

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUP-PORTING

Recommended separation distances between portable and mobile RF communications equipment and the HC-03			
The HC-03 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HC-03 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HC-03 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmittre(W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=\frac{3.5}{\sqrt{1}}\sqrt{P}$	80 MHz to 800 MHz $d=\frac{3.5}{\sqrt{E1}}\sqrt{P}$	800 MHz to 2.5 GHz $d=\frac{7}{\sqrt{E1}}\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above the recommended separation distance d in 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.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electro-magnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

General description

Thank you for using this Health Monitor. Please read this User Manual carefully in order to use the medical device safely and correctly.

Intended Use

Health Monitor is intended to be used for measuring, displaying and storing of body temperature, blood pressure and pulse rate in the home or in healthcare facilities.

The device obtains the body temperature by measuring the forehead area.

The device obtains the blood pressure by measuring the upper arm site.

The device can not be used for self–diagnosis.

This product should not encourage self–medication or adaptation of the treatment.

Always consult the doctor if the patient has any questions or he believes he has abnormal measurements.

Blood pressure measurement isn't used for neonatal or children under 12 years old.

Body temperature measurement isn't used for neonatal or children under 5 years old.

The operator must be able to read English.

Functions

Health Monitor is the wireless device which depends on the bluetooth for signal transmission and needs to be combined with a mobile phone application. The product through infrared sensors, pressure sensors to collect the test requirements of body temperature, blood pressure and pulse rate information, and through Bluetooth to transfer information to the phone application to display. The users can observe the temperature, blood pressure, pulse rate and history measurement records in the mobile phone application. The users can also set the temperature measurement, blood pressure measurement, history record and other function according to their demand.

Contraindications

- ◆ Please children or those who can't express themselves do not use the device.
- ◆ Do not use the device on body part with injury and skin infection.
- ◆ Please use under the guidance of doctor for those who have disturbance of blood circulation or blood disease.

- ◆ Self measurement for blood pressure is not suggested for those with high psychic anxiety.
- ◆ Blood pressure measurement isn't used for neonatal or children under 12 years old.
- ◆ Body temperature measurement isn't used for neonatal or children under 5 years old.
- ◆ This device does not apply to the ICU.

Product Composition

Health Monitor is composed with noumenon, cuff and mobile-phone application program.

Noumenon is mainly composed of PCB, Plastics, Rechargeable Lithium-Ion Battery, Pump, etc.

Product specification and performance characteristics

Product name	Health Monitor	Product Model	HC-03
Software	Health Monitor	SW Version	V0.0.10
Battery Nominal Voltage	3.7V	Input Voltage	5V±0.25V
Battery Rated Capacity	400mAh	Size	70mm×70mm×18.4mm
Working frequency	2.4000-2.4835GHz	Net Weight	about 70g
Communication Protocol	Bluetooth 4.0	Resting pressure rated range	0-300mmHg
Validity period of product	3 years	Validity period of cuff	2 years
Lifetime of battery	charge-discharge cycles 300 times		
Blood pressure measurement		Body temperature measurement	
Measurement body part	Upper arm	Measurement body part	Forehead
Applied arm circumference of cuff	22-35cm	Measurement scope	28-42 C
Measurement scope of systolic pressure	60-230mmHg	Measuring error	±0.2 C, for 35-42 C ±0.4 C, for <35 C
Measurement scope of diastolic pressure	40-130mmHg	/	/
Pressure error	±3mmHg	/	/
Measurement scope of pulse rate	40- 180bPm	/	/
Pulse rate error	± 5%	/	/
Working condition		Storage/Transport condition	
Temperature	5 C~40 C	Temperature	-25 C~+70 C
Humidity	15%~93%	Humidity	≤93%
Atmospheric Pressure	70-106 kPa	Atmospheric Pressure	50-106kPa

Guidance and manufacturer's declaration– electromagnetic immunity – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

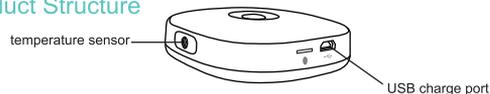
Guidance and manufacturer's declaration – electromagnetic immunity			
The HC-03 is intended for use in the electromagnetic environment specified below. The customer or the user of the HC-03 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V (V1)	Portable and mobile communication equipment should be used no closer to any part of the HC-03, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \frac{3.5}{\sqrt{f}} \sqrt{P}$ $d = \frac{3.5}{\sqrt{f}} \sqrt{P}$ 80 MHz to 800 MHz $d = \frac{7}{\sqrt{f}} \sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m (E1)	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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic 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 HC-03 is used exceeds the applicable RF compliance level above, the HC-03 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HC-03. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.			

