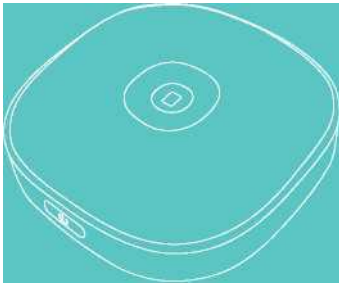


# **RHEMOS**

## **Health Monitor**

### **User Manual**



Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM -for Medical equipment and systems that are not LIFE SUPPORTING

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 transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
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. Electromagnetic 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 ECG, Respiratory rate, HRV, Blood pressure, Heart rate, Body temperature, and Blood Glucose 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, and does not encourage self-medication or adoption of any medical treatment. Always consult the doctor if the patient has any questions or sees any abnormal measurements.

Blood pressure measurement is not for neonatal or children under 12 years old.

Body temperature measurement is not used for neonatal or children under 5 years old.

The App operator must be able to read English.

## Functions

The Health Monitor is a wireless device which connects with your Smartphone bluetooth for signal transmission and needs to be combined with a mobile phone application. It uses infrared sensors, pressure sensors etc. to collect various body vitals data for of body temperature, blood pressure, pulse rate information, and uses 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 is not meant for use in the ICU.


## Product Composition

Health Monitor is composed of the Health monitor unit, the blood pressure cuff and the mobile-phone application. The Health monitor units 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	00.0.10
Battery Nominal Voltage	3.7V	Input Voltage	5V ± 0.25V
Battery Rated Capacity	400mAh	Size	70mmx70mmx 18.4mm
Working frequency	2.4000-2.4835GHz	Net Weight	about70g
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	28-42C
Measurement scope of systolic pressure	60-230mmHg	Measuring error	±0.2C for >35-42C ±0.4C for <35C
Measurement scope of diastolic pressure	40-130mmHg	N/A	N/A
Pressure error	±3mmHg	N/A	N/A
Measurement scope of pulse rate	40-180bPm	N/A	N/A
Pulse rate error	±5%	N/A	N/A
Working condition		Storage/transport condition	
Temperature	5C-40C	Temperature	-25C-+70C
Humidity	15%-93%	Humidity	60%
Atmospheric Pressure	70-106 kPa	Atmospheric Pressure	50-106kPa

Guidance and manufacturers declaration- electromagnetic immunity -for Medical equipment and manufacturers systems that *are* not LIFE-SUPPORTING

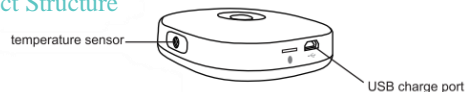
Guidance and manufacturers declaration - electromagnetic immunity			
The HC-03 is intended fix use in the electromagnetic environment specified below. The customer or the user of the HC-03 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC6100C-6	3\Ams 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  $d = \frac{3.5}{\sqrt{1}}$  $d = \frac{3.5}{\sqrt{E1}} \sqrt{P}$ 80 MHz to 800 MHz  $d = \frac{7}{\sqrt{E1}} \sqrt{P}$ 800 MHz to 2.5 GHz  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 feed 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: 
			Radiated RF IEC61010M-3
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 manufacturers 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 CISPR11	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 EC 610003-2	Class A	
7	Voltage fluctuations / flicker emissions EC 61000-3-3	Complies	

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

Guidance and manufacturers 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 610004-2	±8kV contact ±15kV air	±8kV contact ±15kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at
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 IEC61000-4-5	± 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 IEC61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 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 cycle 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 uninterrupted power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	400A/m	400A/m	Porter frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: UT is the AC 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

## Mobile phone for App

Health Monitor shall be used together with an App running on 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 x 1	Cuff x 1	User Manual x 1
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## Accessories list

Cuff (XD-01) x 1	USB line x 1
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## Battery Charging status

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 in a timely manner when low power appears on APP.
- ◆ Power light will be blue and blinking during charging.
- ◆ Do not use the device during charging.

## Power on/off

Power on: Press power key for 2 seconds. The device vibrates slightly & switches on. The Blue power light will display on the device.



- ◆ Power off: Press power key for 2 seconds. The device vibrates slightly & switches off. The Power light will be switched off.

## Device Connection

- ◆ Press power key and hold 2 seconds to power on.
- ◆ Open the APP, and look for the “Connect” button on the App screen
- ◆ Click the ‘Connect’ button to connect the device to your phone. (Pls ensure that Bluetooth on your phone is switched on)

## 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. In case of any malfunction, please reboot the device and APP.

## Trouble shooting

Malfunctions	Reason	Solution
Failure of downloading APP	Mobile phone does not satisfy the base 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 the mobile phone	Restart the device and re-log in the App.

## Instruction for blood pressure measurement

Blood pressure measurement is heavily influenced by body posture, proper wearing of cuff, physical condition, surrounding environment etc. 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 of tightness should be comfortable & the cuff should have some room to inflate.

## The guarantee is not applicable under following conditions.

1. Any damage or malfunctions caused by using the device under abnormal working environment, by not following the instruction for use, or by not using the device under specified environment.
2. Damage due to accident, abuse, negligence, or disassembly and attempted repair without informing 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.

