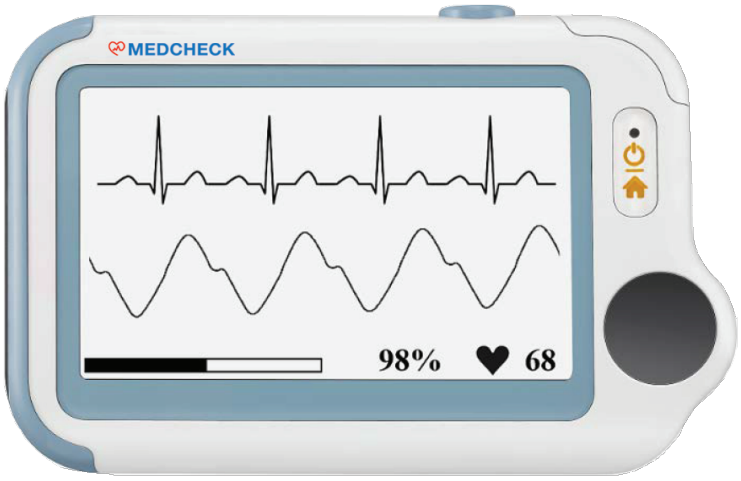
VITAL SIGNS MONITOR

THE COMPLETE MANUAL TO MEDCHECK'S VITAL SIGNS MONITOR



VITAL SIGNS MONITOR MANUAL BY SMARTFUTURE PTE LTD

CONSISTING OF

DEVICE MANUAL

APPLICATION MANUAL

MEDCHECK

DISCLAIMER

This manual and product are not meant as a substitute for advice provided by your doctor. You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

INTENDED USE

The Vital Signs Monitor is intended to be used for measuring, displaying, reviewing and storing of multiple physiological parameters including ECG, pulse oxygen saturation (SpO2), pulse rate, temperature and blood pressure variation in home or healthcare facilities environment.

ECG and Blood pressure variation 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.

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Warnings and Cautionary Advices

▸ 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 SpO2 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.

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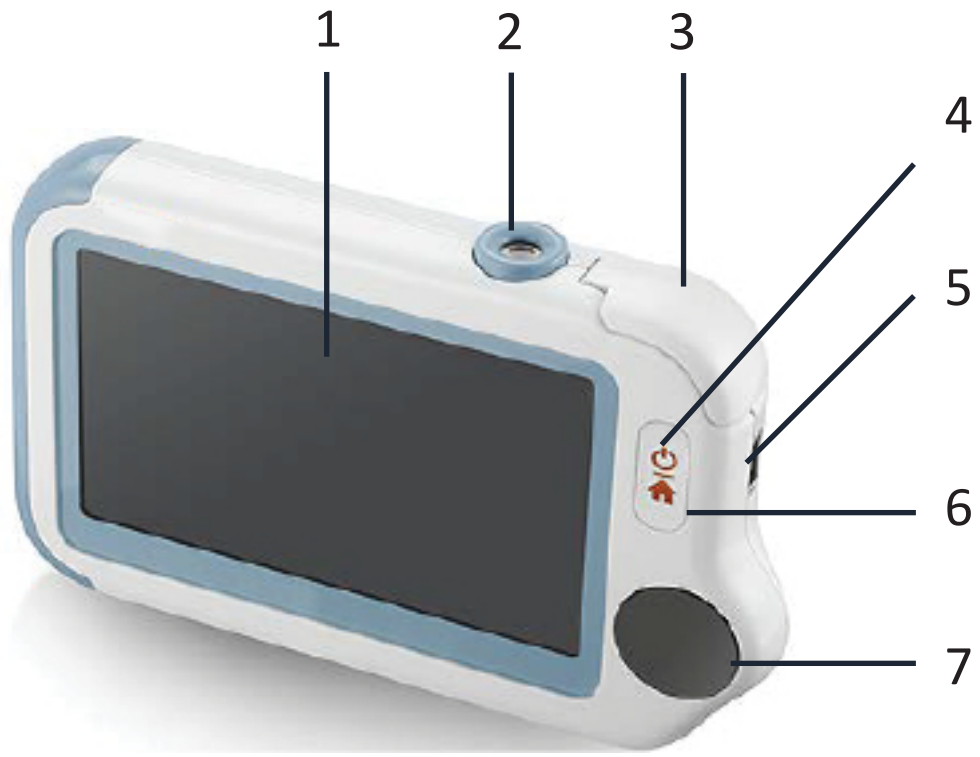
DEVICE OVERVIEW



