

User's Manual

VitalsRx Monitor



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1. The Basics

Caution: Federal law restricts this device to sale by or on the order of a physician.

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration of VitalsRx Monitor. Some functions may be not available on your model.

1.1 Safety



Warnings

- Before using the device, please ensure that you have read this manual thoroughly and fully understand corresponding precautions and risks.
- This device has been designed for practical use, but is not a substitute for a visit to the doctor.
- The data and results displayed on the device are for reference only and cannot be directly used for diagnostic interpretation or treatment.
- 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.

- The VitalsRx is MR unsafe. Do not use this device in an MR environment as it contains strongly ferromagnetic materials.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the 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. Children should be supervised around the device to ensure they do not play with it.
- Do not allow the electrodes of the device to come into contact with other conductive parts (including earth).
- Do not use the device with persons with sensitive skin or allergies.
- 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.
- Do not swing the device with the strip, which may result in injury.
- This device displays changes in the heart rhythm and blood oxygenation etc. which may have various different causes. These may be harmless, but may also be triggered by illnesses or diseases of differing degree of severity. Please consult a medical specialist if you believe you may have an illness or disease.

- 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.
- This device is not a substitute for a medical examination or your heart or other organ function, or for medical electrocardiogram recordings, which require more complex measurements.
- It is not possible to use this device to diagnose illness or diseases. This is exclusively the responsibility of your doctor.
- We recommend that you record the ECG waveforms and other measurements and provide them to your doctor if required.
- This product doesn't provide on-device data backup function.

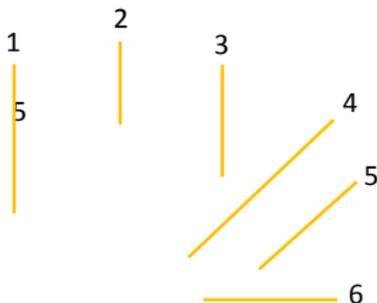
2. Introduction

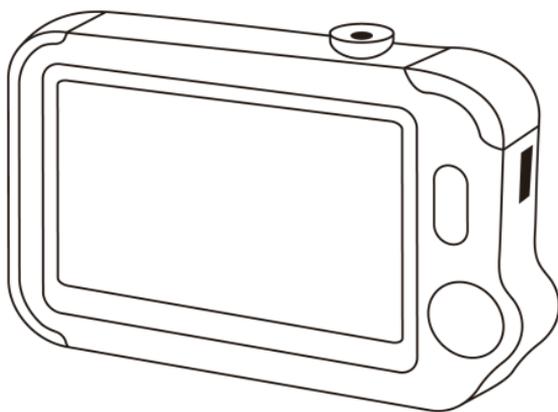
2.1 Intended Use

The VitalsRx Monitor is intended to be used for measuring, displaying, reviewing and storing of ECG (adults only), oxygen saturation and pulse rate (Continuous data collection and recording is for adult only, spot checking is for adults and pediatrics) and temperature in the home or in healthcare facilities.

This device is not intended to substitute for a hospital diagnostic ECG device and also not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (ICDs).

2.2 About VitalsRx



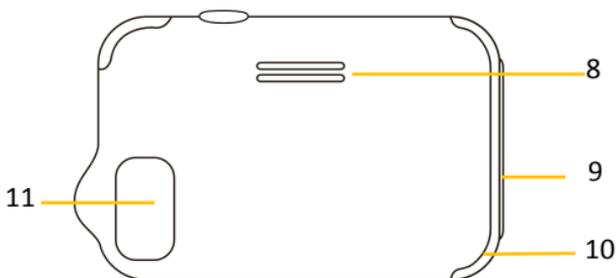


1. Touch Screen
2. Infrared temperature sensor
3. Internal SpO₂ sensor
4. LED indicator
 - Off: the monitor is turned off or working in Standby Mode;
 - Green: the monitor is turned on, and working normally; or when the battery is fully charged;
 - Blue: the battery is being charged;
 - Red and flash: the battery is low;
5. Multi-functional micro D connector
It connects with external SpO₂ 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, pressing this button will switch to Main Screen, or Standby Mode, 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.

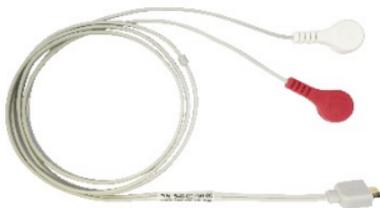
10. Neck strip hole

11. ECG back electrode

Use right index finger or middle finger to press on it.

13 _____

_____ $\frac{7}{12}$



12. ECG cable with lead wires

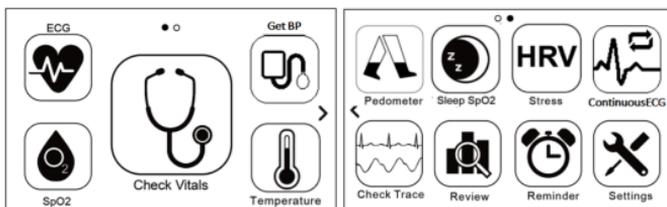
Connect the cable to the device via micro D USB port, and put the other ends to your left/right wrists or right clavicle/left lower abdomen.

13. SpO₂ external finger sensor

Connect the cable to the device via micro D USB port, and put your index finger in with the fingernail facing up against the cable side of the sensor.

2.3 Main Screen

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



Tapping an icon on the Screens will start a measurement, activate a function, or open corresponding menu.

2.4 Standby Mode

The device will enter Standby Mode when:

- No operation is detected for 120 seconds on the screen interface, the device will automatically switch to the ultra-low power consumption Standby Mode.
- 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. "Check Vitals".

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. Please refer to **Section 5.4** for details.

3. This arrow indicates users to press the Home button to exit the Standby Mode.

4. Battery indicator

Please refer to **Section 7.1** for details.

5. If you failed to respond to the previous reminder event, then that event will be shown in this area.

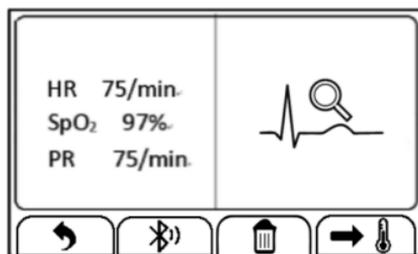
6. This icon appears when **<Quick ECG>** is enabled. Please refer to **Section 5.4** for details.

