制作工艺：

封面:157g铜版纸，过哑胶，彩色；

内页：80g书写纸，黑白

胶装

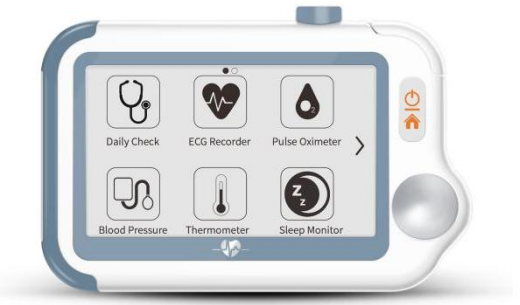
尺寸：110*165mm

此页不印刷

Wellue®
Powered by Viatom

Checkme Pro Health Monitor

User Manual



Contents

1. Introduction

1.1 Safety

Warnings and Cautionary Advice

- We recommend not to use this device if you have a pacemaker or other implanted devices. Follow the advice given by your doctor, if applicable.
- Do not use this device with a defibrillator.
- Do not use this device during MRI examination.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- Do not place this device in pressure vessels or gas sterilization device.
- This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device.
- Do not allow the electrodes of the device to come into contact with other conductive parts (including earth).
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
- Vital signs measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should consult your doctor immediately if you experience symptoms that could indicate acute disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- The device has no alarms and will not sound if the measurement reading is too low or too high.
- Check the SpO_2 sensor application site every 6-8 hours to determine the positioning of the sensor and the circulation and skin sensitivity of the patient. Patient sensitivity varies depending on medical status or skin condition. For patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- Do not use the Oximeter on the same hand/arm when using a blood pressure cuff or monitor.

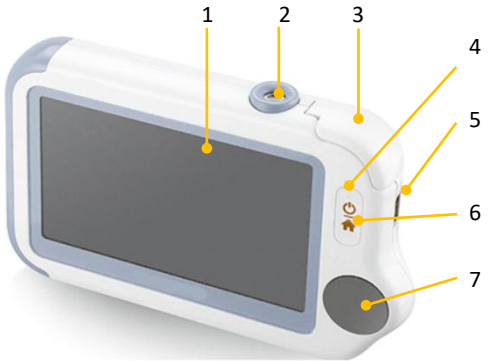
1.2 Intended Use

The Checkme Pro health monitor is intended to be used for measuring, displaying, reviewing and storing of multiple physiological parameters including ECG, pulse oxygen saturation (SpO_2), pulse rate, and temperature in home or healthcare facilities environment.

ECG is intended for use with adult.

The data and results provided by this device are for pre-check screening purpose only and cannot be directly used for diagnostic or treatment.

1.3 About Checkme



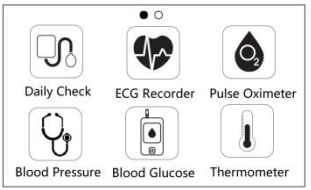
1. Touch Screen
2. Infrared temperature sensor
3. Internal SpO_2 sensor
4. LED indicator
   - Off: the monitor is turned off or working in Standby Mode;
   - Green: the monitor is turned on, and working normally; or when the battery is fully charged;
   - Blue: the battery is being charged;
   - Red: the battery is low;
5. Multi-functional connector
   It connects with external SpO_2 cable, ECG cable, or charging cable.
6. Home, Power On/Off
   - When the monitor is off, press this button to power it on.
   - When the monitor is on, press and hold it for 2 seconds to turn it off.
   - During operation, press this button will switch to Main Screen, or Calendar Screen, or return to upper menu.

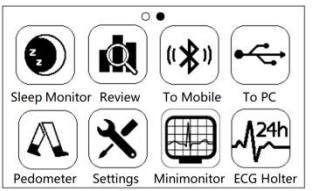
7. ECG right electrode
   Use right thumb to press on it.

8. Speaker
9. ECG left electrode
   Put it to your left palm, left abdomen or left knee.
10. Neck stripe hole
11. ECG back electrode
    Use right forefinger or middle finger to press on it.

1.4 Main Screen

The Main Screen is shown as below. Slipping your finger from right to left can switch to the second page, and vice versa.