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: the battery is low;

5. Multi-functional 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, press this button will switch to Main Screen, or Calendar Screen, or return to upper menu.

7. ECG right electrode

Rest right thumb against it.

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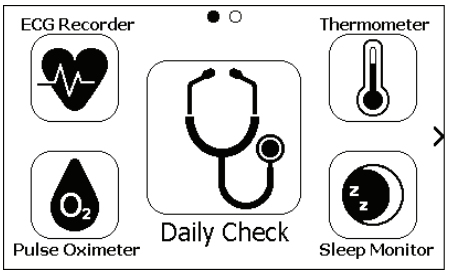
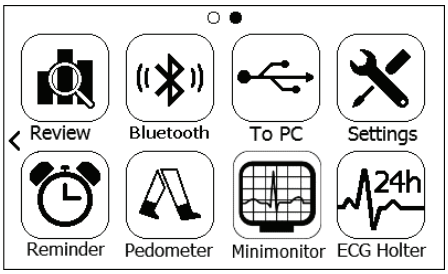
DEVICE OVERVIEW

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.

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.





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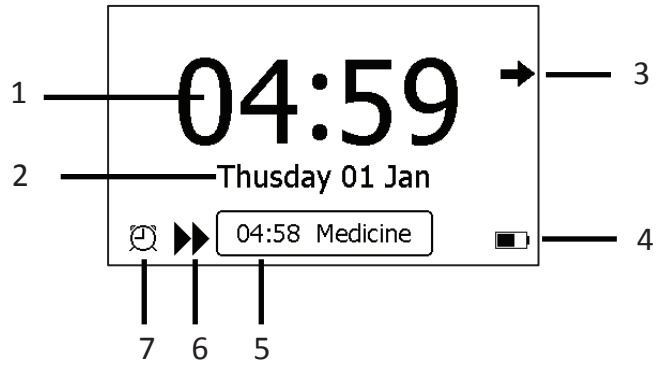
DEVICE OVERVIEW

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.

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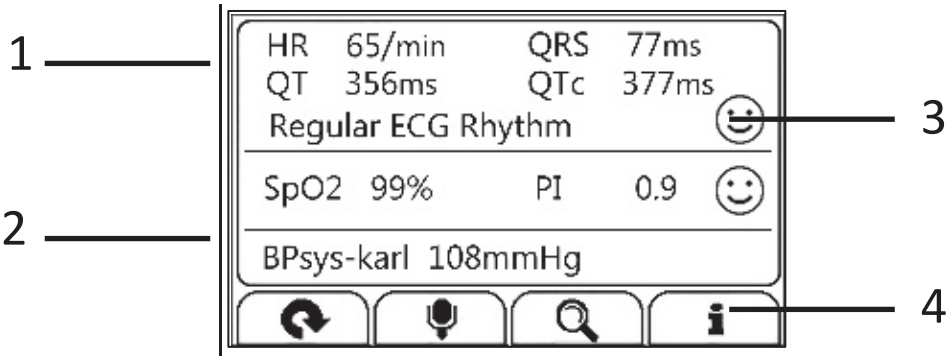
DEVICE OVERVIEW

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.

▸ Press and hold the button to add voice memo. Voice memo is only available for Daily Check and ECG Recorder measurements.

▸ Select button to review previous results.

▸ Press button to open the help information.

