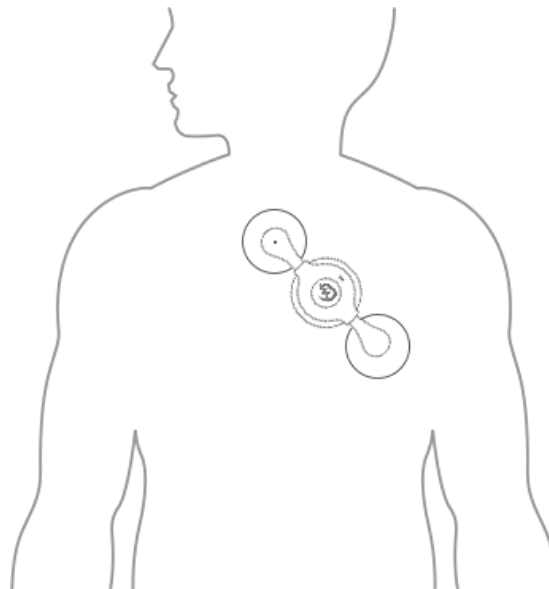
#### 3.3.2 Attach the single-use disposable ECG electrodes

1) Connect the device to the single-use disposable ECG electrodes as shown in illustration a below:



(a)

2) Clean skin area with warm water where the electrodes would be attached, wait till dry. Place the device as shown in illustration b below and gently press the electrodes on to the skin. Apply light pressure to ensure good contact between the electrodes and the skin for best conductivity.



(b)



Warning: the device should be attached on your left chest with the side marked with red dot pointing up at a 45 degrees angle towards your right shoulder, as shown in illustration b above.

### **3.3.3 Starting measurements**

Method 1 (recommended) : Use the smartphone app to start the measurements. Ensure the device has sufficient power, indicated by a steady green light. Start the app, turn on Bluetooth as instructed, connect to the device. Once the connection is successful, the “Start measurements” button will appear, tap to start. The green light on device will blink once every 5 seconds to indicate measurements in progress.

Method 2: Use the button on device to start the measurements. Long press the button on device for at least 4 seconds until the green light starts to flash, the device will start a new measurements session, the green light will blink once every 5 seconds to indicate measurements in progress.



Warning:

1. Using the device to start measurements may overwrite previous measurement results, so the recommended way to start measurements is from the smartphone app.
2. When using, storing device, be careful to protect from moisture and avoid liquid or foreign material entering the device to damage internal electronics, causing failure.

### **3.3.4 View Real-time ECG Waveform**

Real-time ECG can be viewed inside the app. Start the app, turn on Bluetooth as instructed, connect to the device. Once the connection is successful, you will land on the measurements page, tap on the “Real-Time ECG” button to start viewing real-time ECG for up to 30 seconds.



Warning: External factors such as strenuous exercises may affect the accuracy of the measurements.

### **3.3.5 View measurement results**

You can use the app to view measurement results. Start the app and go to the data upload page, tap the “View Results” button to view measurement results. Tap the “Records” menu to see historical measurement results.

### **3.3.6 Stop Measurements**

The device is capable of continuous measurements for up to 24 hours. Use the “Stop measurements” button on the measurements page to stop measurements. The green light on the device will return to the steady state, the device needs to keep connecting with smartphone through Bluetooth to upload measurement data to the cloud for safe storage.

### **3.3.7 Data Upload**

Measurement data collected by the device will be sent via the app to store in our cloud storage for up to 3 years. The app is capable of sending data to the cloud during measurement sessions, once measurement is complete (steady green light), the device should be connected to the app via Bluetooth for some time, in order to complete the data upload from the device to the cloud. Once the upload completes, you can examine the new measurement results in the app or start a new measurement.

### **3.3.8 Device restart**

To restart a new measurement, Please press and hold the button on the device for 4 seconds till the green light starts to blink. This can be used to effectively start a new measurement session when your smartphone is not near the device.

 **Warning:** This operation will discard any measurement data that didn't upload last time, so it is not recommended to use this under normal circumstances.

### 3.3.9 Disposable ECG electrodes

After a measurement session is completed, please detach the device first, then remove the disposable electrodes from your body. Please do not throw the electrodes as trash, but recycle it according to the medical device recycling standards instead.