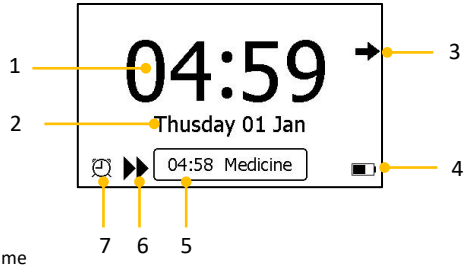


*Minimonitor and ECG Holter are optional function.

1.5 Calendar Screen / Standby Mode

The device will enter Calendar Screen / Standby Mode when:

- No operation is detected for 120 seconds in other screen interface, the device will automatically switch to the Calendar Screen.
- Pressing the Home button in the Main Screen.



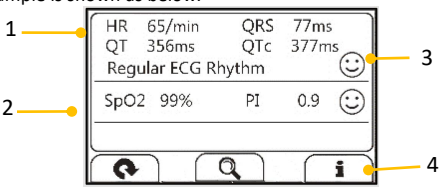
1. Current time
2. Current date
   When a reminder event happens, this area displays the event name, e.g. “Daily Check”.

You are allowed to change the current time and date when the device is powered on at the first time. Or you can also go to the Setting menu to change it.

3. This arrow indicates users to press the Home button to exit the Calendar Screen / Standby Mode.
4. Battery indicator
5. If you failed to respond to the previous reminder event, then that event will be shown in this area.
6. This icon appears when <**Quick ECG**> is enabled.
7. This icon appears if you have set reminder event.

1.6 Result Screen

For each measurement, a Result report will be provided after the measurement is finished. An example is shown as below.



1. Measured parameters and readings
2. A summary of this measurement
3. A graphic indicator about the health status
   ☺: All measured parameters are within the reference range;
   ☹: One or more than one measured parameter(s) is (are) out of reference range. When the ☹ icon appears, it is suggested to test again, and consult your doctor for help.

4. Buttons
   - Select  button to start a measurement again.
   - Select  button to review previous results.
   - Press  button to open the help information.

1.7 Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates a medical device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	Type BF Applied Part
	No alarm system
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	Resistant to liquid ingress
	CE marking
	Authorized representative in the European community
	UKCA marking
	Authorized Representative in the United Kingdom
	This product complies with the rules and regulations of the Federal Communication Commission.
	Non-ionizing radiation

	Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).
	This product complies with verpackG.

2. Using Checkme

2.1 Prior to Use

Charge the Battery

To charge the battery,

1. Connect the smaller end of the USB charging cable to the multi-functional connector
2. Connect the other end of the USB charging cable to the USB charging port.
3. When the LED turns to green, it means the battery is fully charged.

⚠ **Warnings and Cautionary Advice**

- The device cannot be used for any measurement during charging.
- Use charging adapter provided by manufacturer, or USB charging devices which comply with the standard of IEC 60950.

Power On/Off

Press the Power On/Off button to power on the device. Press and hold Power On/Off button for 2 seconds to power off the device.

2.2 Daily Check

About Daily Check

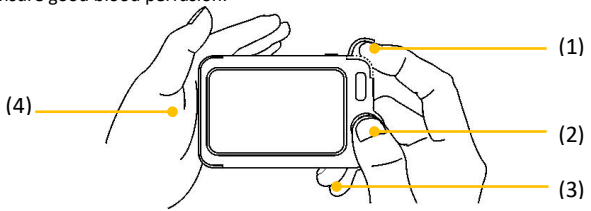
Daily Check measurement is a function that combines the measuring of ECG (Electrocardiograph) and SpO_2 (blood oxygenation). It takes only 20 seconds to collect your vital signs before giving you vital signs readings and your health evaluation.

Using Daily Check

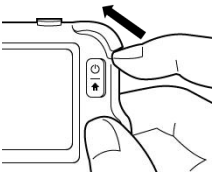
To start a Daily Check, follow the steps as below.

1. If you have not created user, then please follow the instruction in **[Settings Section]** to add your user account.
2. Tap the <**Daily Check**> icon in the middle of the screen.

3. Choose the right user.
4. Hold the device according to the instruction, keep the device at the same level as your heart, and keep stable posture and stay calm. Don't exert too much pressure on the ECG electrode, which may result in EMG (electromyograph) interference. Just hold gently and ensure good contact with the ECG electrode. Do not exert pressure on the finger that put in the SpO_2 sensor. Just fit it inside but gently to ensure good blood perfusion.

