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CHAPTER 1 INTRODUCTION

1.1 Brief Introduction

Handheld Multi-parameter Patient Monitor MMED6000RD-FG6 is a non-invasive device intended for measure patient physiological parameter, such as TEMP, ECG, NIBP, SpO_2 and PR. With the RF wireless module and center monitor, the equipment help the physician know the patient condition at anytime.

1.2 Safety Information

Warnings: alert the user to potential serious outcomes, such as injury or adverse events to the patient or user.

Cautions: alert the user to exercise care necessary for the safe and effective use of the monitor.

Notes: contain important information that may be overlooked or missed.

Warnings!

- Before use, carefully read the manual.
- Operation of the equipment may be affected by the use of an electrosurgical unit (ESU) or high-frequency interference.
- Do not use the equipment in an MRI or CT environment.
- Do not use the equipment in an explosive flammable or anesthesia atmosphere.
- Do not use the equipment on the airplane.
- Do not use with defibrillator, pacemaker or hearing-aid.
- The equipment is intended only as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms.
- In order to ensure correct sensor alignment and skin integrity, the maximum application time at a single site for our device should be less than half an hour.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing, or immersing the device in liquid. The device is not intended for sterilization.
- Only the qualified physician can use the equipment, the patient should follow the physician's advice use the equipment.

- Only use the accessories approved by our company. Other accessories may affect the equipment performance. The accessories contain battery, external power supply line, cuff, SpO_2 sensor and temperature sensor.
- Avoid extremes in temperature and humidity. Do not use this device in locations subject too high or too low temperature or humidity.
- Avoid to store in the place that has chemicals or gas leakage dangerous.
- Follow local ordinances and recycling instructions regarding disposal or recycling of the device and device components, including batteries.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Handheld Multi-parameter Patient Monitor MMED6000RD-FG6, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Chemicals from a broken panel are toxic when ingested. Use caution when the monitor has a broken display screen.
- Defibrillation protection only implement on the ECG cable which has the defibrillation function.
- When using defibrillation, it needs to remove other non-defibrillation applied parts from patients.
- The use of the device is restricted to one patient at a time.
- Use a defibrillator on a patient, the device requires special protection when the discharge of a defibrillator affects the device.
- Please use the accessories that approved by the manufacturer.
- If the device has the battery, it still working after interruption of the supply mains exceeding 30s. Or else it power off.
- PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter ALARM SIGNALS.
- To avoid the risk of leakage on the patients, the cable is isolated by high voltage and adopted the insulation material. In order to improve the service life of the cable, we use the high quality cables. The

classification is BF type.

- These materials that contact with the patient's skin are all pass the ISO10993-5 Tests for invitro cytotoxicity and ISO10993-10 Tests for irritation and delayed-type hypersensitivity.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The operator should not use the system and should inform customer service, if the ESSENTIAL PERFORMANCE is lost or degraded to EM DISTURBANCES.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Do not use the equipment near AM, FM, or TV broadcast antennas .

Cautions!

- Check whether the equipment in the correct status or not.
- Check all the leads connection; make sure all of them connect well.
- Check the quantity and status of the battery.
- Make sure the safety of the patient, if it needs cut off the power supply, take out the leads or sensor.
- Do drop the fire goods, medal or liquid into the equipment. If these things drop into the equipment, please cut off the power supply and stop working.
- Please remove the battery, when the equipment will not be used for a long time.
- Pull out the leads and other accessories lightly.
- All the components of this equipment, the user can be maintenance.

- This equipment don't need to calibration.
- If the screen display “?”, it means the signal is unstable or weak, please keep your hands still and retry.

1.3 Intended Use

The portable multi-parameter monitor is intended for checking the TEMP, ECG, NIBP, SpO_2 and PR of adult in medical unit (including remote medical center, patient room and ward). This equipment is not for ICU use.