1	Guidance and manufacturer's declaration – electromagnetic emission	
2	The HC-03 is intended for use in the electromagnetic environment specified below. The customer or the user of HC-03 should assure that it is used in such an environment.	
3	Emissions test	Compliance Electromagnetic environment - guidance
4	RF emissions CISPR 11	Group 1 The HC-03 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.
5	RF emissions CISPR 11	Class B
6	Harmonic emissions IEC 61000-3-2	Class A
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies The HC-03 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.

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS.

Guidance and manufacturer's declaration – electromagnetic immunity			
The HC-03 is intended for use in the electromagnetic environment specified below. The customer or the user of the HC-03 should assure that it is used in such an environment.			
Immunity test	EN 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 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 differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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 sec	<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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HC-03 requires continued operation during power mains interruptions, it is recommended that the HC-03 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m	400A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Product Structure



Product Safety Class

Protection against electric shock	Class II
APPLIED PARTS	BF
Protection against harmful ingress of water or particulate matter	IP22
Mode of operation	NOT-CONTINUOUS OPERATION
Used in an OXYGEN RICH ENVIRONMENT	Not intended for using in OXYGEN RICH ENVIRONMENT

Applied mobile phones(NETWORK/DATA COUPLINGS)

Health Monitor shall be used together with application program in mobile phones. The mobile phone shall satisfy the following 2 requirements.

1. Bluetooth 4.0
2. Android 4.3 or higher version, iOS 7.0 or higher version.

Package List

Health Monitor ×1	Cuff ×1	User Manual×1
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Accessories list

Cuff (XD-01) ×1	USB line ×1
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Battery Charging

The color of battery icon on APP means electric quantity status.

Red: The battery is near to exhausting	Yellow: Low power of battery
Green: Sufficient power of battery	Blue: Full power of battery

⚠ Cautions for battery charging

- ◆ Please charge timely when low power caution appears on APP.
- ◆ Power light is blue and flickering during charging.
- ◆ Do not use the device during charging.

Power on/off

- ◆ Power on: press power key 2 seconds. The device shakes slightly. Power on is successful with blue power light.

- ◆ Power off: press power key 2 seconds. The device shakes slightly.
Power off is successful with power light off.

APP Download

Log in <http://www.foinoe.com> , click“download center” to download the APP.

Device Connection

- ◆ Press power key and hold 2 seconds to power on.
- ◆ Open the APP. The device will connect to APP automatically with appearing of electrical quantity icon on APP.
- ◆ If the electrical quantity icon is not shown on APP, click the Bluetooth icon to set up the connection manually.



Cautions for using APP

1. Confirm the system specification in mobile phone comply with the requirements before downloading the APP.
2. In order to set up the automatic connection between mobile phone and device, the device shall be powered on before logging in APP.
3. Most of malfunctions could be solves after rebooting device and APP.

Trouble shooting

Malfunctions	Reason	Solution
Failure of downloading APP	Mobile phone is not satisfy the requirements	Check the version of Bluetooth and system of mobile phone.
Failure of automatic connection	Wrong operation sequence	Power on the device firstly, then log in APP. Or connect manually.
Failure of connection or finding the device	Weak sensitivity of Bluetooth of mobile phone	Restart the device and re-log in the App.

Instruction for blood pressure measurement

Blood pressure measurement will be influenced by body posture, wearing method of cuff, physical condition, surrounding environment. The position of cuff and heart shall be kept at a same horizontal level during measurement.

1. Keep calm for 5 minutes before measurement. Do not speak or talk during measurement to avoid influence on accuracy. Arm shall be kept naked or dressed with thin cloth.
2. Power on the device and buckle in the cuff correctly. Tie up the cuff 1-2 cm upper elbow joint. Degree tightness should be comfortable.

The guarantee is not applied for below conditions.