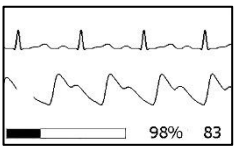


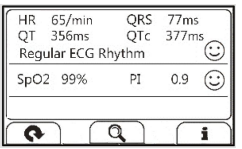
(1) Put the right forefinger into the built-in SpO_2 sensor. Use the finger nail to squeeze the edge of the SpO_2 sensor cover, then move in upward to the left to raise it up as shown below.



(2) Press the right thumb on the right electrode.
(3) Press the right middle finger on the back electrode.
(4) Press the left electrode to the left palm.

5. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
6. When the bar is fully filled, the device will analysis your data, and then show the measurement result.



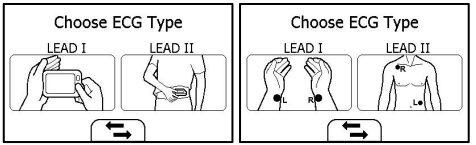


Daily Check provides the trending graph of heart rate and SpO_2. To view the trend, tap the button, then select one record, and then tap the button.

2.3 ECG Recorder

About ECG Recorder

The ECG recorder offers four different methods to measuring ECG. Tap the icon to switch between two pages.



As shown above, from left to right, there are:

- Method A: Lead I, right hand to left hand
- Method B: Lead II, right hand to left abdomen
- Method C: Lead I, left wrist to right wrist
- Method D: Lead II,upper right chest to left lower abdomen

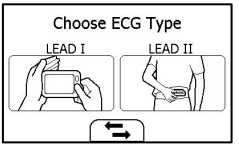
ST segment analysis is performed on selected LEAD.

Method A and B offer maximum comfort, than method C and D, but no ST segment value. No matter which method you choose to measure ECG, please keep stable posture and stay calm during the measurement.

Measuring without Cable

To start an ECG Recorder measurement without cable,

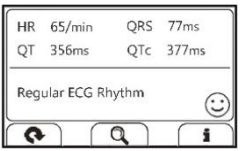
1. Choose the method A or B.
2. Follow the instruction according to the mode you selected.



- Press the right thumb on the right electrode;
- Press the right forefinger on the back electrode;
- For method A, press the left electrode to the left palm;
- For method B, press the left electrode to the left lower abdomen;

Do not press the device too firmly against your skin, which may result in EMG (electromyograph) interference. After you finish the above steps, hold the device stably and stay calm.

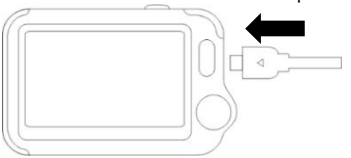
3. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
4. When the bar if fully filled, the device will analysis your data, and then show the measurement result.



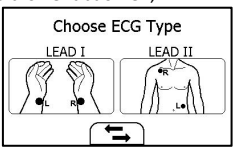
Measuring with Cable

To start an ECG Recorder measurement with cable,

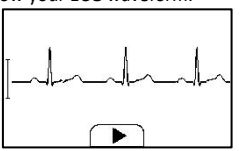
1. Choose the method C or D.
2. Follow the instructions to connect the ECG cable and place the ECG electrodes.



- Sit down or stand, stay calm;
- For method C, palms facing up, place an electrode in the middle of right wrist, place another electrode in the middle of left wrist;
- For method D, place an electrode on the upper right chest, place another electrode in the left lower abdomen;



3. The display will then show your ECG waveform.



The device will monitor your ECG continuously, however no data will be saved until you press the ▶ button.

4. Press the ▶ button to start collecting your ECG data. The countdown bar moves from left to right.
5. When the bar is fully filled, the device will analysis your data, and then show the measurement result.

Quick ECG

If the <**Quick ECG**> function is enabled, then you can start an ECG measurement very quickly by picking up the device and hold it according to method A. This saves time and is much easier for use.

In the Settings menu and tap **<Quick ECG>** to enable or disable this function.

2.4 Temperature

About thermometer

⚠ **Warnings and Cautionary Advice**

- The thermometer is only designed for the measuring area on the human body stated in this manual.
- The device needs to be in the room which the measurement is taken for at least 10 minutes before use.
- Physical activity, increased perspiration on the forehead, taking vasoconstictive medication and skin irritations can distort the result.
- The forehead (temples) must be free from perspiration and cosmetics.