### 3.3.10 Device shutdown


When measurement is completed and all data has been uploaded, please remove the battery from the device to shut it down.

**3.3.11 Viewing historical data** All measurement data properly uploaded can be viewed from the app. You can view the measurement data at any time point, and provide the data to medical professionals for further diagnosis.

Start the app, tap the “skip connection” button, then tap the “Records” menu to select the desired measurement record, and drag the scroll bar to view the ECG data at any time point.

### 3.3.12 Uninstall the smartphone app

If you need to uninstall the app, you can do so via Android's “system settings” – “applications” menu, find the app in the menu and select “uninstall”.

 **Warning:** Uninstalling the app does not cause the loss of historical measurement data.

## 4、Auxiliary functions

### 4.1 Indicator lights and meaning:

Meaning	Light state
The device is powered up, no measurement in-progress	Steady green light
Measurement in-progress	Green light flashes every 5 seconds
After press and hold the device button for 4 seconds, the device is restarting	Blinking Green light

### 4.2 Replacing consumables

(The disposable ECG electrodes are consumables that should be disposed after use, and should not be reused.

(The disposable ECG electrodes are disposable consumables, customers are advised to purchase products with valid medical device registration certificates from trusted sources, alternatively you could also purchase by contacting our company directly.)

### 4.3 Replacing the battery

This device uses one non-rechargeable CR2032 cell battery.

The device is designed for continuous use. We recommend replacing the battery with a new one after each use.

Batteries should be purchased from trusted sources to ensure stable voltage and measurement quality.

### 4.4 Handling the Product

Do not treat the device and its accessories as ordinary domestic waste. In the end stage, they shall be treated according to the requirements of medical device standards. Do not discard them at will.

## 5、Troubleshooting

Problems	Reasons	Measures
The indicator light no longer flash during measurement (Every 5 seconds)	The battery is depleted	Replace with a new battery
After putting in the battery, the green light does not come on or stay on	The battery is running low	Replace with a new battery
	Device malfunctioned	Please contact our company
	Bluetooth is not turned on	Turn on Bluetooth
The app cannot connect to the device	The device is already connected to another smartphone	Disconnect the device from other smartphones
	The battery on the device is depleted	Replace with a new battery

## 6、Service and maintenance

### 6. 1 Battery storage and maintenance

The old battery should be taken out after using the device. Please store it in a cool, dry and well-ventilated place. Please put in a new battery before use.

### 6. 2 Cleaning and disinfection

Cleaning: Please clean the surface of the device with a dry, clean and soft cotton cloth, or with a dry cotton cloth dipped in a small amount of water. Organic solvents should be avoided. Pay attention not to allow any liquid to enter the device.

Disinfection: The outer surface of the Swcan ECG Monitor can be sterilized by wiping with a dry cloth dipped in 75% medical alcohol. Please pay attention to not allow any alcohol to enter the device. Air dry afterwards and wipe clean with a dry cloth.

### 6. 3 Preventive checks

The battery compartment, lead snap button, lead and other parts of the device should be inspected and maintained before each use and at least once every 30 days.

### 6. 4 Device circuitry and components

Device circuitry and components are sold by the manufacturer only. The maintenance and repair of the device must be carried out by the manufacturer or by an agency authorized by the manufacturer. Users are not allowed to disassemble or repair the device without authorization.

## 7、Technical parameters and performance

## 7. 1 Main parameters:

Product model	SWK801	Note
Channel	Single lead	
Shock proof type	CF type	
Internal power supply	DC. 3V	
Working current	<30mA	
A/DA/D conversion	16 bits	
Continuous operation time	24h	
Data transmission medium	Bluetooth	
Sampling rate	=250Hz	
Overall dimensions	98X35X10mm	
Expected service life	5 years	
Method of heart rate calculation	Heart rate in current minute is deduced from ECG data every 10 s	
Identification of cardiac arrest	Asystole will be judged when the RR interval is greater than a certain value	

## 7. 2 Main performance:

### 7. 2. 1 Dynamic input range

The SWCAN ECG Monitor can detect and display cardio electric signals with added DC bias voltage of  $\pm 300\text{mV}$  at a change rate of  $125\text{mV/s}$ , in increments of  $10\text{mV}$  (peak to trough value, gain of  $10\text{mm/mV}$ ). The error in amplitude between the time-varying output signal and the input signal should not exceed 10% or  $50\mu\text{V}$ , whichever is bigger.