1. Any non-artificial damages, and damages or malfunctions caused by using under abnormal working environment, by not following the instruction for use, or by not using the device under specified environment.
 2. Disassembly, repair or change the device by yourself without agreement with manufacturer.
 3. Damage caused by improper transportation after purchase.
 4. Damage caused by force majeure (e.g. flood, thunder strike, earth quake, abnormal voltage, etc)
 5. Normal wear and other conditions not influencing normal operation.
 6. Purchase from unauthorized channel by Foinoe .
- This guarantee clause is only applied for the device itself.

Symbol Definition

	Product serial number		Expiry date
	Manufacturer		Batch number
	Date of manufacture		Characters of "Catalogue number"
	European union authorization representative		Temperature Limit
	Part recycled separately from other waste		Characters of "Keep away from sunlight"
IP22	Protection grade		Characters of "Keep dry"
	Follow "Instructions for use"		Characters of "Do not use if package is damaged"
	BF type		Class II device
CE	CE mark		Caution



EMC Declaration

Guidance and manufacturer's declaration– electromagnetic emission– for all EQUIPMENT AND SYSTEMS.

- ◆ Keep the device away from places which could cause slant, shaking and impacting.
- ◆ Keep the device away from places with chemicals or corrosive gas.
- ◆ Do not fall the device from height.
- ◆ Do not fold the cuff tightly.

Please do the repair with following methods.

- ◆ Do not disassemble or repair by yourself. Please dial customer service hotline for consultation due to product quality issues or any doubts for measurement results.
- ◆ The cuff is specified for the device. Please contact manufacturer for repair or purchase. Do not change by yourself.
- ◆ The repair can only be done by authorized persons.

Clean and disinfection

- ◆ Please clean by using soft dry cloth.
- ◆ When the device is very dirty, water or neutral agent could be used but twist before cleaning.
- ◆ If necessary degreasing cotton with ethanol could be used for disinfection.

Environment protection

The handling of the device, cuff or waste battery refers to the local regulation. Please do not discard it casually.

After-sales Guarantee

1. If malfunctions happen within 7 days after selling, consumers could select refund, exchange goods, or repair. Free repair is provided for non-artificial damage within 1 year after selling. For the reasonable requests outside the free exchange or repair, technical service is provided with charging of material, repair and service.
2. Purchase date is determined by the invoice issued by manufacturer or authorized dealer.

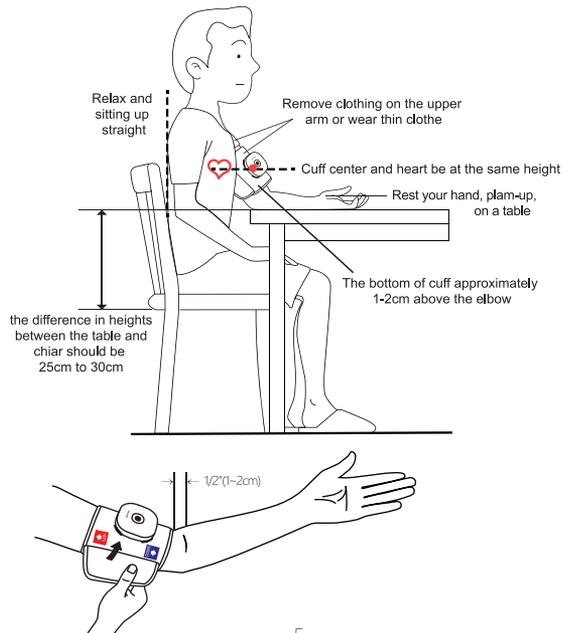
3. Sit up straight. Keep limb positioned on a stable table or platform with proper height. Keep the palm up and relaxed. The position of cuff and heart shall be kept at a same horizontal level during measurement.

4. Open the APP. The device can connect to APP automatically or manually with appearing of electrical quantity icon on APP. After the device connects to APP successfully, select blood pressure in App interface and click "Start". The cuff will be inflated and measurement will be started. Keep calm during measurement.

5. System will stopped automatically after measurement. The measured value will be shown.

6. Take off the cuff and clear up.

Do not evaluate the result only by your own experience. Please consult the doctor.