7. This icon appears if you have set reminder event.

When the device enters Standby Mode, it also begins to work in Standby Mode, which is an ultra-low power consumption mode. In Standby Mode, the touch screen operation is invalid.

2.5 Result Screen

This device provides powerful measurement functions including Check Vitals, ECG Recorder, Pulse Oximeter, Thermometer, SpO2 (Oximeter), and Pedometer. For each measurement, a Result report will be provided after the measurement is finished. An example is shown below.



1. Measured parameters and readings: Heart Rate (from ECG), Blood

Oxygenation and Pulse Rate (from Pulse Oximetry).

2. Buttons

- Select  button to start a measurement again.
- Press  button to add voice memo for this measurement.
- Press  button to play the ECG waveform.
- Select  button to review previous results.
- Press  button to open the Bluetooth to share the data.

On the Result Screen, if there is no operation for 2 minutes, the device will automatically return to Standby Mode.

2.6 Symbols

Symbol	Meaning
	Application part type BF
	Manufacturer
	Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”.
IP22	Against ingress of solid foreign objects $\geq 12.5\text{mm}$ diameter, Against dripping (15° tilted)

	MRI unsafe, Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
	Follow operating instructions
	No alarm system.

3. Getting Started

3.1 Unpacking

Before unpacking, examine the box carefully for signs of damage. If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage.

Warnings

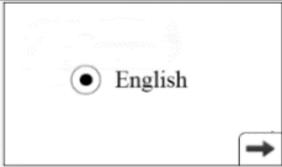
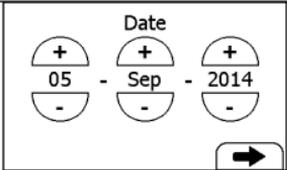
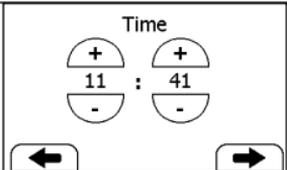
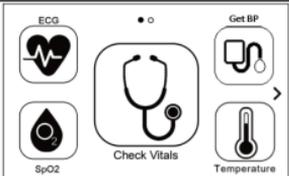
- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
- The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact. In case of any damage, do not apply it to patients.

3.2 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.

3.3 Initial Settings

The first time when the VitalsRx is powered on, you can follow the steps below to set up your VitalsRx monitor.

Step	User Interface	Action
1		Tap the language you want the device to use. Then Tap ➡.
2		Tap the "+" or "-" button to change the date, month and year. Then Tap ➡.
3		Tap the "+" or "-" button to change the time. Then Tap ➡.
4		The Main Screen shows when you finish the steps as above.

4. Using VitalsRx

4.1 Prior to Use

Warnings

- Use only cables, sensors and other accessories specified in this manual.
- The device has no alarms and will not sound if the measurement reading is too low or too high.

Before using ECG

Before using Check Vitals or ECG Recorder function, pay attention to the following points in order to obtain precise measurements.

- The ECG electrode must be positioned directly against the skin.
- If your skin or hands are dry, moisten them using a damp cloth before taking the measurement.
- If the ECG electrodes are dirty, remove the dirt using a soft cloth or cotton bud dampened with disinfectant alcohol.
- During the measurement, do not touch your body with the hand with which you are taking the measurement.
- Please note that there must be no skin contact between your right and left hand. Otherwise, the measurement cannot be taken correctly.
- Stay still during the measurement, do not speak and hold the device still. Movements of any kind will affect the measurements.
- If possible, take the measurement when sitting and not when standing.

Warnings

- When connecting external electrodes and/or patient cables, make sure that the connectors never come into contact with other conductive parts, or with earth. In particular, make sure that all of the ECG electrodes are attached to the patient, to prevent them from contacting conductive parts or earth.
- If using the ECG for long-term monitoring, periodically inspect the electrode application site to ensure skin quality. If the skin quality changes, replace the electrodes or change the application site.
- Do not use this device during defibrillation.
- Interference from a non-grounded instrument near the patient and electro surgery interference can causes problems with the waveform.

Before using Oximeter

Before using Check Vitals or Oximeter functions, pay attention to the following situations that may interfere with precise measurements.

- The finger inserted in SpO₂ sensor must be clean to ensure proper reading.
- Any of the following conditions may cause inaccurate measurements, including but not limited to:
 - Flickering or very bright light;
 - Poor blood circulation;
 - Low hemoglobin;
 - Hypotension, severe vasoconstriction, severe anemia or hypothermia;
 - Dark nail polish, and/or artificial nails;
 - Any tests recently performed on you that required an injection of intravascular dyes.
- The Oximeter may not work if you have poor circulation. Rub your

finger to increase circulation, or place the SpO₂ sensor on another finger.

- The Oximeter measures oxygen saturation of functional hemoglobin. High levels of dysfunctional hemoglobin (caused by sickle cell anemia, carbon monoxide, etc.) could affect the accuracy of the measurements.
- 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 towers, and TV broadcast towers may affect accuracy.
- The pleth waveform displayed on the device is normalized.

Warnings

- Limit finger movement as much as possible when using the Check Vitals or Oximeter, which might result in incorrect reading or measurement result.
- Do not use the Oximeter on the same hand/arm when using a blood pressure cuff or monitor.
- Do not use the Oximeter outside the specified operating and storage temperature ranges.
- The VitalsRx is MR unsafe. Do not use this device in an MR environment as it contains strongly ferromagnetic materials. Induced current could potentially cause burns. The SpO₂ sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Prolonged continuous SpO₂ recording may increase the risk of undesirable changes in skin characteristics, such as irritation; reddening, blistering or burns.
- Check the SpO₂ sensor application site every 2 hours to determine proper positioning of the sensor, 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.

4.2 Check Vitals

About Check Vitals



Warnings

- Before using this function, please read the **Section 4.1**.
- When using Check Vitals, please ensure you select the right user.
- The external pulse oximeter feature is only intended for users over 12 years old (adults and adolescents).

Check Vitals measurement is a function that combines the measuring of ECG (Electrocardiograph) waveform, HR (heart rate), R-R (R-R interval) Pleth waveform, SpO₂ (blood oxygenation), PR (Pulse Rate). It takes only 20 seconds to collect your vital signs before giving you vital signs readings.

Before using Check Vitals measurement or reviewing the Check Vitals data, ensure that the correct user is selected. Please refer to **Section 5.8** to know how to manage users.