1.4 Electromagnetic Interference

Under the normal measuring, the equipment is not interference the surrounding people, unit and environment. During the process of sending data, the device interference the surrounding people, unit and environment. If the equipment in the high-frequency electromagnetic environment, it will do harm to the equipment, and the intended function will failure. During the operation, you should prevent, identify and solve the adverse electromagnetic effect. Make sure the functions of the equipment are normal.

The reasons of the interference and solutions

- From the RF wireless module electromagnetic interference

If the interference from the RF wireless module, please replace the equipment location.

- Direct or indirect ESD

Before use the equipment, make sure the user and the patient without the direct or indirect ESD. The damp room can alleviate problems.

- From the radio receiver (radio or television) interference

Keep away from the interference source

If the above proposals cannot solve the problems, please contact the consumer service center.

1.5 Symbols Definition

Symbol	Definition	Symbol	Definition
⚠	Caution		Defibrillation –proof type CF applied part
	Type BF applied part	SN	Serial number

+55℃ max −20℃ min RH≤93% non-condensing	Storage temperature and humidity		Manufacturer’s information
	Data of manufacture		Quantity of the battery
	Conformity to WEEE Directive	IPX1	The degree of protection against ingress of water
	HR		Follow operating instruction
CE 0123	European union approval	EC REP	Authorized representative in the European community
	USB interface		Power button
	SD card place		General warning
?	The signal inadequacy indicator		Use by date

1.6 Product Properties

- Portable to carry, convenient to operate and easy to measure.
- 3.5 TFT display screen, it can display physiology parameter, TEMP, ECG, BP, SpO_2 and PR.
- Rechargeable Lithium battery
- Support external AC-adapter
- Real time transmission through WiFi.

1.7 Contraindication

Not yet found.

CHAPTER 2 GENERAL DESCRIPTIONS

2.1 Appearance

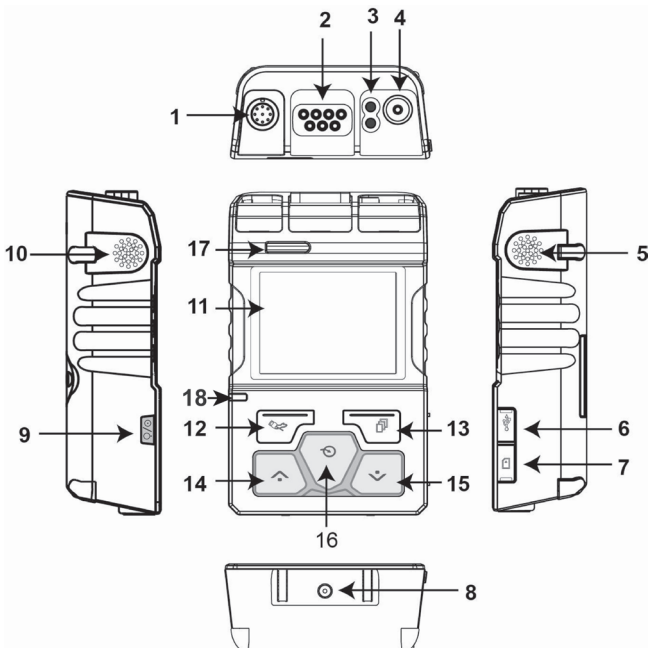


Fig.2.1

1.SpO_2 interface: connect the SpO_2 sensor
2.ECG interface: connect the ECG leads
3.T1 T2 temperature interface: connect the temperature sensor
4.NIBP interface: connect the extended BP wires and cuff
5.Speaker: reserved
6.USB interface: reserved, Do not connect other equipment through the USB

interface.
7.SD card place
8.Power adapter interface: one end of the power line connect to this interface, the other end connect to the AC power interface.
9.Power button: press and hold this button for 3S to power on and 4S to turn off
10.Speaker: reserved
11.Display screen
12.Shortcut button of BP measuring: under the whole parameter interface or the single BP measuring interface
13.Mechanical button
14.Up button/ adjust button
15.Down button/ adjust button
16.Return button: enter to the setting menu or return to the main menu
17.Alarm indication light: red (high), yellow(medium)
18.Indication light:
Without battery: connect the adapter, it will be green.
With battery: connect the adapter, the battery is on the charging status and become green. When the battery capacity becomes full, the light is blue.
NOTE: 12-16 buttons are have other functions on the different interface

2.2 SD Card Installation

Insert SD card as illustrated in the picture below. When you hear “Di…”, it means SD card install well. Make sure the chip side towards up.