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SYMBOLS DEFINITIONS

SYMBOLS	DEFINITIONS
	Application part type BF
	Manufacturer
CE0197	In conformity with Directive 93/42/EEC
	European Representative
	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 ≥12.5mm diameter, Against dripping(15° tilted)
	Follow operating instructions
	No alarm system.

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 Advices

▸ 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.

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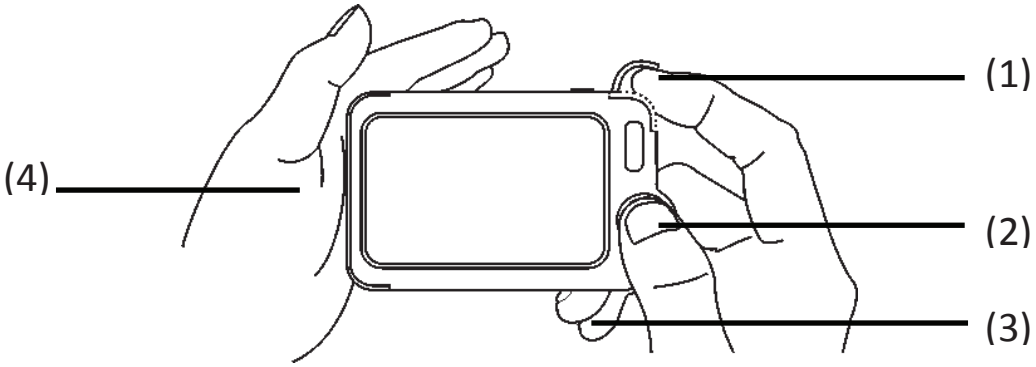
DAILY CHECK

Daily Check measurement is a function that combines the measuring of ECG (Electrocardiograph), SpO2 (blood oxygenation) and systolic blood pressure. It takes only 20 seconds to collect your vital signs before giving you vital signs readings and your health evaluation.

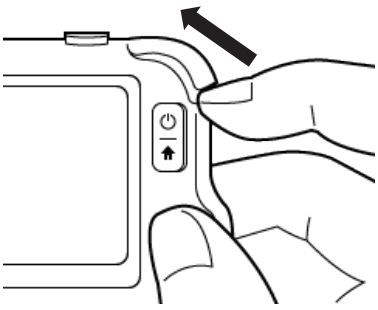
Using Daily Check

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 SpO2 sensor. Just fit it inside but gently to ensure good blood perfusion.



(1) Put the right forefinger into the built-in SpO2 sensor. Use the finger nail to squeeze the edge of the SpO2 sensor cover, then move in upward to the left to raise it up as shown below.



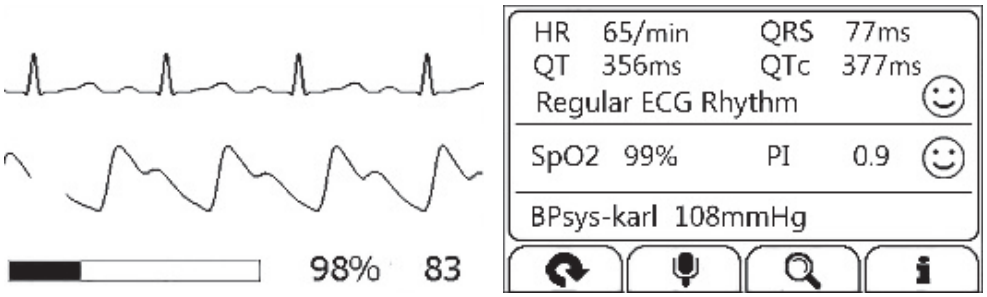
(2) Press the right thumb on the right electrode.

(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.

MEDCHECK



Daily Check provides the trending graph of heart rate, SpO2 and blood pressure. To view the trend, tap the button, then select one record, and then tap the button.

BP Calibration

Warnings and Cautionary Advices

▸ For a given user, it is suggested to make BP calibration every three months.

To get blood pressure readings, this device should be calibrated by a doctor with a traditional cuff blood pressure (BP) meter. Because of individual differences, each user must make his/her own calibration before using Daily Check to measure or track the blood pressure. The calibration should be performed when the user is under calm status.