### 7. 2. 2 Input impedance

Under the specified test frequency ( $10\text{Hz}$ ,  $5\text{mV}$ ), the impedance of the input channel shall be higher than  $10\text{M}$ . This requirement shall also be met within the specified DC bias voltage range ( $\pm 300\text{mV}$ ).

### 7. 2. 3 Common mode rejection

For the sinusoidal signals produced at the frequency of the network power supply, common mode rejection is greater than  $60\text{dB}$ . For signals produced at 2 times the frequency of the network power supply, common mode rejection is greater than  $45\text{dB}$ .

Applying a  $5\text{Hz}$   $2\text{mV}$  (Peak to trough value) sinusoidal signal at input, the output signal is equal to the input signal, with maximum amplitude error of  $\pm 10\%$ .

**7. 2. 4 Gain precision** Provide a  $5\text{Hz}$ .  $2\text{mV}$  sinusoidal signal to the input channel, output signal equals input signal, the maximum amplitude deviation is  $\pm 10\%$ .

### 7. 2. 5 Gain stability

After powering up the device for  $1\text{min}$ , the fluctuation in gain is no greater than 3% for a  $4\text{h}$  period (in stable ambient temperature).

### 7. 2. 6 System noise

In any  $10\text{s}$  intervals, electrical noise level converted to input does not exceed  $50\mu\text{V}$  peak-to-peak.

### 7. 2. 7 Frequency response

After applying a  $3\text{mV}$ ,  $100\text{ms}$  square wave pulse to the device, the baseline shift should not exceed  $0.1\text{mV}$ , the slope after the end of the pulse should not exceed  $0.3\text{mV/s}$ , and the overshoot at the edge of the pulse should be less than 10%.

For sinusoidal signals with frequency between 0.67Hz and 40Hz, the response amplitude should be between 140% and 70% of the response amplitude at 5Hz (+3dB to -3dB).

The response amplitude for simulating a series of R wave narrow-wave 1.5mV 40ms triangular wave clusters should be between 60% and 110% of the response amplitude for 1.5mV 200ms triangular wave clusters.


#### 7. 2. 8 Minimum detectable signal

Applying a 10Hz 50uV (Peak to trough) sinusoidal signal with tracing speed 25mm/s and gain 10 mm/mV can produce a noticeable deflection.

#### 7. 2. 9 Measurement duration:

The device can measure for up to 24 hours continuously with a new and fully charged battery.

### 7. 3 Electromagnetic compatibility declarations and recommendations:

 All electrical medical devices require a special note on electromagnetic compatibility and is installed and used according to the electromagnetic compatibility information tested with random files. Other portable and mobile rf communication devices may affect the use of this device.

Please use electrodes with medical device registration certificates to ensure optimal EMC performance of your SWK801 SWCAN ECG Monitor.

The transducers and cables sold by SWCAN as internal OEM parts to the SWK801 SWCAN ECG Monitor are the most suitable to the optimal function of the device. Any other transducers or cables not manufactured according to the standards may lead to increased emission levels or reduced noise resistance.

The SWK801 SWCAN ECG Monitor should not be used in close proximity to or on top of other devices. If it must be used in this fashion, then it should be observed and verified that it can operate normally in such configurations.

When using the SWK801 SWCAN ECG Monitor to detect minimum physiological signals at 50uV, inaccurate measurements may result.

#### 7. 3. 1 Functional description of basic performance:

The SWCAN ECG Monitor can detect and display cardio electric signals with added DC bias voltage of  $\pm 300\text{mV}$  at a change rate of  $125\text{mV/s}$ , in increments of  $10\text{mV}$  (peak to valley value, gain of  $10\text{mm/mV}$ ). The error in amplitude between the time-varying output signal and the input signal should not exceed 10% or 50uV, whichever is bigger.