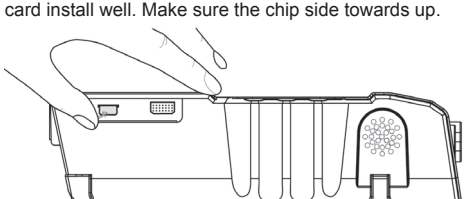


Fig.2.2

2.3 Battery Installation

1. Unscrew the screw which fixed in the battery door, and then open the battery door, as shown the following picture

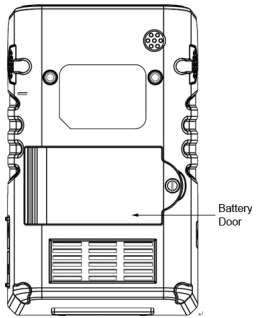


Fig.2.3

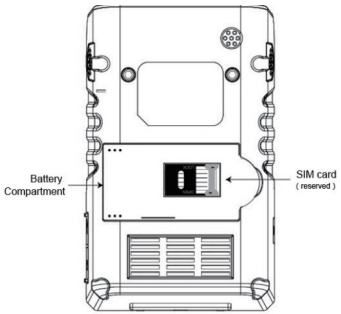


Fig.2.4

2. Put the lithium battery in the battery compartment; make sure the polarity of the battery is correct.

3. Close the battery door, fixed the screw tightly.

NOTES:

- External AC adapter: AC-input 100-240V, 50/60Hz, 1.0A; DC-output 9.0V, 3.0A
- Internal battery: one piece of lithium battery, rated voltage is 7.4V, 3050mAh
- The capacity of the battery will be display on the screen. It will take about 2 or 3 hours to complete charging, and then you can use about 24 hours.
- Use the AC power supply, make sure put the device in the safety and proper place and convenient to power off.

Warnings!

- The battery should be replaced by a professional person.
- Install the battery with the correct polarity, incorrect placement may cause damage to the bracket.
- Keep away from source of fire or heat.
- Do not disassemble the battery.
- Avoid water ingress the battery.
- Only use the attached battery charger.

- Please use the specified battery, other battery may cause the device damage or injure the patient
- Please take the battery out. If the device will not be used for a long time. Store the battery at 0℃ ~ 45℃
- Do not use the battery in the unassigned application area.
- Please regularly check or replace the battery. If the batterry power low, please charger the battery immediately.

2.4 Charging the device

Plug the power adapter into a wall adapter, press the other end of the power adapter into the charging port located on the bottom of the device, then the battery power indication light become green. When the battery reaches 100%, the battery power indication light become blue. Unplug the power adapter after finish charging.

The battery is new and fully charged; the minimum operating time of the device is 8h.

The battery charge time from depletion to 90 % charge is 3h.

The battery charge time from depletion to 100 % charge is 4h.

2.5 Check the proper function of the device and accessories

The device: press and hold the power button for 3s, the device turn to the normal interface, and press and hold the power button for 4s to power off the device. It means the device in good condition.

SpO_2 probe: SpO_2 probe is not wear out. Rightly insert the SpO_2 probe with the device, the red light of the SpO_2 probe flash. Open the clamp, the red light is on. After insert the finger into the SpO_2 probe, the measurements display in the device, it means the SpO_2 probe in good condition.

ECG cable: ECG cable is not wear out. Rightly insert the ECG cable with the device, and make sure the ECG cable in the right place on the patient body. The measurements display in the device, it means the ECG cable in good condition.

Temp probe: Temp probe is not wear out. Rightly insert the Temp probe with the device, the device displays the environment temperature, when connect with the patient, the device displays the body temperature. It means the ECG cable in good condition.