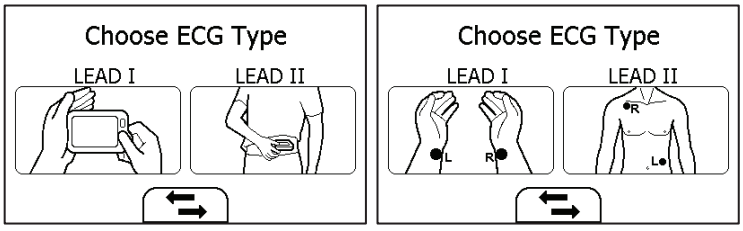
To calibrate with a cuff BP meter, follow the steps as below.

1. Select the **<Settings>** icon, select **<BP Calibration>**, and then choose the right user.
2. Ensure that the cuff and the Vital Signs Monitor are at the same level as your heart. Then start the blood pressure measurement from the cuff BP meter.
3. Press the ▶ button on thescreen, and start the DailyCheck measurement.
4. When the blood pressure measurement is finished, manually input the readings of systolic pressure.
5. Repeat the calibration once again by following the above steps.

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.

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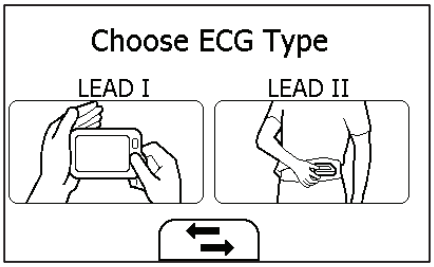
Method A and B offer maximum comfort, than method C and D, but no ST segment value. No matter which method you choose to measure ECG, please keep stable posture and stay calm during the measurement.

Measuring without Cable

To start an ECG Recorder measurement without cable,

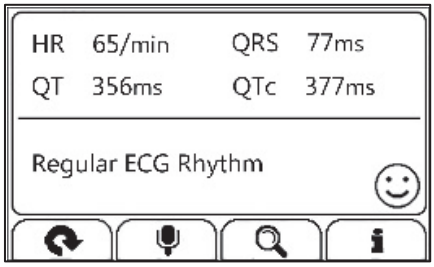
1. Choose the method A or B.
2. Follow the instruction according to the mode you selected.



- ▸ 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.



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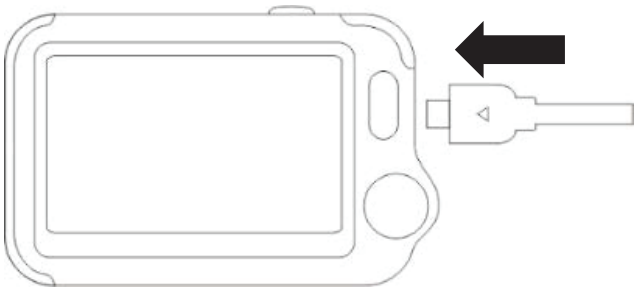
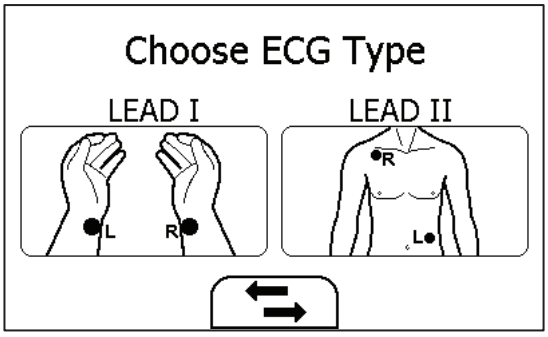
Measuring with Cable

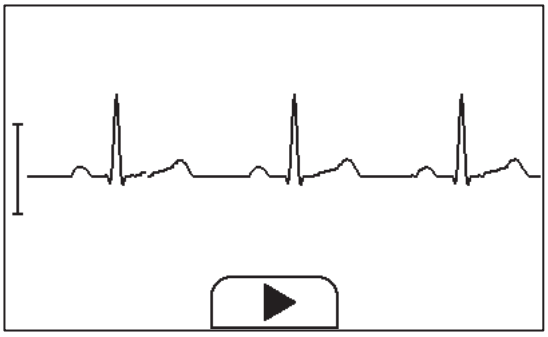
To start an ECG Recorder measurement with cable,
1. Choose the method C or D.
2. Follow the instructions to connect the ECG cable and place the ECG electrodes.