Influences on forehead temperature include but not limited to

- A person's individual metabolism;
- Age; Forehead temperature is higher in babies and infants than in adults. Greater temperature fluctuations occur faster and more often in children. Normal forehead temperature decreases with age.
- Environmental temperature;
- Time of day; Forehead temperature is lower in the morning and increases throughout the day towards evening.
- Activities; Physical and, to the lesser extent, mental activities increases forehead temperature.

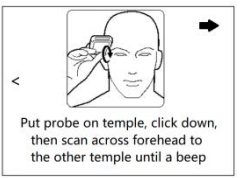
Taking Temperature Measurement

Checkme offers two different methods to measuring temperature.

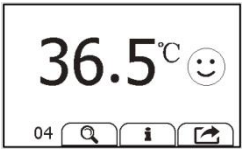
Measuring without Cable

To start a temperature measurement,

1. In the Main Screen, select <**Thermometer**>.
2. Choose the measured method <**Infrared sensor**>, and follow the instruction according to the mode you selected.
3. Put the thermometer sensor on your temple.



4. Press the Home button once, you will hear “Bi-Bi” beep, which indicates the measurement starts. Then move the thermometer around the temple for around 3 seconds until you hear a long “Bi” beep, which indicates the measurement is finished.
5. Take down the device, and the screen shows the measurement result.



In the Settings menu, tap the <**Thermometer**> area to change between Celsius degree (°C) and Fahrenheit degree (°F).

Measuring with Cable (Optional)

To start a temperature measurement,

1. In the Main Screen, select <**Thermometer**>.
2. Choose the measured method <**Cable contact**>.
3. Plug in the external temperature senor.
4. The display will then show the real-time temperature.

2.5 Oximeter

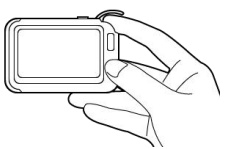
About Oximeter

The Checkme Health Monitor measures the amount of oxygen in your blood, your pulse rate and pulse index. The oxygen saturation (SpO_2) is measured and displayed as a percentage of full capacity.

Measuring without Cable

To start a Oximeter measurement without cable,

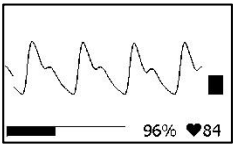
1. In the Main Screen, tap the **<Pulse Oximeter>** icon.
2. Insert the forefinger into the built-in SpO_2 sensor as shown below.



Relax your forefinger and do exert pressure.

3. When the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
4. When the bar is fully filled, the device will analysis your data, and then show the

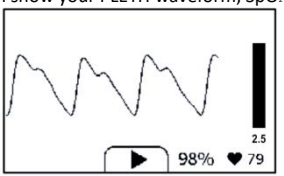
measurement result.



Measuring with Cable

1. Connect the external SpO_2 sensor to the multi-functional connector.
2. Put your index finger or middle finger into the external SpO_2 sensor. Make sure the cable is positioned along the top of the hand, and the finger nail is in the position as shown below.

3. Tap the <**Pulse Oximeter**> icon.
4. The display will then show your PLETH waveform, SpO_2 and pulse rate.



The device will monitor continuously, however no data will be saved until you press the ▶ button.

5. Press the ▶ button to start collecting your SpO_2 data. The countdown bar moves from left to right.
6. When the bar is fully filled, the device will analysis your data, and then show the measurement result.

2.6 Sleep Monitor

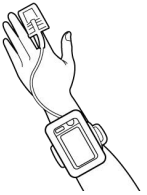
Checkme offers a non-invasive method to monitor sleep status for adult users who have sleep problem, sleep related breathing disorders and obstructive sleep apnea.

⚠ **Warnings and Cautionary Advice**

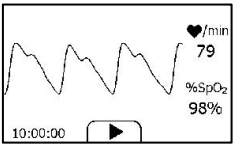
- Before using as a sleep monitor, please ensure the battery is fully charged.

To start a sleep monitor measurement,

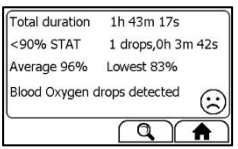
1. Tie the wristband on one of your left hand.
2. Insert the SpO_2 cable into the multi-functional connector.
3. Put one of your finger into the sensor. Forefinger or middle finger is suggested. If needed, remove the colored nail polish from the finger. Make sure that the sensor is correctly placed so that the cable goes above your hand back.