BP cuff: the BP cuff is not wear out. During the measurement, the device

Continuous inflation without leakage, and the measurements display in the device, it means the BP cuff in good condition.

Power adapter: Rightly insert the power adapter with the device, the power indication light is on in green, it means the power adapter in good condition.

Lithium battery charger: install the lithium battery into the device, and connect the battery charger. During charging the indication light is on in red, and when the battery becomes full the indication light is on in green. It means the battery charger in good condition.

CHAPTER 3 SETTING

Long press the power button for 3s to turn on the device, it goes from the startup screen to the main interface.

Fig.3.1

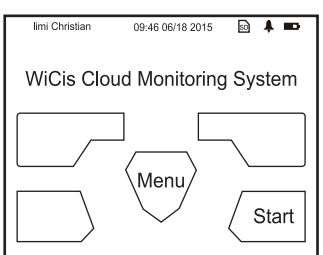


Fig.3.2

Press the menu button; enter the following interface to set the parameters.

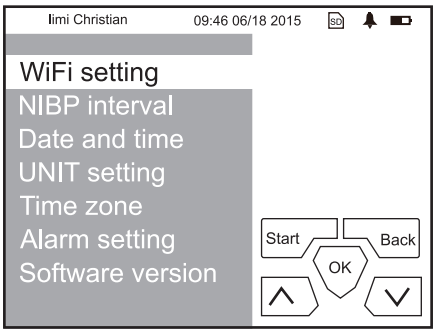


Fig.3.3

WiFi setting: set WLAN on or off

●In the Fig.3.3, press up/down to choose “WiFi setting”

●Press OK button to choose WLAN on or off.

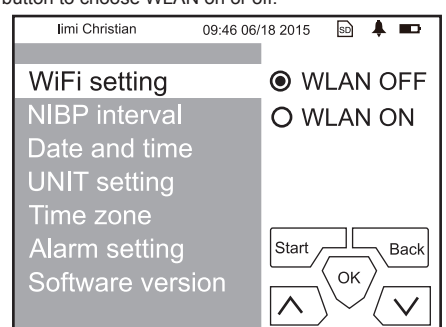


Fig.3.4

Input password:

●Press up/down button to choose your wifi name and then press OK button enter into the password interface.

●Press button 12 & 13 to switch in the line, press button 14 & 15 to switch in

the row, press OK button to confirm.

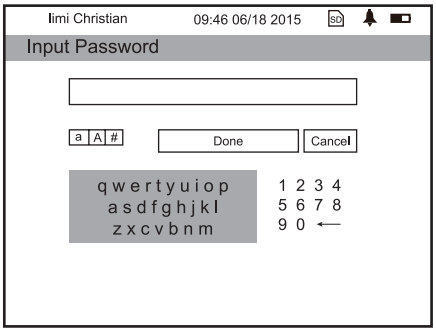


Fig.3.5

NIBP interval: set the interval of NIBP.

There are two modes: Manual and Auto. The intervals of auto are 5min, 10min, 15min, 30min, 60min, 90min and 120min.

●Press OK to choose manual or auto

●Press up/down button to choose the time interval.

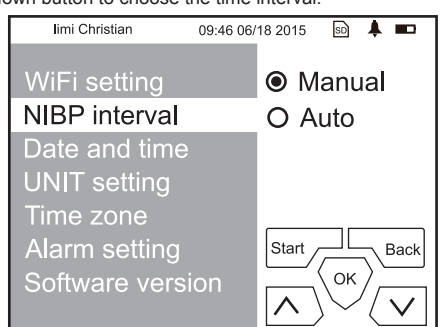


Fig.3.6

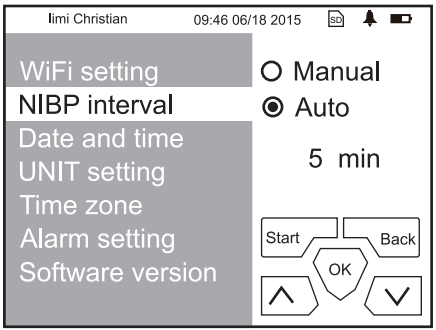


Fig.3.7

Date and Time: set date and time.