Setting Check Vitals Reminder

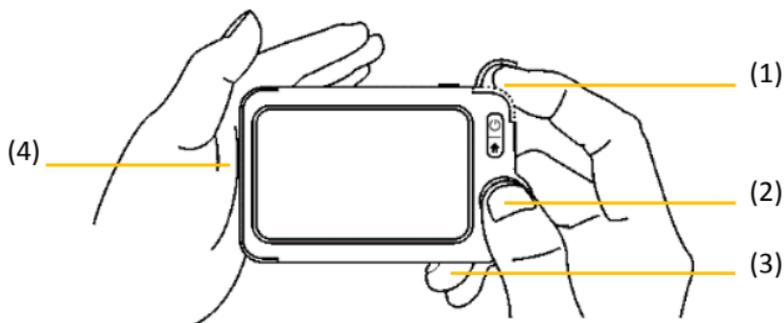
To ensure that you never forget to take a Check Vitals measurement, you can set a Check Vitals reminder. When this Check Vitals reminder event is triggered, the device gives audio alarm prompt, which will last for one minute if you don't cancel it manually.

To set the Check Vitals reminder event, please refer to **Section 4.8**.

Using Check Vitals

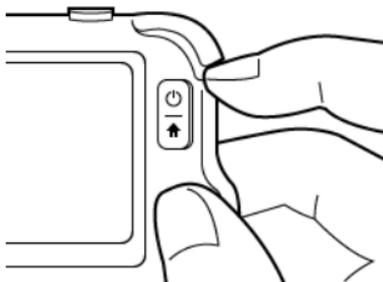
To start a Check Vitals, follow the steps as below.

1. If you have not created user, then please follow the instruction in **Section 5.8** to add your user profile.
2. Press the Home button to enter the Main Screen.
3. Tap the <Check Vitals> icon in the middle of the screen.
4. Choose the right user.
5. Hold the device according to the instruction, keep stable posture and stay calm. Don't exert too much pressure on the ECG electrode, which may result in EMG (electromyography) interference. Just hold gently and ensure good contact with the ECG electrode. Do not overexert pressure with the finger used in the SpO₂ sensor position. Slide index finger inside gently to ensure good blood perfusion.

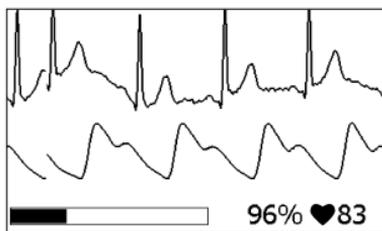


- (1) Put the right index finger into the built-in SpO₂ sensor by sliding your finger nail under the edge of the SpO₂ sensor cover and then move upward to the left to raise it up as shown on next page.





- (2) Press the right thumb on the right front electrode.
 - (3) Press the right middle finger on the back electrode.
 - (4) Press the left side electrode to the left palm.
6. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
 7. When the bar is fully filled, the device will show the measurement result.

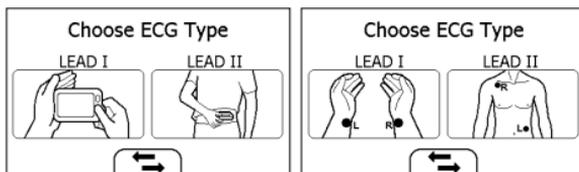


Please refer to **Section 2.4** to understand the result screen. Check Vitals provides the trending graph of heart rate, SpO₂. To view the trend, tap the  button, then select one record, and then tap the  button. For details, please refer to **Section 6.1**.

4.3 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, right wrist to left lower abdomen

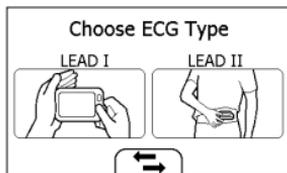
ST segment analysis is performed on selected LEAD.

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 (electromyography) interference. After you finish the above steps, hold the device stably and stay calm.

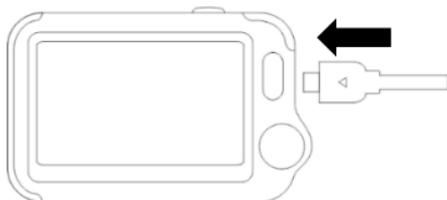
3. Once the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
4. When the bar is fully filled, the device will analyze your data, and then show the measurement result.



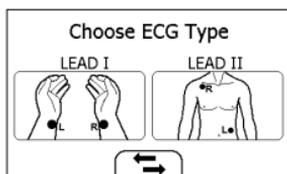
Measuring with Cable

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;
- Palms facing up, place an electrode in the middle of right wrist;
- For method C, place another electrode in the middle of left wrist;
- For method D, 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.

4.4 Real Time Wireless Display

About Real Time Wireless Display

Simply placing the VitalsRx on patient's arm, the Real Time Wireless Display function is able to continuously monitor and display patient's ECG and SpO₂. Real-time waveform and readings can be sent and displayed on a tablet or phone.

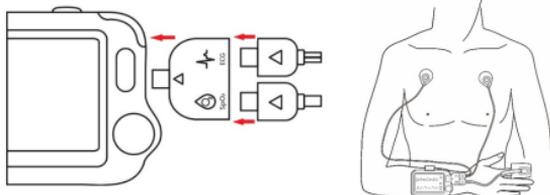
Warning and cautions advices

- To ensure better tracking of your health status, you should try to stay still during the measurement.
- The finger inserted in SpO₂ sensor must be clean to ensure proper reading.
- Before using this function, please search and download "Check Trace" from APP store or Google Play to your tablet or phone.

Using Check Trace Display

To start a Check Trace Wireless Display function, follow the steps as below.

1. In the VitalsRx Main Screen, select < Check Trace >
2. Correctly connect the "Check Trace adaptor", SpO₂ cable and ECG cable with VitalsRx device.
3. Put finger into the external SpO₂ sensor. Place the ECG electrodes as shown below.



4. Turn on the Bluetooth on your pad and open “Check Trace “app. The app will search the VitalsRx device through Bluetooth.
5. Choose the device you’re monitoring via SN.
6. When the devices are connected successfully, you can see the waveform and measurement data on both VitalsRx and app. Please see below the displaying screen on app.