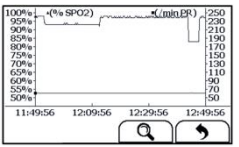


4. Press the Home button to enter the Main Screen. Then Tap the Sleep Monitor icon to enter the screen as below.



5. Tap the ▶ button to start the sleep monitoring. During monitoring, a countdown timer is always displayed at the lower left part.
6. You can press Home button to lock the screen, as shown below. The device will work in a very low power consumption mode.
7. Insert the device into the wrist band cover, and then begin to sleep.
8. When you get up, or when you want to stop monitoring, you can press the Home button again to unlock the screen, and then tap icon ■ to stop sleep monitoring.
9. You can tap 🔍 button to view the SpO_2 trending during your sleep, or tap "Close" button and return to the Main Screen.





2.7 Blood Pressure (Optional)

Checkme can work with the AirBP unit (optional accessory) to measure blood pressure.

1. Turn on the blood pressure monitor AirBP.
2. Turn on Checkme Pro, choose the item <**Blood Pressure**> on the screen.

3. Choose the desired user on the screen, then Checkme will start to search AirBP.
4. Choose your AirBP "BP XXXX" on the screen, then Checkme will start to connect with AirBP.

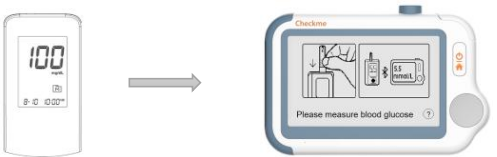
5. Sit correctly. Place the cuff on the left upper arm. Press the **<start>**.
6. Following the instruction on Checkme, pump to the target pressure then keep still until the results.
7. Deflate the cuff.

Note: *Keep AirBP turning on during connection.*

2.8 Blood Glucose (Optional)

Checkme can work with the blood glucose meter unit (optional accessory) to blood glucose.

1. Use the blood glucose meter to complete a blood glucose measurement.
2. Turn on Checkme and select the item "Blood Glucose" on the screen.
3. Checkme will start to connect with your blood glucose meter.
4. After your blood glucose measurement data uploads successfully to Checkme, you can view the measurement result on Checkme.



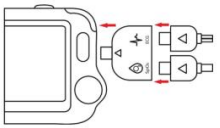
Note

- Refer to the blood glucose meter user manual for a blood glucose measurement.
- Please keep the Bluetooth of the blood glucose meter turning on during connection.

2.9 Minimonitor (Optional)

To start a Minimonitor function, follow the steps as below.

1. In the Checkme Main Screen, select <**Minimonitor**>
2. Correctly connect the "Minimonitor adaptor", SpO_2 cable and ECG cable with the device.
3. Put finger into the external SpO_2 sensor. Place the ECG electrodes as shown below.



2.10 ECG Holter (optional)

2.10.1 Choose Holter Lead

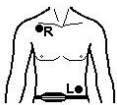
Choose the proper ECG lead in the setting menu.

There are 4 options: LEAD II; CC5; CM5; User defined.

2.10.2 Measurement

1. In the Main screen, tap the ECG Holter icon.
2. Choose the right user, enter the guidance screen.
3. Plug ECG cable and place electrodes on the right positions as guided.

4. The display will show ECG waveform, press the button ▶ to start recording. (The recording will start to record 1 minutes later automatically without pressing the button)



5. Wear the Holter Belt around your waist

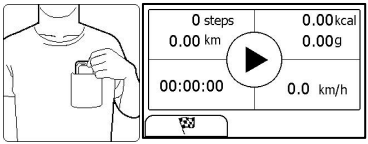
6. Put Checkme in the pocket of the Belt, then close the pocket.

Keep recording for 24 hours or less. During this process, the device will beep if the cable or any electrode is off.

2.11 Pedometer

To start a Pedometer measurement,

1. In the Main Screen, select <**Pedometer**> icon. If you have not created user, then please add your user account.
2. Select a user to enter the screen as below.