- ▸ 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.

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Temperature

About thermometer

Warnings and Cautionary Advices

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.

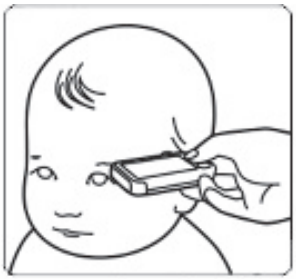
▸ Environmental temperature;

▸ 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.

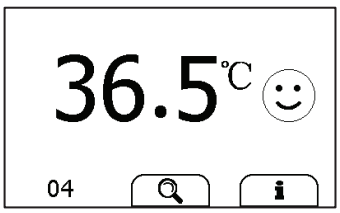
Taking Temperature Measurement

To start a temperature measurement,
1. In the **Main Screen**, select **<Thermometer>**.
2. Put the thermometer sensor on your temple.



Put sensor on temple, click button then scan to forehead until you hear a beep

3. 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.
4. 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).

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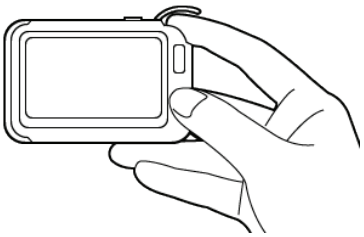
Oximeter

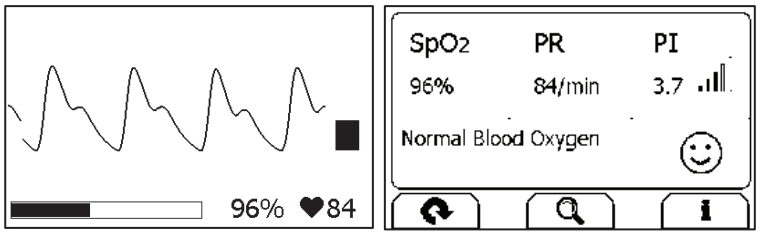
The Vital Signs Monitor measures the amount of oxygen in your blood, your pulse rate and pulse index. The oxygen saturation (SpO2) is measured and displayed as a percentage of full capacity.

Measuring without Cable

To start a Oximeter measurement without cable,
1. In the Main Screen, tap the **<Pulse Oximeter>**
2. Insert the forefinger into the built-in SpO2 sensor as shown below.

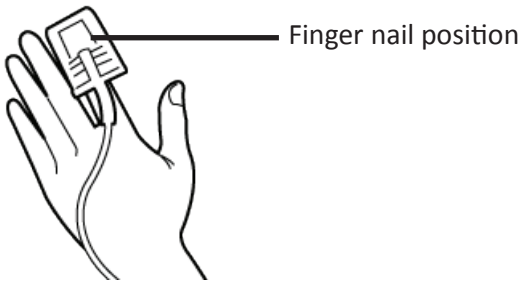


3. When the device detects stable waveform, it will automatically start the measurement. The countdown bar moves from left to right.
4. When the bar is fully filled, the device will analysis your data, and then show the measurement result.

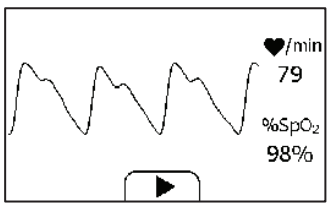


Measuring with Cable

1. Connect the external SpO2 sensor to the multi-functional connector.
2. Put your index finger or middle 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. Tap the **<Pulse Oximeter**> icon.
4. The display will then show your PLETH waveform, SpO2 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 SpO2 data. The countdown bar move from left to right.
6. When the bar is fully filled, the device will analysis your data, and then show the measurement result.