7. When you finish measuring, press the Home button to stop monitoring.

4.5 Continuous ECG

4.5.1 Change Continuous ECG Recording Lead

If you need to change Continuous Recording ECG lead, choose the lead in the path below:

Settings-> General-> 24hr ECG Recording Lead

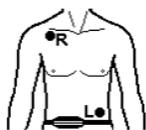
There are 4 options: LEAD II; CC5; CM5; User defined.

4.5.2 Measurement

1. In the Main screen, tap the **Continuous ECG** 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 with pressing the button)



5. Wear the **Continuous ECG** Recording Belt around your waist



6. Put VitalsRx 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.

4.5.3 Report on PC

VitalsRx **Continuous ECG** Recording Browser is a PC software to check and print the report.

1. Connect device and PC by USB cable.

2. Operation on device:

Settings->To PC; or Review-> **Continuous ECG** icon->To PC icon



3. Operation on PC:

4.6 Open the software, press the button in the upper left corner to download the data from device. Then you can check the report.

4.7 Oximeter (SpO₂)

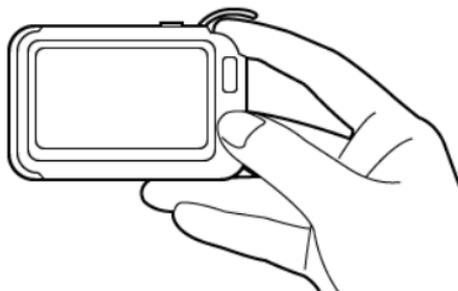
About Oximeter

The VitalsRx Health Monitor is calibrated to display functional oxygen saturation and pulse rate. The VitalsRx works by shining two light beams into the small blood vessels or capillaries of the finger, reflecting the amount of oxygen in the blood and displaying the measurement.

Measuring without Cable

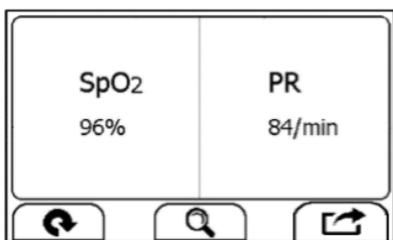
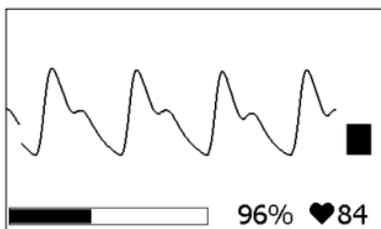
To start a Oximeter measurement without cable,

1. If the device is in Standby Mode, press the Home button.
2. In the Main Screen, tap the “**SpO₂**” icon.
3. Insert the index finger into the built-in SpO₂ sensor as shown below.



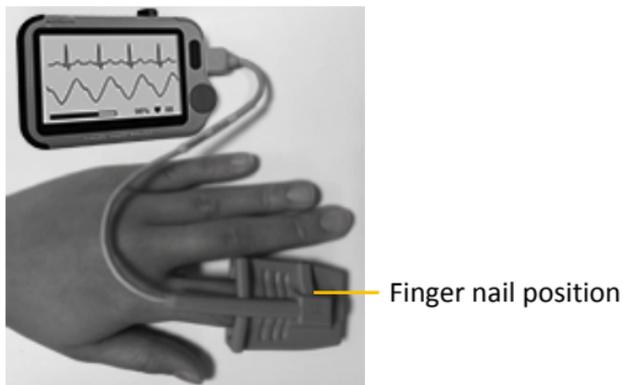
Relax your index finger and do exert pressure.

4. When the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
5. When the bar is fully filled, the device will show the measurement result.



Measuring with Cable

1. Connect the external SpO₂ sensor to the multi-functional connector.
2. Put your index finger into the external SpO₂ sensor. Make sure the cable is positioned along the top of the hand, and the finger nail is in the position as shown below.

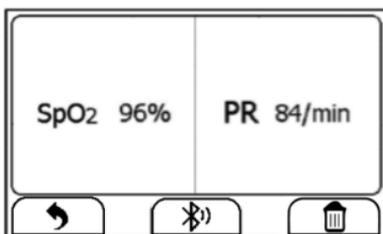


3. If the device is in Standby Mode, press the Home button.
4. Tap the <SpO₂> icon.
5. The display will then show your PLETH waveform, SpO₂ and pulse rate.



The device will not analysis your data until you press the button.

6. Press the ► button to start collecting your SpO₂ data. The countdown bar moves from left to right.
7. When the bar is fully filled, the device will show the measurement result.



4.8 Temperature

About thermometer

Warnings

- The thermometer is only designed for the measuring area on the human body stated in this manual.
- Check before each use that the lens is intact. If it is damaged, please contact your retailer or the service address.
- The device needs to be in the room which the measurement is taken for at least 30 minutes before use.
- Holding the device for too long in the hand or within your cloth can cause the device to warm up, which may result in incorrect readings.
- Physical activity, increased perspiration on the forehead, taking vasoconstrictive medication and skin irritations can distort the result.
- The forehead (temple) must be free from perspiration and cosmetics.
- Taking the forehead temperature provides a current measurement of a person's temperature. If you are uncertain about interpreting the results or if the values are abnormal (e.g. fever), please consult your doctor. This also applies in the case of slight temperature changes if there are other symptoms of illness such as agitation,

severe sweating, flushed skin, fast pulse rate, tendency to collapse, etc.

- Dirty temperature sensor window will cause low temperature reading. Clean sensor window to remove dust or dirt in case of doubtful reading.

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.

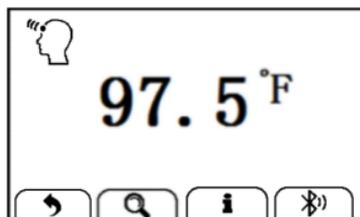
Taking Temperature Measurement

To start a temperature measurement,

1. If the device is in Standby Mode, press the Home button.
2. In the Main Screen, select **<Temperature>**.
3. Straightly aim the thermometer sensor at temple area with a distance of less than half an inch.
4. Press the Home button once, you will hear a "Bi" beep, which indicates the measurement starts. After 2 seconds, you will hear a

“Bi-Bi” beep, which indicates the measurement is finished.

5. Take down the device, and the screen shows the measurement



result.

4.9 Continuous SpO₂ Recording

About Sleep SpO₂

In order to use the Sleep SpO₂ for continuous recording, you will need a wristband. The wristband must be able to accommodate a device with the following dimensions (88×56×13mm) and be of the correct size to accommodate the user’s wrist. In order to obtain an accurate reading, ensure that the wrist band is attached securely, but not so tight to avoid discomfort.