Trouble shooting

Malfunctions	Reason	Solution
Low reading	Wrong wrapping of cuff Moving, speaking, or wrong sitting posture during measurement	Wrap the cuff correctly. Adjust the sitting posture, keep calm during measurement Please refer to user manual for operation details.
Failure of inflating	Air leakage of cuff or wrong position of device	Re-position the device. Contact the manufacturer for replacing the cuff if cuff is broken.
Failure of measurement	Wrong position of device, or inadequate power	Check the position of device by referring to user manual. Check the power quantity. Charge timely due to low power. Please refer to user manual for operation details.

Calibration of blood pressure by using static pressure

HC-03 is based on oscillometry, which means the blood pressure calculated is accurate only if the static pressure is accurate. Therefore, in order to calibrate the blood pressure, static pressure should be calibrated. FLUCK BP Pump 2 Blood Pressure Simulator is used to calibrate the static blood pressure.

Calibration process:

1. Use airway tube to connect HC-03 and FLUCK BP Pump 2.
2. Press CUFF and select Internal.
3. Press Option and select static pressure of 0~300mmHg.
4. Run the APP to connect HC-03. Enter engineering test mode by inputting engineering code.
5. Select static pressure test item HC-03 closed pressure on APP.
6. Press Start button on FLUCK BP Pump 2 to start the inflation. The inflation will be stopped automatically when the pressure reach the setting.
7. Compare the static pressure value on FLUCK BP Pump 2 and APP. The gap shall be smaller than $\pm 3\text{mmHg}$.

- ◆ When common arrhythmia (e.g. APB, VPBs, Af) appears, measured value may be incorrect, or measurement may be failed.
- ◆ The high blood pressure referred is $\geq 135/85\text{mmHg}$.
- ◆ Keep forehead clean before body temperature measurement.
- ◆ Do not keep the detector head contacting skin of forehead.
- ◆ Try to measure in the stable environment. Do not measure near to the air outlet of fan or air conditioner, or in the place with directional sunshine.
- ◆ The body temperatures are different for different time and body parts. The deviation of $0.2\text{ }^{\circ}\text{C}$ for same body parts is reasonable.

Maintenance



Do not do servicing and maintenance while the device is in use. Please do the maintenance with following methods.

- ◆ Do not wash the cuff with water. Clean with soft and clean fabric.
- ◆ Do not scrub the device with wet fabric since the device is not water-proof.
- ◆ Fabric stained with neutral detergent or water could be used for cleaning. The fabric shall be twisted before cleaning. If necessary degreasing cotton stained with ethanol could be used for disinfection.
- ◆ Keep the device away from fire or heat source since it contains battery and electronic components.
- ◆ Calibration is suggested to be conducted every 2 years, although strict test is finished for each function before delivery. Please contact manufacturer when calibration is needed.
- ◆ Do not disassemble or repair by yourself. Please dial customer service hotline for consultation due to product quality issues or any doubts for measurement results.

Please do the storage with following methods.

- ◆ Keep the device away from high temperature, moist, direct sunshine, dust, salty air.

The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Cautions

- ◆ Please relax at least 5 minutes before measurement. Do not feed, drink alcohol or coffee, exercise, bath, and etc 30 minutes before measurement.
- ◆ Please relax as much as possible and not talk during the measurement procedure.
- ◆ Use the device in the specified environment, otherwise the result might be affected.
- ◆ Do not use the device in vehicle while moving.
- ◆ The result of blood pressure measurement can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition.
- ◆ The result of blood pressure measurement might be affected by the environment, such as temperature, humidity and altitude.
- ◆ Do not measure the same arm continuously. If several times measurements are needed, the interval between two measurements shall be more than 30s.
- ◆ Too frequent blood pressure measurements can cause injury to the PATIENT due to blood flow interference.
- ◆ Inflating cuff may cause discomfort for arm during measurement. Do not use it measure blood pressure for whose arm injured.
- ◆ Blood pressure measurement can not be used for the same arm as other monitor equipment at the same time.
- ◆ The cuff is dedicated for the device. Do not disassemble and replace by yourself. Please contact manufacturer when needed.
- ◆ Do not keep limb pressured by cuff for a long time. Risk of resulting harm to arm exists while cuff is inflating continuously. Please take off the device directly from cuff while the inflating is not stopped automatically.