Guidance and Manufacturer' s Declaration - Electromagnetic Emissions		
The SWK801 SWCAN ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
Rf emissions GB 4824	1 Group	The SWK801 SWCAN ECG Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are unlikely to cause any interference to nearby electronics.
Rf emissions GB 4824	B Class	The SWK801 SWCAN ECG Monitor is suitable for use in common households with electronics that are not connected directly to the public household low voltage supply network.
Harmonic emissions GB 17625.1	Not Applicable	
Voltage fluctuations/flicker emissions GB 17625.1	Not Applicable	

Guidance and Manufacturer' s Declaration - Electromagnetic Immunity
The SWK801 SWCAN ECG Monitor is intended for use in the electromagnetic environment specified below. The



customer or the user should assure that it is used in such an environment.			
Immunity Test	IEC 60601 IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) GB/T 17626.2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
GB/T 17626.4 Electrical Fast Transient /Burst GB/T 17626.4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Main power quality should be suitable for using in the typical commercial or hospital environment.
GB/T 17626.5 Surge GB/T 17626.5	±1kV line-to-line ±2kV line-to-earth	Not applicable	Main power quality should be suitable for using in the typical commercial or hospital environment.
GB/T 17626.11 Voltage dips, short interruptions, and voltage variations on power supply input lines GB/T 17626.11	< 5%U <sub>T</sub> for 0.5 cycle, , (>95% dip in U <sub>T</sub> for 0.5 cycle) 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles < 5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 seconds	Not applicable	Main power quality should be suitable for using in the typical commercial or hospital environment. If the user of the SWK801 SWCAN ECG Monitor requires continued operation during power outages, it is recommended that the SWK801 SWCAN ECG be powered from an uninterruptible power supply or a battery.
GB/T 17626.8 Power Frequency (50/60Hz) Magnetic field GB/T 17626.8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Note: U <sub>T</sub> is the a.c. voltage prior to application of the test level.			

Guidance and Manufacturer' s Declaration – Electromagnetic Immunity			
The SWK801 SWCAN ECG Monitor is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	IEC 60601 IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
GB/T 17626.6 Conducted RF GB/T 17626.6  GB/T 17626.3 Conducted RF GB/T 17626.3	3V( (Effective Value) 150kHz~80MHz 3V/m 80MHz~2.5GHz	3V( (Effective Value)  3V/m	<p>Portable and mobile rf communications equipment shall be used no closer to any part of the SWK801 SWCAN ECG Monitor than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ $d=2.3\sqrt{P}$ <p>80MHz~800MHz 800MHz~2.5GHz</p> <p>P——P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer; d——d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should</p>

			<p>be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note1: At 80MHz and 800MHz, the higher frequency range applies.</p> <p>Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p>a Fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SWK801 ECG Monitor is to be used exceeds the applicable RF compliance level above, the SWK801 SWCAN ECG Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the device.</p>			
<p>b Over the frequency range 150kHz to 80MHz, field strength should be less than 3V/m.</p>			

Recommended separation distance between portable and mobile RF communication equipment and the SWK801 SWCAN ECG Monitor			
The SWK801 SWCAN ECG Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SWK801 SWCAN ECG Monitor as recommended below, according to the maximum output power of the communication equipment.			
(W) Rated Maximum Output Power of Transmitter (W)	Separation Distance According to the Frequency of Transmitter (m)		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance 'd' in meters can be estimated using the equation applicable to the frequency of the transmitter, where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>Note1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.</p> <p>Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