The maximum recording time is 10 hours. If the recording time exceeds 10 hours, the device will automatically stop and only keep 10 hours of data for post review.

Before using this function, please ensure the battery is fully charged.

Warnings

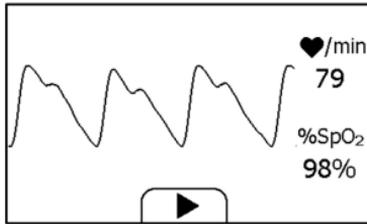
- Do not use Sleep SpO₂ function on babies and children.
- If the SpO₂ sensor causes skin sensitivity, change to another finger.

To start a continuously SpO₂ recording,

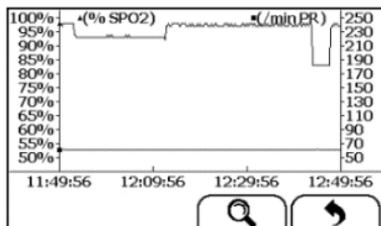
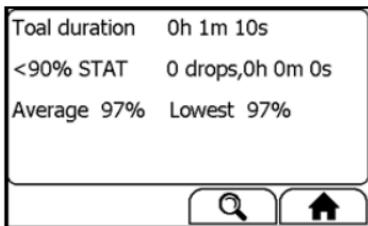
1. Place the device on your left hand at a proper position.
2. Attach the device to your hand comfortably with the wristband. (Wristband not provided)
3. Insert the SpO₂ cable into the multi-functional connector.
4. Put one of your fingers into the sensor. Index finger is suggested. If needed, remove the colored nail polish from the finger. Make sure that the sensor is correctly placed so that the cable goes above you're the back of your hand.



5. Press the Home button to enter the Main Screen. Then Tap the Sleep SpO₂ icon to enter the screen as below.



6. Tap the ▶ button to start the SpO₂ recording. During this process, a countdown timer is always displayed at the lower left part.
7. Press Home button or one minute later, the screen will lock.
8. Insert the device into the wrist band cover, and then begin to record.
9. When you want to stop it, you can press the Home button again to unlock the screen, and then tap ■ button to stop SpO₂ recording.
10. You can tap 🔍 button to view the SpO₂ trending during your recording.



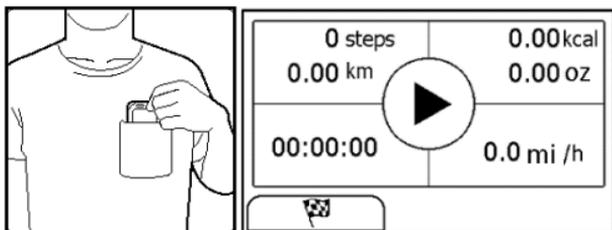
4.10 Pedometer

To start a Pedometer measurement,

1. If the device is in Standby Mode, press the Home button.
2. In the Main Screen, select <Pedometer> to enter <Choose User>

screen. If you have not created user, then please follow the instruction in **Section 5.8** to add your user profile.

3. Select a user to enter the screen as below.



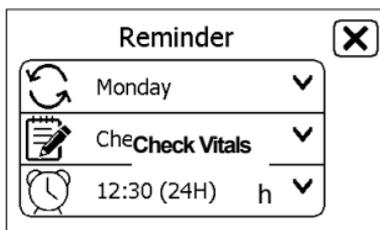
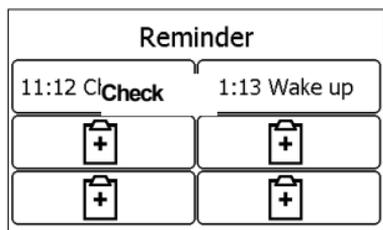
4. Tap the  button to set your target, if needed.
5. Place the device into your pocket.
6. Tap the  button to start calculating steps.
7. When you finished calculating steps, press the Home button to stop the pedometer.
8. Press Home button again to exit pedometer function.

4.11 Reminder

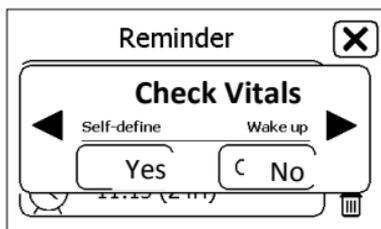
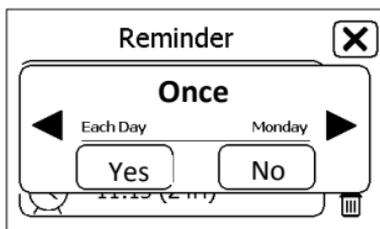
Up to 6 reminder events can be set by user. You can add, edit and delete reminder events. To track your health every day, it is suggested to set a reminder for Check Vitals.

To add a reminder:

1. In the Main Screen, tap **<Reminder>** icon.
2. In the **<Reminder>** menu, tap  icon to add a reminder.



3. Tap the first row to set the repeat interval. Tap the ◀ or ▶ button to change the setting.
4. Tap the second row to set the event. You can define the event by selecting “Self-define”.



5. Tap the third row, set the time when the reminder is triggered, then tap →.
6. Tap [X] to save this reminder.

To edit or delete a reminder, in the <Reminder> menu, choose the reminder which you want to edit or delete.

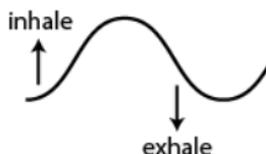
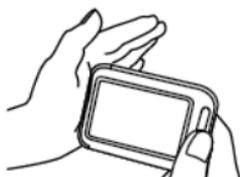
- Change the repeat interval, event, and/or time, then save the change by following the same procedure as adding a reminder.

- Tap the  button, and then “Yes” to delete a reminder.

4.12 HRV

To start an HRV recording,

1. Tap <HRV> icon in the Main Screen.
2. Press User name or add a new one.
3. Before beginning, sit down, relax, hold device gently as shown and rest your hands on a table.