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"
<b>IP22</b>	Protection grade		Characters of "Keep dry"
	Follow "Instructions for use"		Characters of "Do not use if package is damaged"
	BF type		Class II device
<b>CE 0197</b>	CE mark		Caution

## EMC Declaration

Guidance and manufacturers declaration- electromagnetic emission-for all EQUIPMENT AND SYSTEMS.

- ◆ Keep the device on a steady & FLAT surface (device should not be slanting, or shaking / vibrating or being impacted at any time)
- ◆ Keep the device away from places with chemicals or corrosive gas.
- ◆ Do not drop the device from a height.
- ◆ Do not fold the cuff tightly.

### **Please do NOT try to repair the device.**

- ◆ 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 using soft dry cloth.
- ◆ When the device is very dirty, a little water or neutral agent can be used on the cloth. Do not spray water etc. on the device at any time.
- ◆ If necessary degreasing cotton with ethanol could be used for disinfection

### Environment protection

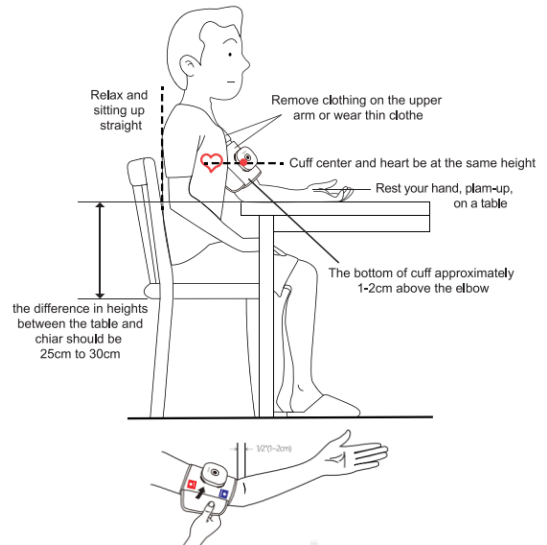
For handling of the device, cuff or waste battery, refer to your local regulations before discarding.

### After-sales Guarantee

1. The device is covered under warranty for a period of 12 months from delivery. If any malfunctions are noticed, the customer can call TigerTech on +91-7720056565 for troubleshooting. The device can then be sent to TigerTech's offices for repair or replacement. Warranty is applicable only for manufacturing defects & not for damage
2. Delivery date is determined by the invoice date 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. Connect device to APP manually by clicking the "Connect" 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 start. Keep calm during measurement.
5. System will stop automatically after measurement. The measured value will be shown.
6. Take off the cuff and clear up.

### **Do not try to evaluate the test results. 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 emails.
Failure of inflating	Cuff wrapped too tight 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: NOT TO BE DONE BY CUSTOMER

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 APR 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 have 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 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 tests are conducted 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.



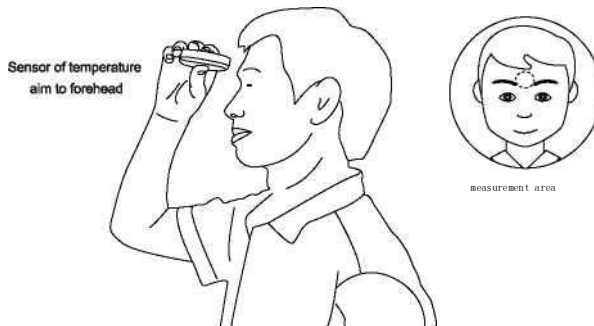
**The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be tested to verify normal operation in the configuration in which it will be used.**

### Cautions

- ◆ Please relax at least 5 minutes before measurement. Do not eat, drink alcohol, tea or coffee, exercise, or shower 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, or the PATIENTS 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 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 patient whose arm is injured.
- ◆ Blood pressure measurement cannot 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. Connect the device to APP manually by clicking on “Connect” 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 1cm away from skin.
3. Select "Temperature" in App. Click "Start" for measurement.



4. System will stop 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 if device is damaged or malfunctioning. Do not attempt to disassemble or repair the device yourself.

Do not disassemble or modify the device by yourselves.

Do not use when the device is under maintenance.

Do not place the device in acidic or alkaline environment. This will affect the life and measurement accuracy.

The Device APP is for Smartphone with Bluetooth 4.0, Android 4.3 or higher version, iOS 7.0 or higher version. Please confirm your smartphone is compliant 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 can use the device under guardians' care. Place the device in the position where children cannot 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 if the device is unsteady or faces an impact due to a fall.

Charger, mobile display 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 mobile phone 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: 28-42C

Operation 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.



# **RHEMOS**

## **Health Monitor**

### **User Manual**

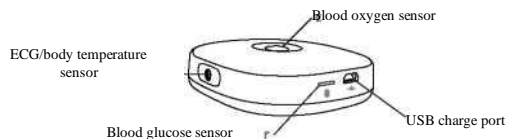
#### **Part-II**



## Instruction for New functions

### Intended Use

Health Monitor is also intended to be used for measuring, displaying and storing of blood oxygen, ECG and blood glucose at home or in clinics.