Instruction for body temperature measurement

1. Power on the device and open the APP. The device can connect to APP automatically or manually with appearing of electrical quantity icon on APP.
2. Keep forehead dry and clean. Take the device and align the infrared detection head to the center of forehead. Keep the device 1–2cm away from skin.
3. Select “Temperature” in App. Click “Start” for measurement.
4. System will stopped automatically after measurement. The measured value will be shown.



Trouble shooting

Malfunctions	Reason	Solution
Big measurement error	sweat, water, oil and etc on forehead	Clean the forehead before measurement.
	Wrong measurement distance	Keep 1-2cm distance between detector head and forehead.

Warning — General

- ◆ Please read this User Manual carefully in order to use the medical device safely and correctly.
- ◆ Please use the device in the specified environment. Do not use the device under environment with strong electromagnetic interference or high frequency surgical equipment.
- ◆ Contact the manufacturer when facing a damage or malfunction. Do not disassemble or repair the device by yourselves.
- ◆ Do not disassemble or modify the device by yourselves.
- ◆ Do not use when the device maintenance.
- ◆ Do not place the device in the environment with strong acid or alkali. Otherwise the lifetime and measurement accuracy of the device may be affected.
- ◆ The APP of device is applied for smartphone with Bluetooth 4.0, Android 4.3 or higher version, iOS 7.0 or higher version. Please confirm your smartphone is complied with the requirements beforehand to avoid damaging the smartphone.
- ◆ Keep the device away from fire or heat source since it contains battery and electronic components.
- ◆ Children shall use the device under guardians' monitor. Place the device in the position which children can not touch since the device contains small components.
- ◆ Do not calibrate by yourselves. The calibration is done before delivery. Please contact manufacturer when calibration is needed.
- ◆ Do not operate the device out of the scope of specified measurement temperature. Otherwise the performance could be affected.
- ◆ Do not store and transport the device out of the scope of specified environmental temperature and humidity. Otherwise the performance could be affected.
- ◆ The device's performance could be affected when the optical component is damaged or polluted.
- ◆ The device's performance could be affected when the device is vibrated or crashed.

- ◆ Charger, mobile displayer with bluetooth and health monitor contribute a ME (medical electrical) system.
- ◆ An ME SYSTEM shall provide:
 - within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and
 - outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.
- ◆ Please use the charger complying with IEC60601-1 or other relative electrical standards (e.g. IEC60950). Otherwise there could be the risk of electrical shock.
- ◆ The mobile devices such as mobilephone connected to Health Monitor shall have a protection level of IP22 at least.
- ◆ Please use the accessories such as cuff and cable specified by manufacturer. Otherwise it could lead to inaccurate measurement or damage to device.
- ◆ Stop using the device and contact after-sales service when finding the performance is changed.

Warning — EMC(Electromagnetic Compatibility)

- ◆ The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.
- ◆ The portable and mobile RF communications equipment can affect the device.
- ◆ The minimum amplitude or value of PATIENT physiological signal :
 - Measurement scope of systolic pressure: 60-230mmHg
 - Measurement scope of diastolic pressure: 40-130mmHg
 - Measurement scope of temperature: 28~42 COperation of the device below this amplitude or value may cause inaccurate results.
- ◆ The use of accessories and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the device as replacement parts for internal components, may result in increased emissions or decreased immunity of the device.

Health Monitor

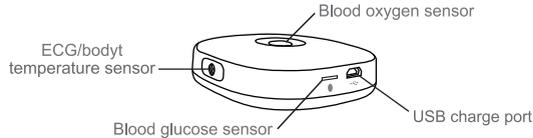
User Manual



Instruction for New function

Intended Use

Health Monitor is also intended to be used for measuring, displaying and storing of blood oxygen, ECG, heart rate and blood glucose in the home or in healthcare facilities.