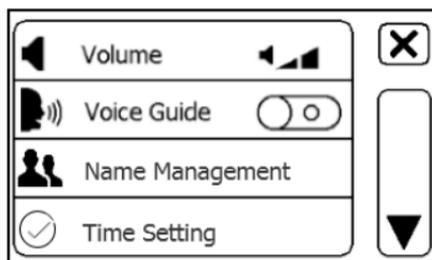
4. Stay relaxed during measurement as exerting too much pressure or actively moving may affect conductivity.
5. Follow the breathing pattern as shown above, inhaling as the indicator moves upward and exhaling as it moves downward.
6. Press the Home button to stop the measurement at any time, and the screen shows your Relaxation Index upon stopping the measurement.

5. Settings

5.1 Opening Settings Menu

To open the Settings menu,

1. Press the Home button to enter the Main Screen.
2. Tap the <Settings> icon to open the menu as below.



In the Settings menu, you can

- Tap ▲ and ▼ button to page up or down
- Tap [X] to close the Settings menu

5.2 Changing Sound Volume

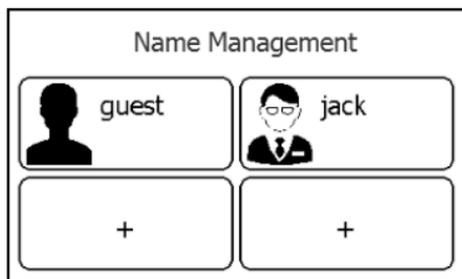
In the Settings menu, tap the <Volume> area to change volume directly. “X” means the volume is turned off.

5.3 Name Management

To use the Check Vitals measurement, you must create your account. If the Check Vitals measurement is used by more than one user, then each user must create his/her own account.

To create a user profile:

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



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

To edit the information of a user:

1. In the Settings menu, choose **<Name 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  to return the **<Name Management >** menu.

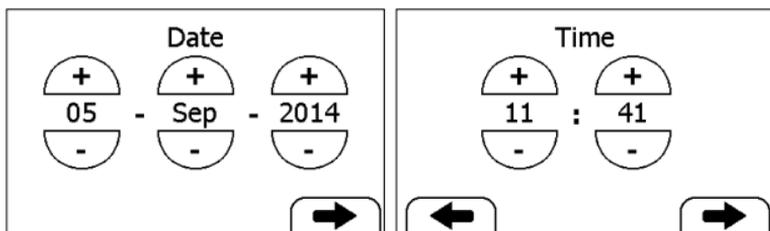
To delete a user:

1. In the Settings menu, choose **<Name Management>**.
2. Choose the user that you want to delete.
3. Tap the  button.
4. Choose **<Yes>** to confirm.

The **<Guest>** user cannot be edited or deleted.

5.4 Setting Date & Time

1. In the Settings menu, Chose <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.

5.5 Enabling/Disabling Quick ECG

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

5.6 Set up Bluetooth PIN code

In settings, you can set up the PIN code for Bluetooth access of this device. The default PIN code is 8888 and you can change it at any time.

5.7 Software Update

Press Settings and then tap <Software Update> to update your device.

5.8 Identify Software Version

Choose <About> in the <Settings> menu to identify the software version of your device.

5.9 Turning On/Off Bluetooth

VitalsRx has built-in Bluetooth wireless connectivity, which enables exporting measured records from the device to mobile devices.

To turn on the Bluetooth:

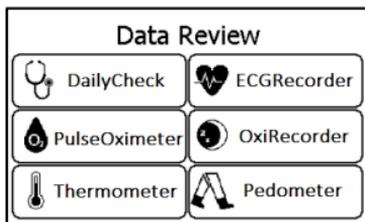
1. Press the Home button to enter Main Screen.
2. Slip your finger from right to left to switch to the second page.
3. Tap the <Bluetooth> icon, then the device will enter Bluetooth mode, and the screen will show the Bluetooth icon in the middle of screen.
4. Pressing the Home button will exit Bluetooth mode.

6. Review

To open the <Data Review> menu,

1. If the device is in Standby Mode, press the Home button.
2. In the Main Screen, tap the <Review> icon.

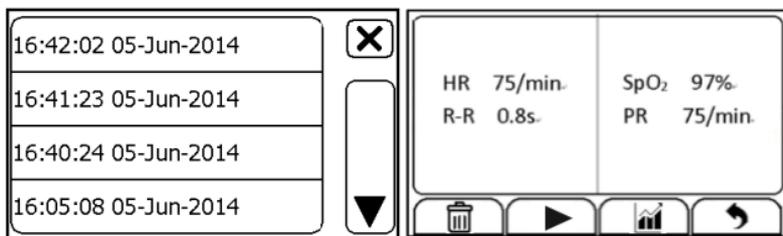




6.1 Review Check Vitals

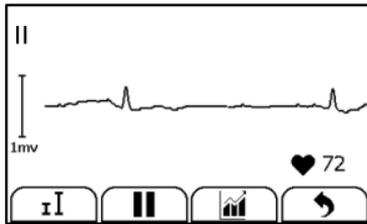
To review Check Vitals records,

1. In the <**Data 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.

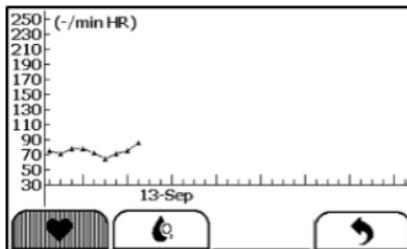


When the ECG waveform is being replayed, you can

- Select **rI** to change the waveform amplitude.
- Select **||** to pause it.
- Select **↶** to return Check Vitals list.

After the ECG waveform is replayed, it will automatically return to the previous interface. Before that, you will hear the voice memo if you added the voice memo for this measurement.

- Select **📈** to view the trend of heart rate, SpO₂.



- Select **↶** to return to the Check Vitals list.

6.2 Review ECG Recorder

To review ECG Recorder records, in the **<Data Review>** menu, select **<ECG Recorder>**.

6.3 Review Oximeter

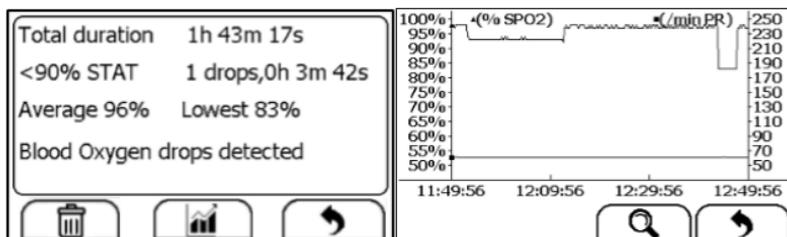
To review Oximeter records, in the <Data Review> menu, select <Oximeter>.