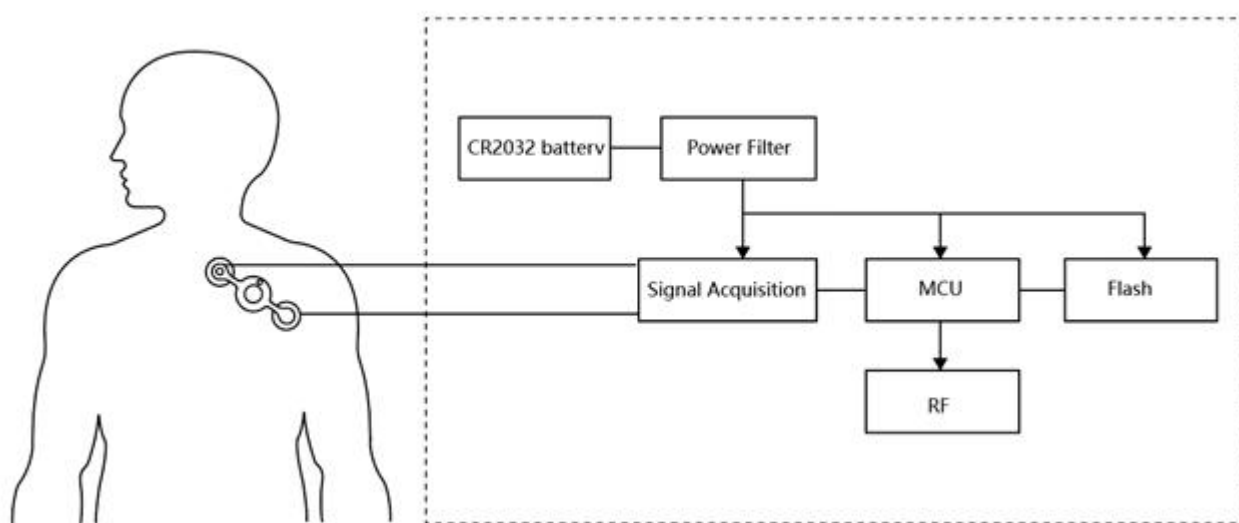
## 8、Warranty

1. The SWK801 Swcan ECG Monitor is covered under warranty for 1 year from the date of purchase.
2. The warranty does not cover malfunction caused by misuse, abuse or improper handling of the device such as unauthorized disassembling; modification of the product; damage sustained during transportation; lack of proper maintenance;

failure to operate the device in accordance to the user manual; repair done by unauthorized repair shops.

3. When submitting a warranty claim, please submit the warranty certificate with clear purchase date and stamp of the shop where the product was purchased (including the name and address of the shop). Please ask the salesperson to stamp your warranty certificate at the time of purchase.
4. Repair costs will be charged for any work that falls outside the scope of the warranty.
5. When requesting a repair, please bring the full set of product components.

## 9、Circuit schematics



## 10、Package content list

Number	Name	Quantity	Unit	Note
1.	Main device	1		
2.	User manual	1		
3.	Warranty card	1		
4.	Product certificate	1		

11、The user manual for the Swcan ECG Monitor mobile app can be found in Appendix A.

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Registrant/manufacturer/post-sales services: Nanjing Swcan Information  
Technology Co.,Ltd

Address: Room 215, Block B4, JIULONGHU International Headquarters Park, No. 19  
Suyuan Avenue, Jiangning District, Nanjing City, Jiangsu China

Production address: Room 215, Block B4, JIULONGHU International Headquarters  
Park, No. 19 Suyuan Avenue, Jiangning District, Nanjing City, Jiangsu China

TEL: 025-58510219 FAX:025-58510219

## Appendix A:

### Swcan ECG Monitor mobile app user manual

#### **Software specifications**

Software name: Swcan ECG Monitor app

Model number: SWK801

Version naming rules:

Naming rules:X.Y.Z.B;

X represents a significant enhancement software update;

Y represents slightly enhanced software updates;

Z stands for corrective software updates;

B is for build;

App Release version of App: V1.9;

App Full version of App: V1.9.1.1;

Software component release version: V2.2;

Full version of software components: V2.2.2.2.

App

Processor: ARM Cortex-M3

Clock:48MHz

RAM:128KB

Data storage:128MB

ADS:16-bit two-channel low power AD converter

Battery:CR2032 Button batteries

Network environment:2.4g low power blue-tooth

#### **Software features**

This software can be connected to the Swcan ECG Monitor, start and end measurements, observe real-time ECG waveform, upload the data to the cloud, view the measurement records, and play back the ECG.

## **System requirements**

Applicable system of this software: Android 6.0 above

Recommended hardware configuration:

Processor:ARM Cortex-M3

clock:48MHz

RAM:128KB

Date storage:128MB

ADS: 16-bit two-channel low power AD converter

Battery:CR2032 Button batteries

Network environment:2.4g low power blue-tooth

## **Use restrictions**

This software must be used with digital via-com electrocardiograph.

Smart devices need to turn on the system blue-tooth switch.

The distance between the smart device and the ECG should be kept within 2 meters to avoid the slow connection or disconnection caused by the unstable blue-tooth signal.

Smart devices need an Internet connection to upload data and view history.

Passwords are 6-20 characters long and must contain uppercase and lowercase letters, Numbers, and special characters.

## **Software maintainability**

On the client side, there is a software running log, which contains the user's behavior of logging into the system, the log record of the product error, and the status log of the communication with the ECG device.