Press OK button to choose the item, press up/down button to change the figure, press OK button to confirm.

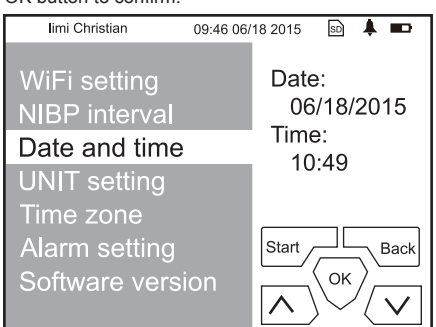


Fig.3.8

UNIT setting: set the unit of temperature and NIBP.

Press the OK button, you choose the NIBP or temperature. Press the UP/ down button, you can choose the unit you need.

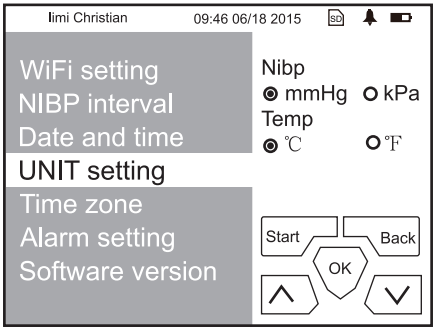


Fig.3.9

Time zone: set the time zone.

●Press OK button to choose the item

●Press up/down button to change the figure

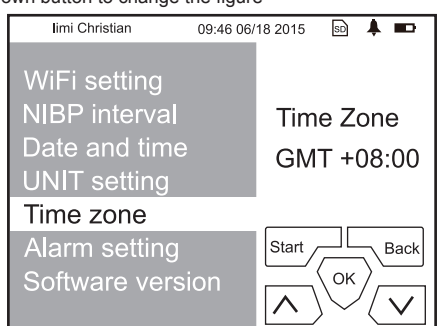


Fig.3.10

Alarm setting:

First, please input the password (2222).

Second, set the upper limit and lower limit for parameters.

●Press up/down button to the choose the item, press OK button to confirm

●Press up/down button to change the figure, press OK button to confirm

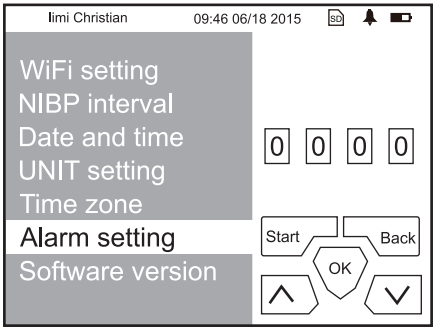


Fig.3.11

Audible Alarm

The high/medium/low-level alarms can be set according to the user's setup in following different audio ways, Level 1 is the most serious warning, level 2 is the serious warning and level 3 is the general warning.

Alarm level	Alarm lamp	Audio prompt
High(Level 1)	Red and flashing	Mode is "DODODO- DODO--- DODODO-DODO", which is triggered once every 6s
Medium(Level 2)	Yellow and flashing	Mode is "DO-DO-DO", which is triggered once every 8 seconds.
Low(Level 3)	_____	Mode is "DO-DO", which is triggered once every 20 seconds.

Visual alarm

When an alarm event occurs, the parameter measurement or corresponding prompt information display will flash.

Technical alarm:

The alarms, which are caused by the technical malfunction or fault of the monitor, are technical alarms. Such as: Battery low, ECG cable off, Sensor off or no finger.

Physiological alarm:

The alarms, which are caused by the physiological parameters of the patient

exceeding alarm limits, are physiological alarms. Such as: HR exceeds HR High alarm.

Silence the alarm

In the measuring screen, short press the button 13 to silence the alarm for 120s. The corresponding indicator displays in the up right of the screen. Long press the button 13 to silence the alarm forever. The corresponding indicator displays in the up right of the screen. Long press the button 13 to recover the alarm. The corresponding indicator displays in the up right of the screen.