6.4 Review Thermometer

To review Thermometer records, in the <Data Review> menu, select <Thermometer>.

6.5 Review Sleep SpO2

To review the records, in the <Data Review> menu, select <Sleep SpO2>.



6.6 Review Pedometer

To review Pedometer records, in the <Data Review> menu, select <Pedometer>.

Realtime Wireless Display

With Realtime Wireless Display adapter, VitalsRx supports continuously real-time ECG and SpO2 data transfer by Bluetooth. Real-time waveform, HR, SpO2, PI and PR value can be sent to mobile pad.

Please be noted that:

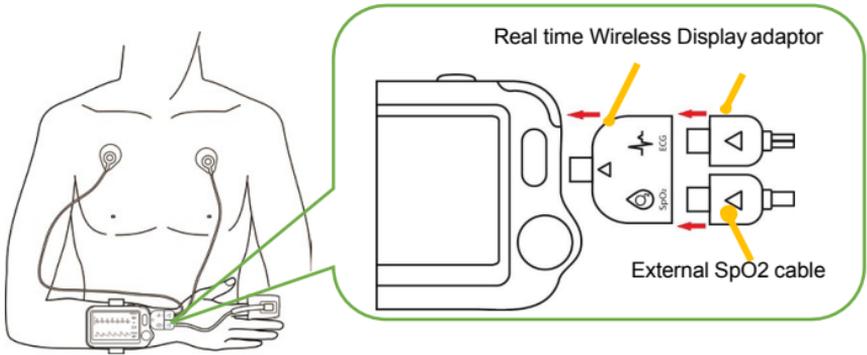
- Realtime Wireless Display adapter is required if you want to use this function.
- Before using this function, please search and download “VitalsRx Realtime Wireless Display” from App Store or Google Play to your pad and make sure that your pad supports Bluetooth 4.0 or above.



To start mini monitor function

1. In the VitalsRx Main Screen, select <Realtime Wireless Display>
2. Connect the “Realtime Wireless Display adapter”, SpO2 cable and ECG cable with VitalsRx device.
3. Put finger into the external SpO2 sensor. Place the ECG electrodes as shown below.

External ECG cable



4. Turn on the Bluetooth on your pad, open <VitalsRx Realtime Wireless Display> app and it will search the VitalsRx device.
5. Choose the device you're monitoring via SN.
6. When the devices are connected, waveform and data will display on both VitalsRx and Pad. Below shows displaying on pad.



7. When you finish measuring, press the Home button to stop monitoring.

7. Maintenance

Warnings

- Have the device repaired by authorized service centers only, otherwise its warranty is invalid.

7.1 Warranty

The product is warranted to be free from defects in materials and workmanship within warranty period when used in accordance with the provided instructions. The warranty extends only to the end user. We will, at our option, repair or replace without charge the product covered by the warranty. Repair or replacement is our only responsibility and your only remedy under the warranty.

7.2 Battery

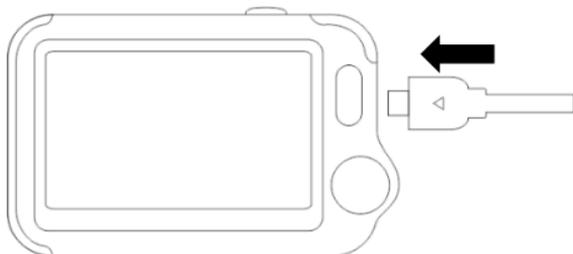
This monitor is designed to operate on rechargeable Lithium-ion battery.

On-screen battery symbols indicate the battery status as follow:

-  The battery is fully charged.
-  The solid portion represents the remained battery energy. If the solid portion moves from left to right, then it means that the battery is being charged.
-  Indicates that the battery is almost depleted and need to be charged immediately. Otherwise the device will shut down automatically.

To charge the battery,

1. Connect the smaller end of the charging cable to the multi-functional connector, as shown below.



2. Connect the other end of the USB charging cable to the USB charging port.
3. Please make sure that the LED is blue, and press the Home button to enter the Main Screen, if needed.
4. When the LED turns to green, it means the battery is fully charged. Then you can unplug the USB cable.

Warnings

- The device cannot be used during charging.
- When choosing a third party USB charging devices, select one that complies with IEC 60950.
- The service life of the battery will depend on the conditions of usage. It support 500 charging / discharging cycles on average.

7.3 Care and Cleaning

Clean the device as demand, carefully swabbing the device surface with a soft cloth or cotton swab with rubbing alcohol. Do not pour alcohol

directly on or into the device.

7.4 Trouble Shooting

Problem	Possible Cause	Solution
The device does not turn on.	<ol style="list-style-type: none">1. The battery may be low.2. The device might be damaged	<ol style="list-style-type: none">1. Charge the battery and try again.2. Please contact with your local distributor.
Low battery indicator is blinking	The battery is low.	Charge the battery and try again.
The ECG waveform amplitude is small	The lead you choose is not suitable for you.	Change another lead and try again.
ECG waveform drifts or disappears and “Touch electrodes properly” displayed.	<ol style="list-style-type: none">1. The pressure exerted on the electrode is not stable or too much.2. Hand or body may be moving.	<ol style="list-style-type: none">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	<ol style="list-style-type: none">1. Finger may not be inserted correctly.2. Finger or hand may be moving.	<ol style="list-style-type: none">1. Remove finger and reinsert, as directed.2. Try to keep perfectly still and test again.
“SpO ₂ cable failed” after inserting SpO ₂ cable.	The SpO ₂ cable might be damaged.	Please contact with your local distributor
“System Error”	Software or hardware	Restart the device and

occurred.	failure.	measure again. If the error persists, mark down the error number and contact with your local distributor.
No voice during ECG and SpO ₂ measurement.	The speaker is muted.	Unmuted the speaker in the Settings menu.
SpO ₂ value is too low when measured using integrated sensor.	<ol style="list-style-type: none"> 1. Finger pressed too hard. 2. Finger may not be inserted correctly. 	<ol style="list-style-type: none"> 1. Reinsert your finger gently and stably. 2. Make sure your finger is in right position.
Temperature value is too low.	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 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.

8. Accessories

Warnings

- Use accessories specified in this chapter. Using other accessories may cause damage to the device or not meet the claimed specifications.