The software will be updated automatically on a regular basis.

If there is any problem in the process of using the software, you can call the customer service number.

## **Software efficiency description**

On the required hardware configuration, the App can enter the main interface within 10 seconds.

The smart device can find the available device within 1 meter of the ecg and the blue tooth scan within 10 seconds.

After scanning, connect to a specified device, can be connected in 10 seconds.

Effect of efficiency: network bandwidth, intelligent device hardware configuration.

#### Software data reliability

All the user data backup generated during the use of the software is stored in Azure cloud database and blob cloud, which has cloud automatic backup and high reliability.

#### **Information security instructions:**

The software and background server uses HTTPS protocol.

The software interface input box uses special character filtering.

The user's password is saved using asymmetrically encrypted cipher-text.

#### Installation and operation

Installation method: scan the qr code to download the software installation package and install the software according to the prompts.



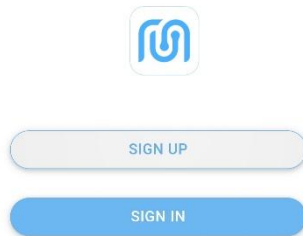
Operation method: after installation, click Swcan ECG APP on the desktop to open the software.

#### **Software functions**

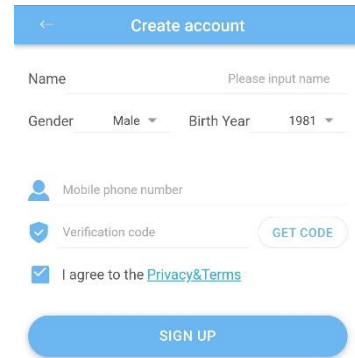
The functions of this software include register, sign in, scan ECG, connect ECG, start measurement, view real-time ECG waveform, end measurement, upload data, view measurement records, playback ECG.

## 1. Introduction to “Register” and “Sign in” functions

After entering the App, the user needs to sign in first. Users can tap “Register” or “Sign in”. Register function allows users to create a user ID with mobile phone quick and easy. SMS verification is required for registration.



(a)

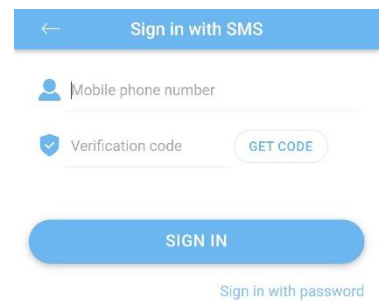


The image shows the 'Create account' screen. It has a blue header bar with a back arrow and the text 'Create account'. Below the header are several input fields: 'Name' with a placeholder 'Please input name', 'Gender' with a dropdown menu showing 'Male', and 'Birth Year' with a dropdown menu showing '1981'. Below these is a 'Mobile phone number' field with a user icon. There is a 'Verification code' field with a checkmark icon and a 'GET CODE' button. At the bottom, there is a checkbox labeled 'I agree to the [Privacy&Terms](#)' and a large blue 'SIGN UP' button.

(b)



(c)



The image shows the 'Sign in with SMS' screen. It has a blue header bar with a back arrow and the text 'Sign in with SMS'. Below the header are two input fields: 'Mobile phone number' with a user icon and 'Verification code' with a checkmark icon and a 'GET CODE' button. At the bottom, there is a large blue 'SIGN IN' button and a link that says 'Sign in with password'.

(d)



## 2. Introduction to “Measuring” function

There is a step-by-step measuring guide for users to set up ECG monitor and wear it. Wear the device correctly, make sure it has enough power, then tap “Connect” to set it up with mobile phone. Tap “Start measuring” to collect ECG data.