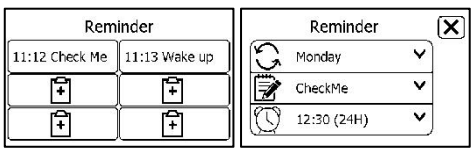
3. Tap the button to set your target, if needed.
4. Tap the ▶ button to start calculating steps.
5. Place the device into your pocket.
6. When you finished calculating steps, press the Home button to stop the pedometer.

7. Press Home button again to exit pedometer function.

3. Settings

3.1 Reminder

Up to 6 reminder events can be set by user. You can add, edit and delete reminder events.



3.2 Changing Sound Volume

In the Settings menu, tap the <**Volume**> area to change volume directly. "X" means the volume is turned off.

3.3 Enabling/Disabling Voice Guide

In the Settings menu, tap the **<Voice Guide>** to enable or disable this function.

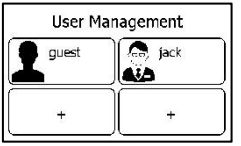
3.4 User Management

To use the Daily Check measurement, you must create your account. If the Daily Check

measurement is used by more than one user, then each user must create his/her own account.

To create a user account:

1. In the Settings menu, choose <**User Management**>.



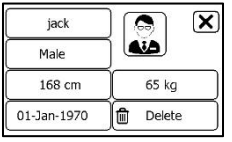
2. Tap a "+" button to open the menu below.
3. Tap each button to edit corresponding information.
4. Tap [X] to return the < **User Management** > menu.

To edit the information of a user:

1. In the Settings menu, choose <**User Management**>.
2. Choose the user that you want to edit.
3. Tap the information that you want to edit, and then modify.
4. Tap <OK> and [X] to return the < **User Management** > menu.

To delete a user:

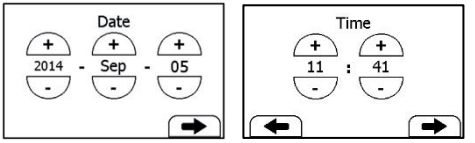
1. In the Settings menu, choose <**User Management**>.
2. Choose the user that you want to delete.
3. Tap the 🗑 button.



4. Choose <**Yes**> to confirm.

3.5 Setting Date & Time

1. In the Settings menu, choose <**Date & Time**>
2. Tap "+" or "-" button to change the date, then tap ➡.
3. Tap "+" or "-" button to change the time.
4. Tap ➡ to finish the setting.



3.6 Choosing Language

1. In the Settings menu, choose <**Language**>.
2. Choose the language from the list.

3.7 Changing Temperature

In the Settings menu, tap the <**Temperature**> area to change between Celsius degree (°C) and Fahrenheit degree (°F).

3.8 Softeare update

Tap the<Software Update>to enter the software upgrade mode.

3.9 Changing ECG waveform length

To change the length of ECG waveform saved for each ECG Recorder measurement:

1. In the Settings menu, choose<**ECG Length**>.
2. Then choose among <**30s**>, <**60s**>. And tap <**OK**> to enable the change.

3.10 Setting ECG Bandwidth

In the Setting menu and choose **<ECG bandwidth>** to change between **<Normal>** and **<Wide>**.

3.11 Changing Holter ECG Lead(optional)

To change the lead of ECG Holter for ECG Holter measurement:

1. In the Settings menu, tap <**Holter Lead**>.
2. choose among <**LEAD II**>, <**CC5**>,<**CM5**> and <**User-defined**>
3. Tap <**YES**> to enable the change.

3.12 Quick ECG

Tap the**<Quick ECG>** to enable or disable this function.

3.13 Configuration

Tap the<**Configuration**>to choose to open or close **<Blood Pressure>**and**<Blood Glucose>**

3.14 Erasing Data

In the Setting menu, Tap <**Erase All Data**>, and then <**Yes**>.
All measurements saved in the device will be deleted.

3.15 Factory Reset

In the Setting menu, Tap **<Factory Reset>**, then tap **<Yes>**.
All measurements, user information and other settings saved in the device will be deleted, and the device will be restored to the factory default settings.

3.16 About

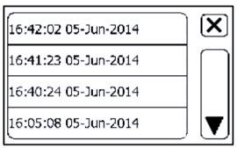
Tap the<About>to check device Information

4. Review

4.1 Reviewing Daily Check

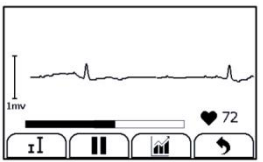
To review Daily Check records,

1. In the <**Review**> menu, select <**DailyCheck**>.
2. Choose the right user to open the list as below, then select one record to review more information as below.