Part Number	Description
540-00758-00	ECG cable with 2 lead wires, snap
540-00193-00	SpO ₂ finger sensor, 25 cm, FP-10

9. Specifications

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	66g (main unit)	
Display	2.7" touch screen, HD	
Connector	Micro D connector	
Wireless connectivity	Bluetooth dual mode, support 4.0 BLE	
Power Supply		
Battery type	Rechargeable lithium-polymer battery 560 mAh	
Battery run time	Check Vitals: > 1000 times Continuous SpO2 Recording: > 12 hours	

	Standby 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
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	External: 0.05 to 40 Hz, Internal: 0.67 to 40Hz * in wide mode
Electrode offset potential tolerance	± 300 mV
HR measurement range	30 to 250 bpm
Accuracy	± 2 bpm or $\pm 2\%$, whichever is greater
Measurement summary	Heart rate, R-R interval
SpO₂	
Standards	Meet standards of ISO 80601-2-61
* Measurement accuracy verification: The SpO ₂ accuracy has been verified in healthy	

adult volunteers by comparing to arterial blood samples measured with a CO-oximeter. Pulse oximeter measurements 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 display range	0% to 100%		
SpO ₂ accuracy (Arms)	Range	Integrated Sensor	External Sensor
	70% to 100%	±3%	±3%
PR display range	30 to 250 bpm		
PR accuracy(Arms)	±2 bpm or ±2% whichever is greater		
Measurement summary	SpO ₂ , PR		
Wavelength / Max emission power	660nm/940nm, 0.8mW/1.2mW		
Thermometer			
Technique	Infrared body temperature		
Environment temperature	16.0 to 40.0 °C		
Measurement site	Forehead		
Measurement range	94.0 to 108.0 °F		
Accuracy	±0.4°F		
Sleep SpO₂			
Continuous recording time	Up to 10 hours		
Data storage	Store SpO ₂ and pulse rate		

Measurement summary	Total duration, <90% STAT, Average saturation, Lowest saturation
Pedometer	
Range	0 to 99999 steps
Distance	0.00 to 999.99 miles
Timer	0 to 1999 minutes
Calories	0.00 to 9999.99 kcal
Fat	0.00 to 199.99 oz
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
Check Vitals	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 SpO2 review	5 pcs of records, 10 hours each record

SpO₂ test summary:

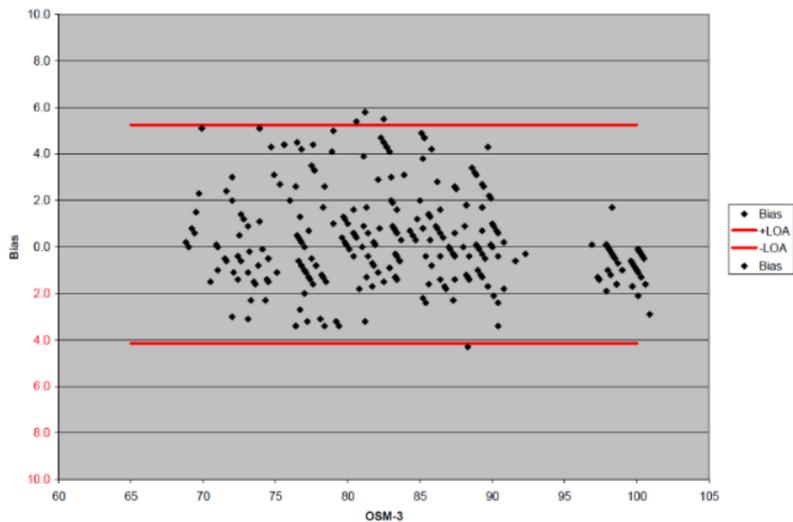
This graph shows plots of the error (SpO₂-SaO₂) by SaO₂ using the VitalsRx Monitor with a linear regression fit and upper 95% and lower 95% limits of agreement. Each sample data point is identified by subject from a clinical study in non-motion conditions. Clinical study was performed using healthy adult subjects.

The device is not intended to be used during motion and therefore testing in accordance with Clause 201.12.1.102 of ISO 80601-2-61:2011 was not conducted. BodiMetrics does not make any claims about the accuracy of SpO₂ measurements under conditions of low perfusion, and therefore testing in accordance with Clause 201.12.1.103 of ISO 80601-2-61:2011 was not conducted.

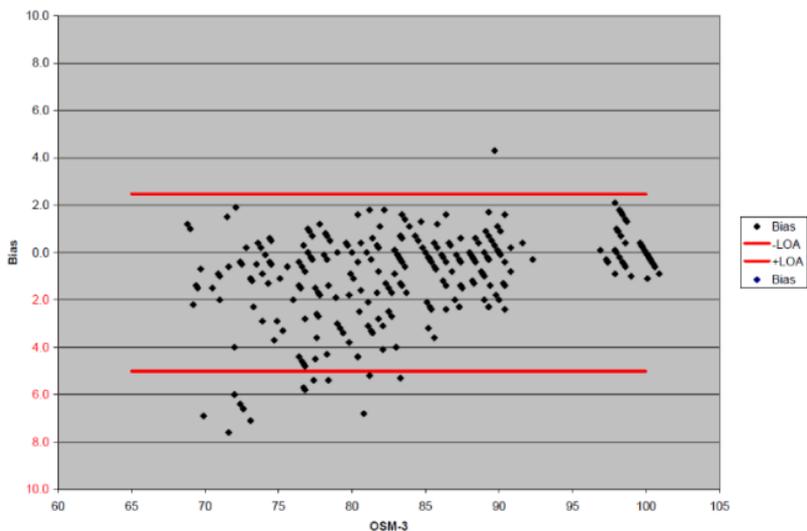
Statistics:

SpO ₂ Accuracy (Arms)	Range	Integrated Sensor	External Sensor(FP10)
	70-80%	2.45	2.26
	80-90%	2.02	1.54
	90-100%	1.76	1.89

VitalsRx Monitor with integrated sensor



VitalsRx with sensor FP10



10. Electromagnetic Compatibility

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

Warnings

- 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 transient/burst fast IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.

	± 1 kV for input/output lines	± 1 kV for input/output lines	
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_i 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
Conducted 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:
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: 800MHz-2.5GHz: 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.

VitalsRx Monitor



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Knowing and Tracking Your Health