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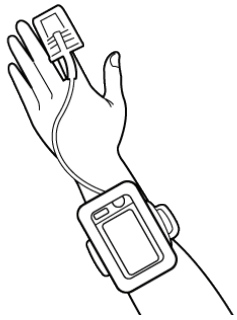
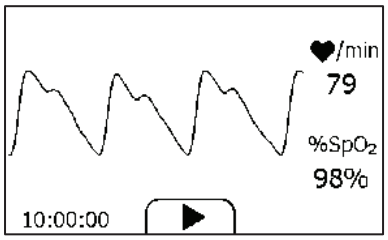
Sleep Monitor

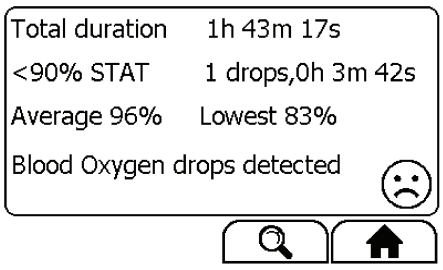
Vital Signs Monitor offers a non-invasive method to monitor sleep status for adult users who have sleep problem, sleep related breathing disorders and obstructive sleep apnea.

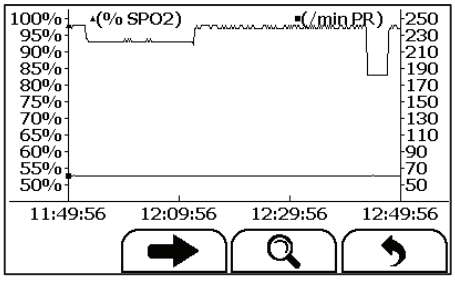


To start a sleep monitor measurement,
1. Tie the wristband on one of your left hand.
2. Insert the SpO2 cable into the multi-functional connector.
3. Put one of your finger into the sensor. Forefinger or middle finger is suggested. If needed, remove the colored nail polish from the finger. Make sure 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 SpO2 trending during your sleep, or tap “Close” button and return to the Main Screen.





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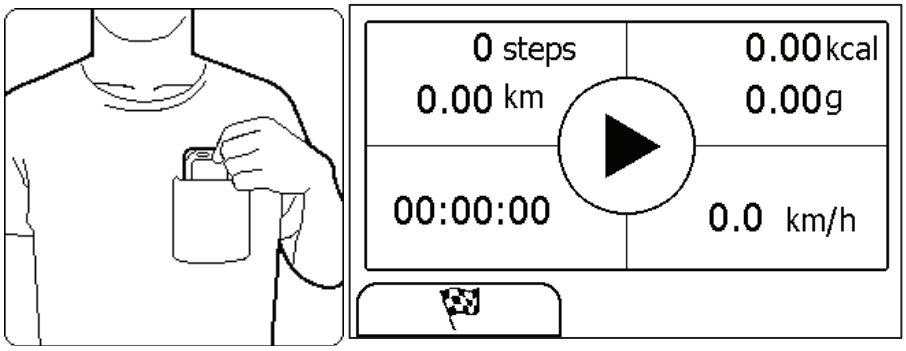
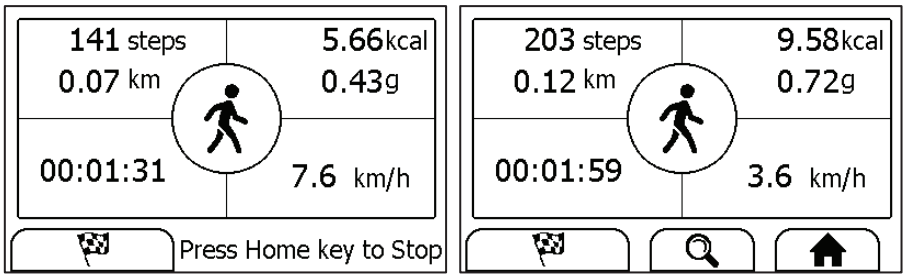
Pedometer

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.