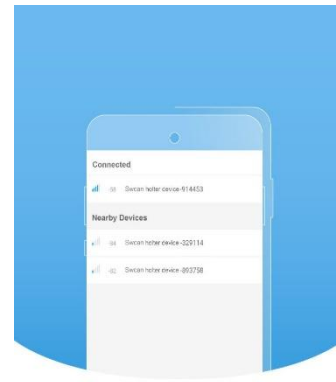


### Step 1 Install battery

Open back cover by turning it counterclockwise.  
Put in a new CR2032 cell battery with positive (+) side up.  
Close and lock back cover by turning it clockwise



(e)

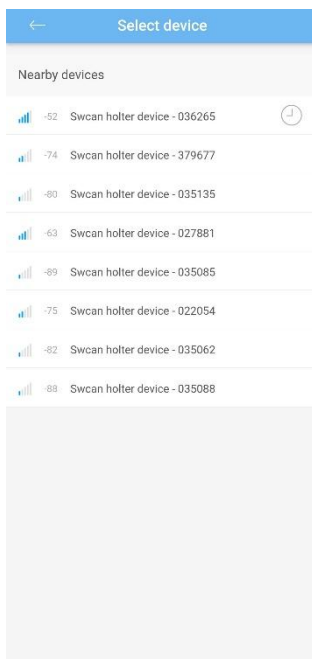


### Step 4 Connect the device to your phone

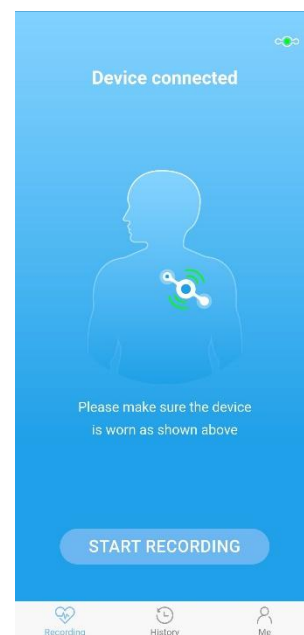
Tap the button below to connect the device via Bluetooth



(f)



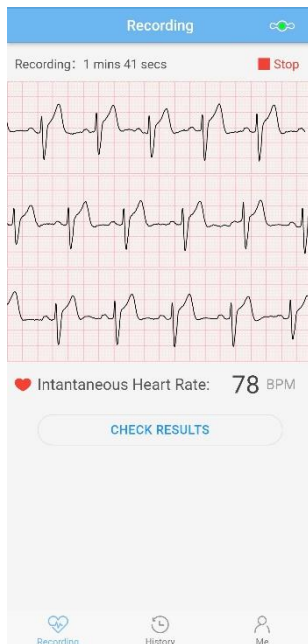
(g)



(h)

### 3.Introduction to a real-time ECG waveform diagram function

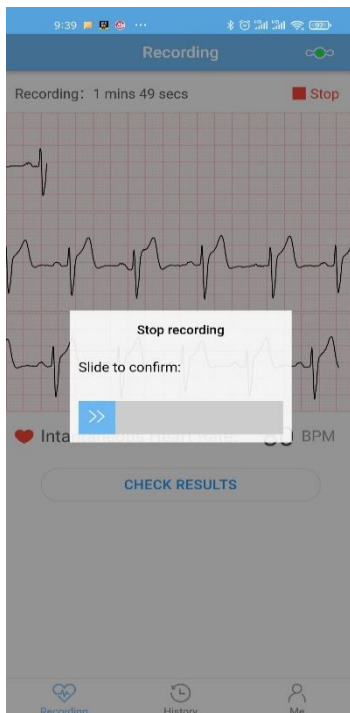
After start measuring, measurement interface automatically pops out a real-time ECG waveform diagram with heart beats per minute and total time of measurement.



(i)

### 3. Introduction to “End Measurement” function

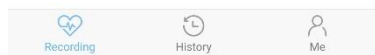
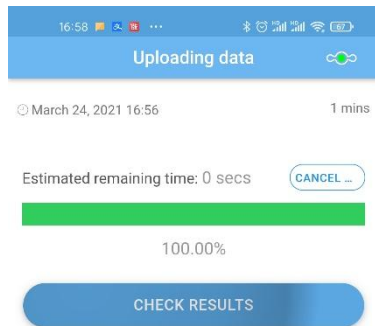
Tap “End Measurement”, slide bar to the right to confirm ending measuring.



(j)

#### 4. Introduction to “Data Uploading” function

After the measurement, “Data uploading” function will pop up automatically. It shows measurement date, timespan, and estimated uploading progress. Tap “Stop” to finish the data uploading.