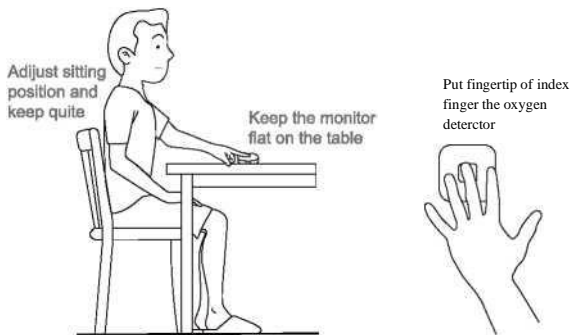


Product name		Health Monitor		Product Model		HC-03	
Blood oxygen measurement				ECG measurement			
Measurement body part	Finger	Measurement body part	Hands (handheld)				
Measurement scope	70%~100%	Calibration voltage	1mV±5%				
Measuring error	±4% for 70% to 80% SaO <sub>2</sub> .	Sensitivity error	M±5%				
	±2% for 80% to 90% SaO <sub>2</sub> .						
	±1% for 90% to 100% SaO <sub>2</sub> .						
Red light wavelength	660nm	Polarization resistance voltage	±300mV				
Infrared wavelength	940nm	Sensitivity variation	M±5%				
/	/	50Hz interference suppression filter	220dB				
Blood glucose measurement							
Measurement scope	1.1 m mol/L~33.3m mol/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						

## Product specification and performance characteristics

### Instruction for blood oxygen measurement

1. Power on the device and open the APP. Connect the device to APP manually by clicking on "Connect" icon on APP.
2. Keep still and calm. Put your middle finger on the blood oxygen sensor and ensure that the center of the finger tip touches the sensor.
3. Select "Blood Oxygen" in App. Click "Start" for measurement.
4. The System will start measuring & will stop automatically after a few seconds once measurement is complete. The measured value will be shown on screen.



### Trouble shooting

Malfunctions	Reason	Solution
Results changed a lot in a short period	Method of measuring or body posture 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

### Caution

- ◆ Please relax at least 5 minutes before measurement. Do not eat, drink alcohol, tea, coffee, or exercise or shower 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 recommended to measure SpO<sub>2</sub> using the middle finger. 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 use nail polish on the measuring finger.
- ◆ DO NOT take measurement under strong light.
- ◆ DO NOT measure after sporting events.
- ◆ The measured blood-oxygen value may be incorrect if the tester's finger skin is too thick or has pigment deposition or calluses.
- ◆ 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. Connect the device to APP manually by clicking on "Connect" icon on APP.
2. Keep still and calm. Hold the device with left hand, the thumb touching 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 finger touches the body temperature sensor. Ensure that your two hands don't touch each other.
4. Select "ECG" in App. Click "Start" for measurement.
5. The System will start measuring & will stop automatically after a few seconds once cycle is complete. The measured value will be shown on screen.



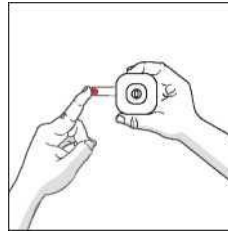
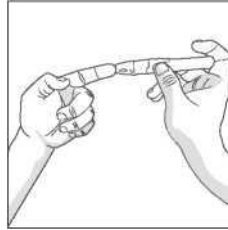
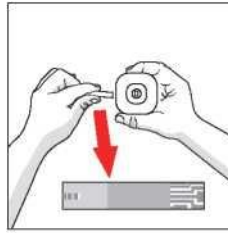
- ◆ Only 0.5 ul of blood sample is required.
- ◆ Blood sample must fill the reaction area on the strip at one time and should not be added repeatedly.
- ◆ The test strip should be used within 5 minutes after unpacking, but under high humidity (>80% relative humidity), it should be used within 3 minutes.

## Factors that affect testing

- Here are some of the factors that may affect results:
  - 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 has not been fully absorbed in the reaction area of the test strip.
  - If the blood sample was insufficient the first time, pls test again after the sufficient sample has been added.
  - Blood samples is contaminated (Blood samples are extracted 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 35C.
  - Fingers disinfected 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.
  - Did not fully balance the device with the ambient temperature (generally about 15 to 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 uses venous blood plasma glucose to test. The hospital certifies 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. Pls don't allow sharing of 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 finger.
- ◆ Don't scrape the blood with a test strip.
- ◆ Don't adopt blood from both ends of the strip.

## Trouble shooting

Malfunctions	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 eat, drink alcohol, tea, coffee, exercise or shower etc 30 minutes before measurement.
- ◆ Please relax as much as possible and not talk during the measurement procedure.
- ◆ Pls avoid any external disturbance, please do the measurement in a quiet environment.
- ◆ DO NOT do the measurement while charging the device.
- ◆ Please place two hands in correct position.
- ◆ DO NOT do the measurement with wet hands.
- ◆ During the measurement, ensure that two hands DO NOT touch each other.

## Instruction for blood glucose measurement

- Power on the device and open the APP. Connect the device to APP manually by clicking on "Connect" 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 tuning 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.