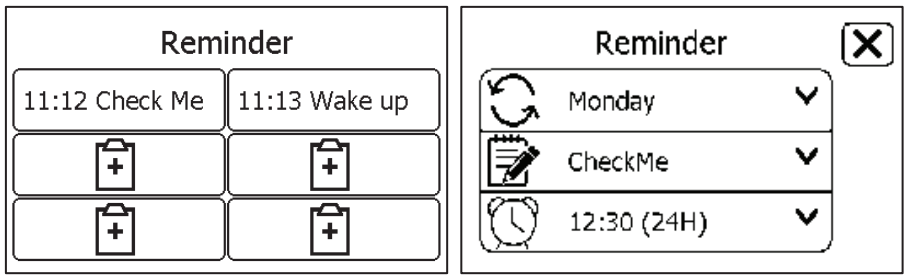
3. Tap the button to set your target, if needed.
4. Tap the button to start calculating steps.
5. Place the device into your pocket.
6. When you finished calculating steps, press the Home button to stop the pedometer.



7. Press Home button again to exit pedometer function.

Reminder

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



MEDCHECK

Settings

Changing Sound Volume

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

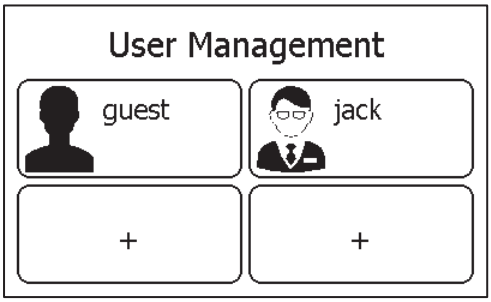
Enabling/Disabling Voice Guide

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

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.

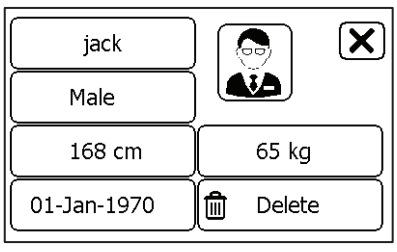
To create a user account:
1. In the Settings menu, choose <User Management>.



2. Tap a “+” button to open the menu below.
3. Tap each button to edit corresponding information.
4. Tap “X” to return to **< 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 to 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.

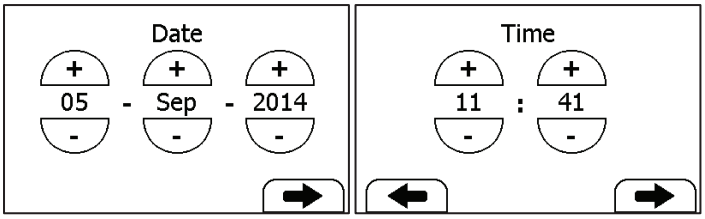


4. Choose **<Yes>** to confirm.

MEDCHECK

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.



Choosing Language

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

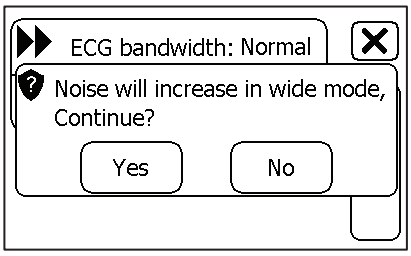
Changing ECG waveform length

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.

Setting ECG Bandwidth

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



MEDCHECK

Erasing Data

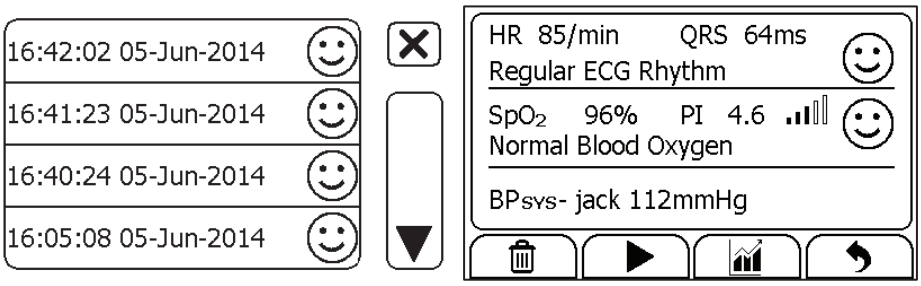
In the Setting menu, Tap **<Erase All Data>**, and then **<Yes>**.
All measurements saved in the device will be deleted.