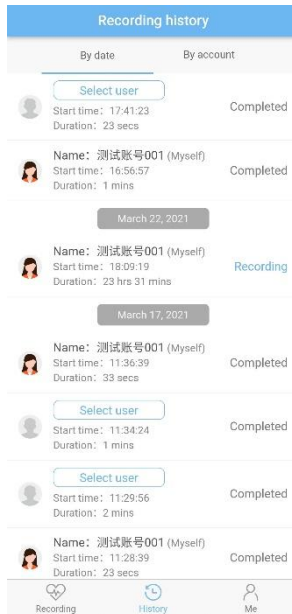


(k)

## 5. Introduction to “Measurement Records” function

Tap "Measurement Record" on the bottom navigation bar to view a list of measurement records.

Measurement records can be sorted by recent measurements or by users.



(l)



(m)



(n)

## 6. Introduction to “User Profile” function

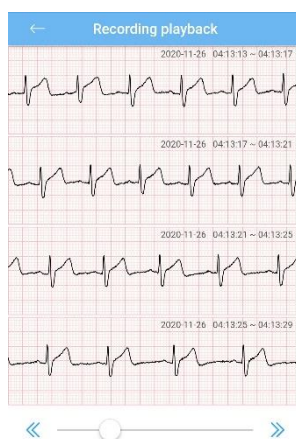
Different users can share the ECG monitor by creating different profiles. Under “Measurement Record” page, select the right person to start measurement and check records.



(o)

## 7. Introduction of “Playback ECG” function

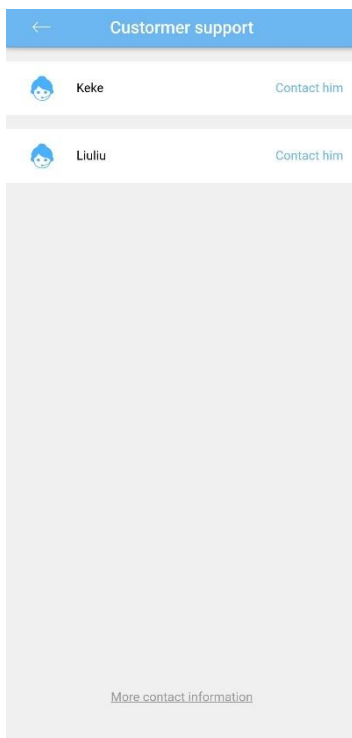
Tap the "Playback ECG" icon at the upper right corner under “Doctor’s Opinions“ page to view the ECG playback. Drag bottom bar icon to view intervals.



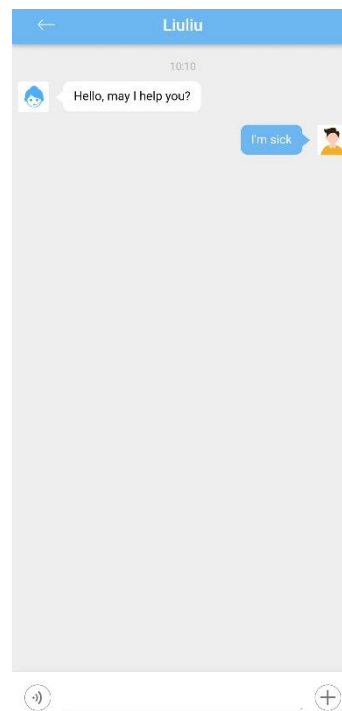
(q)

## 8. Introduction of online customer service function

Click the "Customer service" in personal center and you can chat with the customer service representatives.



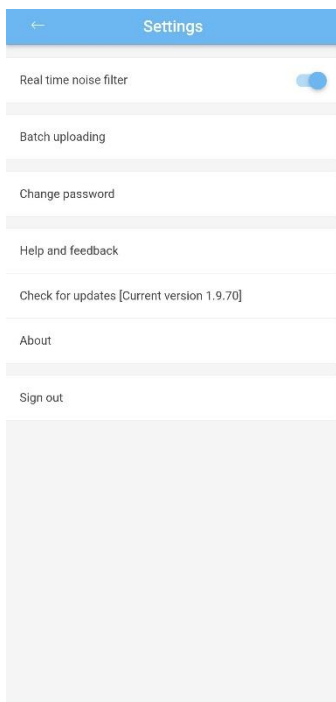
(y)



(z)

## 9. Set Sign-in password

Click "Settings". Under "Settings", click "Setting Password".



(A1)

### FCC Caution:

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

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

#### FCC RF Radiation Exposure Statement:

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

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