In this menu, you can:

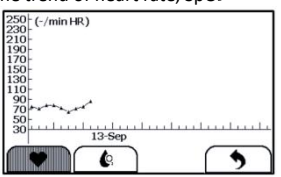
- Select to delete this measurement
- Select to replay the ECG waveform as shown below.



When the ECG waveform is being replayed, you can

- Select to change the waveform amplitude.
- Select to pause it.
- Select to return Daily Check list.

- Select to view the trend of heart rate, SpO_2



- Select to return to the Daily Check list.

5. Maintenance

5.1 Care and Cleaning

Clean the device per week, carefully swabbing the device surface with a soft cloth or cotton swab with rubbing alcohol.

5.2 Trouble Shooting

Problem	Possible Cause	Solution
The device does not turn on.	1. The battery may be low. 2. The device might be damaged	1. Charge the battery and try again. 2. Please contact with your local distributor.
The ECG waveform amplitude is small	The lead you choose is not suitable for you.	Change another lead and try again.
ECG waveform drifts	1. The pressure exerted on the electrode is not stable or too much. 2. Hand or body may be moving.	1. Hold the device stably and gently. 2. Try to keep perfectly still and test again.
SpO_2 or pulse rate shows no value, or the number fluctuates	1. Finger may not be inserted correctly. 2. Finger or hand may be moving.	1. Remove finger and reinsert, as directed. 2. Try to keep perfectly still and test again.
“System Error” occurred.	Software or hardware failure.	Restart the device and measure again.If the error persists, mark down the error number and contact with your local distributor.
BP calibration failed.	1. Wrong height. 2. The difference between two calibrations is too large.	1. Reconfirm your height. 2. Try to keep perfectly still and calibrate again.
No voice during ECG and SpO_2 measurement.	The speaker is muted.	Unmuted the speaker in the Settings menu.
Temperature value is too low.	1. The measurement area is covered by hair. 2. The thermometer sensor is too far away from your skin. 3. The thermometer sensor is dirty.	1. Remove hair from the measurement area. 2. Keep the sensor contact with your skin. 3. Clean the sensor with a soft cloth or cotton.

6. Accessories

⚠ **Warnings and Cautionary Advice**

- Use accessories specified in this chapter. Using other accessories may cause damage to the device or not meet the claimed specifications.
- Depending on the configuration, May not all the accessories are included in your package.

Part Number	Description
540-00192-00	ECG cable with 2 lead wires, snap
540-00193-00	SpO_2 finger sensor, 25 cm, FP-10
540-00194-00	USB charging cable, micro D
560-00198-00	ECG electrode, 10 pcs

7. Specifications

Classifications		
EC Directive	MDD, 93/42/EEC	
	R&TTE, 1999/5/EC	
	ROHS 2.0, 2011/65/EU	
Degree protection against electrical shock	Type BF	
Environmental		
Item	**Operating**	**Storage**
Temperature	5 to 45°C	-25 to 70°C
Relative humidity (noncondensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	
Drop test	1.0 m	
Physical		
Size	88×56×13 mm	
Packing size	178*123*75 mm	
Weight	Less than 80 g (main unit)	
Display	2.7" touch screen, HD	
Connector	Micro D connector	
Wireless connectivity	Built-in Bluetooth dual mode, support 4.0 BLE	
Power Supply		
Battery type	Rechargeable lithium-polymer battery	
Battery run time	Only daily check: > 1000 times Continuous sleep monitoring: > 12 hours Pure standby calendar mode: > 3 months	