Factory Reset

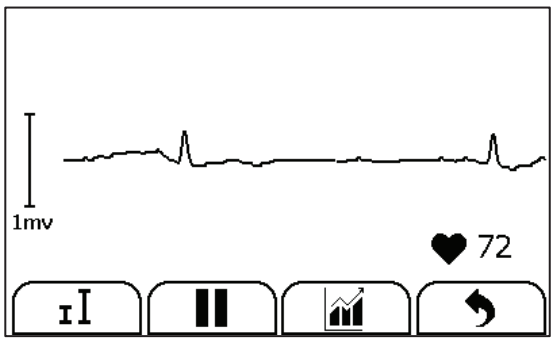
In the Setting menu, tap **<Factory Reset>**, then tap **<Yes>**.
All measurements, user information and other settings saved in the device will be deleted, and the device will be restored to the factory default settings.

Review

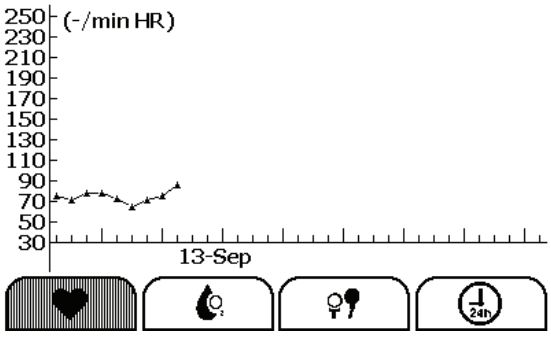
Reviewing Daily Check
To review Daily Check records,
1. In the **<Review>** menu, select **<DailyCheck>**.
2. Choose the right user to open the list as below, then select one record to review more information as below.



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, SpO2 and blood pressure.



▸ Select to return to the Daily Check list.

MEDCHECK

Maintenance

Care and Cleaning

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

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.
The app cannot find the device.	The Bluetooth may not be turned on.	Turn on the Bluetooth on the second page of Main Screen.
“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.

MEDCHECK

Accessories

Warnings and Cautionary Advices

▸ 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 leadwires, 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
540-00354-00	Minimonitor adaptor

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%	

MEDCHECK

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 range	70% to 100%
SpO Accuracy (Arms)	80-100%:± 2%, 70-79%:± 3%
PR range	30 to 250 bpm
PR accuracy	± 2 bpm or ± 2%， whichever is greater

MEDCHECK

PI range	0.5-15
Measurement summary	SpO_2, PR, PI, Summary (Normal Blood Oxygen, Low Blood Oxygen, Unable to analyze)
Blood Pressure Variation	
Measurement method	Cuff-free non-invasive technology
Measurement summary	Systolic pressure based on individual calibration coefficient
Thermometer	
Technique	Infrared body temperature
Environment temperature	16.0 to 40.0 °C
Measurement site	Temple
Measurement time	3s
Measurement range	34.0 to 42.2 °C (94.0 to 108.0 °F)
Accuracy	±0.2°C or ±0.4°F
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
Mobile APP	
Operating system	IOS 7.0 or above, Android 4.4 or above
IOS Capability	iPhone 4s and models launched subsequently; iPad 3 and models launched subsequently;
Android Capability	Mobile phone or tablet with Bluetooth 2.1 or above
Functionality	Data export, data review, waveform replay, trend review, data sharing

* : 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

MEDCHECK

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 Advices

▸ 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.		

MEDCHECK

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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: $d = 1.2\sqrt{P}$

MEDCHECK

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.