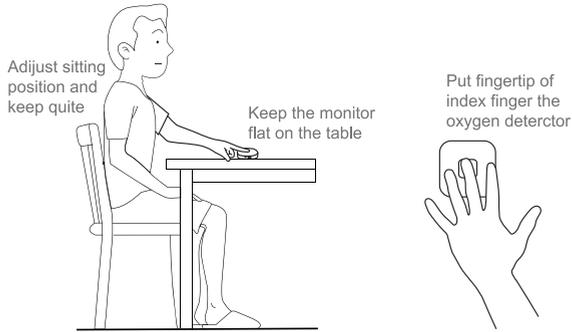


Product specification and performance characteristics

Product name	Health Monitor	Product Model	HC-03
Blood oxygen measurement		ECG measurement	
Measurement body part	Finger	Measurement body part	Hands (handheld)
Measurement scope	70%~100%	Calibration voltage	1mV±5%
Measuring error	±4% for 70% to 80% SaO ₂ .	Sensitivity error	≤±5%
	±2% for 80% to 90% SaO ₂ .		
	±1% for 90% to 100% SaO ₂ .		
Red light wavelength	660nm	Polarization resistance voltage	±300mV
Infrared wavelength	940nm	Sensitivity variation	≤±5%
/	/	50Hz interference suppression filter	≥20dB
Blood glucose measurement			
Measurement scope	1.1mmol/L~33.3mmol/L		
Accuracy	±0.83 mmol/L (±15mg/dL), for ≤5.55mmol/L (≤100mg/dL); ±15%, for >5.55mmol/L		
Repeatability	SD<0.42 mmol/L (<7.7mg/dL), for <5.5mmol/L (<100mg/dL); CV<7.5%, for ≥5.5mmol/L (≥100mg/dL)		
Model of test strip	5D test strip		

Instruction for blood oxygen measurement

1. Power on the device and open the APP. The device can connect to APP automatically or manually with appearing of electrical quantity icon on APP.
2. Keep still and calm. Put the middle finger above the blood oxygen probe and make the finger pulp touch the probe.
3. Select "Oximetry" in App. Click "Start" for measurement.
4. System will stopped automatically after measurement. The measured value will be shown.



Trouble shooting

Malfunctions	Reason	Solution
Data changed a lot in a short period	Measured way or body gesture was wrong	Re-measure according to the instruction
Unable to get measured results	Finger overexerted	Lightly press the middle finger on the device, do not overexert
	Finger is too thin	Use another finger to measure, ensure the finger covering the blood-oxygen light during the process



Cautions

- ◆ Please relax at least 5 minutes before measurement. Do not feed, drink alcohol or coffee, exercise, bath, and etc 30 minutes before measurement.
- ◆ Please relax as much as possible and not talk during the measurement procedure.

- ◆ The health monitor should be horizontally placed during the measurement.
- ◆ It's recommendable to measure by middle finger, nails hold up. Clean the fingers before the measurement.
- ◆ DO NOT move the finger during the measurement.
- ◆ There are some differences on the blood pressure on different fingers, blood circulation, physiological features, hence try to use the same finger to take measurements.
- ◆ The paralysis state caused by the continuous blood-pressure measurements can influence the blood circulation, which may affect the oximetry values, so do not measure the blood oxygen after finishing the blood pressure measurement.
- ◆ DO NOT paint the nail polish on the measuring finger.
- ◆ DO NOT take measurement under strong light.
- ◆ DO NOT measure after sporting.
- ◆ The measured blood-oxygen value may be incorrect if the tester's finger skin is too thick or has pigment deposition.
- ◆ If there are foreign matters between the probe and the measured parts, it may influence measured result.
- ◆ Cold fingertip skin or poor peripheral circulation caused by low temperature treatment or prolonged exposure to low-temperature environment can result in insufficient pulse signal, too low measured value or unable to measure.

Instruction for ECG measurement

1. Power on the device and open the APP. The device can connect to APP automatically or manually with appearing of electrical quantity icon on APP.
2. Keep still and calm. Hold the device by left hand, and the thumb touches the metal part on the top of blood oxygen sensor, other fingers touch the metal label at the back of device. The power button aims to palm.
3. Right hand touches the body temperature sensor. Two hands don't touch each other.
4. Select "ECG" in App. Click "Start" for measurement.
5. System will stopped automatically after measurement. The measured value will be shown.



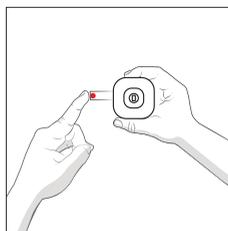
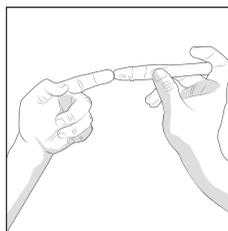
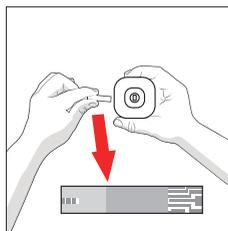
- ◆ Only 0.5 ul of blood sample is required.
- ◆ Blood samples must be filled with the reaction area at one time and should not be added repeatedly.
- ◆ The test strip should be used within 5 minutes after unpacking, but under high humidity (>80% relative humidity), it should be used within 3 minutes.