Charge time	Less than 2 hours to 90%	
ECG		
Lead type	Integrated ECG electrodes External ECG cable and electrodes	
Lead set	Lead I, lead II	
Measurement mode	Episode, continuous	
Sampling rate	500 Hz	
Sampling accuracy	16 bit	
Display Gain	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV 10 mm/mV, 20 mm/mV	
Sweep speed	25 mm/s	
Bandwidth*	0.05 to 40 Hz	
Electrode offset potential tolerance	±300 mV	
HR measurement range	30 to 250 bpm	
Accuracy	±2 bpm or ±2%, whichever is greater	
ST measurement range	-0.5 to +0.5 mV	
Measurement summary	Heart rate**, QRS duration, ST segment***,QT/QTc Rhythm analysis (Regular ECG Rhythm, High Heart Rate, Low Heart Rate, High QRS Value, High ST Value***, Low ST Value***, Irregular ECG Rhythm, Unable to analyze)	
SpO_2		
Standards	Meet standards of ISO 80601-2-61	
Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurement are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.		
SpO_2 range	70% to 100%	
SpO_2 Accuracy (Arms)	80-100%: ±2%, 70-79%:±3%	
PR range	30 to 250 bpm	
PR accuracy	±2 bpm or ±2%，whichever is greater	
PI range	0.5-15	
Measurement summary	SpO_2, PR, PI, Summary (Normal Blood Oxygen, Low Blood Oxygen, Unable to analyze)	
Thermometer		
Item	**Infrared sensor**	**Cable Contact**
Technique	Infrared body temperature	Contact temperature

Environment temperature	16.0 to 40.0°C	
Measurement site	Temple	Armpit
Measurement time	3s	Stable value after 2 minutes
Measurement range	34.0 to 42.2°C (94.0 to 108.0°F)	30.0 to 45°C (86.0 to 113.0°F)
Accuracy	±0.2°C or ±0.4°F	±0.2°
Sleep Monitor		
Monitoring time	Up to 10 hours	
Data storage	Store SpO_2 and pulse rate	
Measurement summary	Total duration, <90% STAT, Average saturation, Lowest saturation, Summary(No abnormal detected, blood oxygen drop detected, Unable to analyze)	
Pedometer		
Range	0 to 99999 steps	
Distance	0.00 to 999.99 km	
Timer	0 to 1999 minutes	
Calories	0.00 to 9999.99 kcal	
Fat	0.00 to 199.99 g	
Reminder		
No. of reminder	6	
Reminder event	Wake up, Check me, Medicine, Self-define	
Review		
Data review	Graphic trend, list trend	
Waveform review	Full disclosure waveform	
Daily check	100 pcs of records without audio memo	
ECG recorder	100 pcs of records without audio memo	
Oximeter	100 pcs of records	
Thermometer	100 pcs of records	
Sleep record review	5 pcs of records, 10 hours each record	

* : External ECG cable, bandwidth mode set to wide

**: Heart rate is calculated based on average of every 5 to 30 QRS complex.

***: Only for measurement with external ECG cable, bandwidth mode set to wide

8. Electromagnetic Compatibility

The device meets the requirements of EN 60601-1-2. All the accessories also meet the requirements of EN 60601-1-2 when in use with this device.

⚠ **Warnings and Cautionary Advice**

- Using accessories other than those specified in this manual may result in increased electromagnetic emission or decreased electromagnetic immunity of

the equipment.

- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet the requirements of CISPR.
- When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.
- Portable and mobile communication equipment may affect the performance of this device.
- Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).

Guidance and Declaration - Electromagnetic Emissions		
The Health Monitor 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.		
Emission tests	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Declaration - Electromagnetic Immunity			
The Health Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Health Monitor should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 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 AC mains voltage prior to application of the test level.

Guidance and Declaration - Electromagnetic Immunity

The Health Monitor is intended for use in the specified electromagnetic environment. The customer or the user of the Health Monitor should assure that it is used in such an environment as described below.

Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conduced RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms 150 kHz to 80 MHz outside ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	Recommended separation distances: 80 MHz～800 MHz: $d = 1.2\sqrt{P}$ 800MHz-2.5GHz: $d = 2.3\sqrt{P}$ Where, *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined

			by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over frequency range 150kHz to 80MHz. For Resp field strength should be less than 1V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The Health Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Health Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

Rated max. output power of transmitter (W)	**Separation distance according to frequency of the transmitter (m)**		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

9. FCC Statement

FCC Warning:
FCC ID: 2ADXK-6600
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.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-Reorient or relocate the receiving antenna.
-Increase the separation between the equipment and receiver.
-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-Consult the dealer or an experienced radio/TV technician for help.
The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

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Vous êtes responsable de remettre tous les appareils électriques et électroniques usagés à des points de collecte correspondants.

Pour en savoir plus:
www. quefairedemesdechets.fr