Factors that affect testing

- When the following situations occur, the test results may be disturbed:
 - Hematocrit value is less than 30% or more than 55%.
 - Peripheral blood circulation disorders, such as severe dehydration, hypotension, shock, and peripheral vascular disease.
 - Triglycerides were higher than 57mmol/L.
 - Vitamin C dopamine uric acid is beyond the normal level.
- Factors that affect test results due to improper operation.
 - The blood volume is insufficient and the reaction area of the test strip is not fully absorbed.
 - The blood sample was insufficient for the first time, and test again after the added in.
 - Blood samples contaminated (Blood samples are adopted by pressing hard, or contained bubbles).
 - After adding the blood sample, the test strip was pulled out and re-inserted into the device.
 - Test strips stored or refrigerated in a low temperature environment below 1 C.
 - Test with a test strip stored at a high temperature above 35 C.
 - Disinfect fingers with iodine or chlorinated disinfectant.
 - Blood is collected without drying fingers after alcohol disinfection.
 - The test strip is placed in a high humidity environment for more than 3 minutes after unwrapping the package.
 - Do not fully balance the glucose meter with the ambient temperature (generally more than 20 minutes).
- Why is there a difference between the peripheral blood glucose measured by the tester and the blood glucose measured by the hospital venous blood glucose tester?

The hospital use venous blood plasma glucose to test. The hospital medical certificate that the maximum error of test value range is 15% between peripheral blood glucose and venous blood plasma glucose. Thus affected by blood sample, this result between system's peripheral blood glucose and venous blood plasma glucose from the hospital will be different. (Quoted: Johnson RN, Baker JR. Accuracy of devices used for self-monitoring of blood glucose [J]. Ann Clin Biochem, 1998, 35(Pt): 68-74.)

11.The measured value will be shown after about 5s.



⚠ Cautions

- ◆ Lancing device is for personal use only, one person one lance. No allow to share the lancet with others.
- ◆ Do not disinfect fingers with iodine or chlorinated disinfectant.
- ◆ The adjusted calibration code must be consistent with the calibration code indicated on the test strip package that is ready to be used.
- ◆ Do not touch the reaction area and insert the end of the test strip with your finger.
- ◆ Do not use the test strip to press the bleeding part.
- ◆ Don't scrape the blood with a test strip.
- ◆ Don't adopt blood from both ends of the strip.

Trouble shooting

Malfuncions	Reason	Solution
ECG diagram reverse	The position of two hands are reverse	Please correctly place both hands, according to instructions.

⚠ Cautions

- ◆ Please relax at least 5 minutes before measurement. Do not feed, drink alcohol or coffee, exercise, bath, and etc 30 minutes before measurement.
- ◆ Please relax as much as possible and not talk during the measurement procedure.
- ◆ To avoid the external disturbance, please do the measurement in a quiet environment.
- ◆ DO NOT do the measurement under the charging.
- ◆ Please place two hands in correct position.
- ◆ DO NOT do the measurement with wet hands.
- ◆ During the measurement, two hands DO NOT touch each other.

Instruction for blood glucose measurement

- Power on the device and open the APP. The device can connect to APP automatically or manually with appearing of electrical quantity icon on APP.
- Select "Blood Glucose" in App. Click "Start" for measurement.
- Select whether you are testing your glucose before or after a meal. Then click "Next".
- Select check code, then click "Next".
- Insert the test strip (sold separately) into the strip receiver.
- Wash your hands with soap and water before touching testing tools.
- Prepare the lancing device:
 - Pull off the cap of the lancing device.
 - Insert a lancet and push down until it's secured.
 - Twist the protective disk of the lancet.
 - Replace the cap by aligning the arrow with the release button.
 - Select the depth of penetration by turning the adjustable tip.
 - Pull the cocking control back until it clicks. You will see a color change in side the release button when it's ready.
- Clean your finger.
- Hold the lancing device firmly against the finger and press the release button.
- Touch the test strip with the drop of blood until the window is filled.