Use the following ways to check the visual alarm system

1. Enter into the alarm setting, adjust the limit of SpO_2, set the upper limit 90, and the lower limit 85.
2. Insert the finger into the SpO_2 probe, take a measurement.
3. If the measured values out of the limits range, it will cause the high alarm.

Notes:

1. When you check the visual alarm system, make sure the device is not silence.
2. If the battery power lower than 5%, it will cause the Physiological alarm.
3. When no or low signal is detected, it will cause the low alarm.

Software version: you can check the version of software.

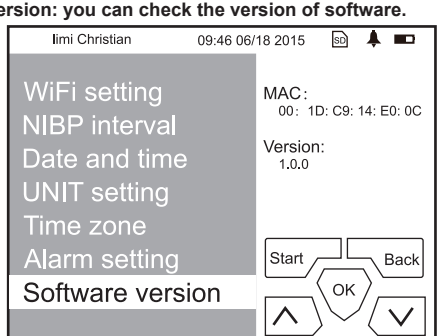


Fig.3.12

CHAPTER 4 TAKE A MEASUREMENT

4.1 Preparation

Before measuring, you should select the physiology parameter, and then connect the sensor (as shown Figure 2.1). Please connect sensors slightly.

4.2 TEMP

This equipment can measure you body temperature.

Attach the temperature sensor to the patient body; then you can measure the body temperature. Press the Start button, enter in the measuring interface. Several minutes, your temperature value will display in the red circle in the screen as shown in Fig.4.1

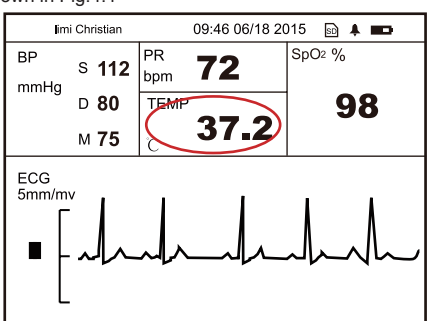


Fig.4.1

Warning! When you use the temperature sensor, please be careful! After using, make the cable become circle. Do not pull the cable tightly, or will be damage the cable.

Note:

1. The measuring site is armpit
2. The working mode is a direct mode.
3. The device is designed for use with specific thermometer or monitoring equipment, and the operator is responsible for checking the compatibility of the thermometer or monitoring equipment, probe before use, and

incompatible components can result in degraded performance.
4. The transient response time for a continuous CLINICAL THERMOMETER is less than 90s.

4.3 ECG

From the measured ECG waveform, evaluate the patient physiology state accurately. Only proper connection of the ECG cables can ensure satisfactory and respected measurement. Through the attached five electrode ECG cable, you can obtain Ⅰ、Ⅱ、V leads ECG waveform. The screen display ECG waveform and PR value.

Warnings!

- Do not touch the patient, table nearby, or the equipment during defibrillation.
- Use only the original patient Monitor ECG cable for monitoring.
- When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient.
- The conductive parts of electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth.
- The heart-rate value may be affected by the operation of cardiac pacemaker pulses or by cardiac arrhythmias.
- If lead wires are intentionally disconnected by the clinical operator, please silence the technical alarm.
- Through the waveform that on the patients to detect the leads-off, the current value is 16 nA.

I.Precondition

- Select and use the leads

a.Select the Ag-AgCl one-time electrodes. Before use, make sure whether the electrodes in the effective period.
b.Avoid having different input-impedance, every patient use the same type electrode.

- For patient's skin is not in a good condition, which need to be preconditioned before placing electrode in order to make the leads connect to skin tightly.

a.Washing skin completely using soap and water. Ether and pure alcohol is

prohibited because they can increase skin's impedance.
b.Shave body hair on where electrodes are placed, if necessary.
c.Rub skin briskly to increase capillary blood flow in the tissues and remove skin scurf and grease.
d. If electrodes without conducting cream are used, conducting cream should be smeared on skin before placement.

- Placing the electrodes for ECG monitoring

For 5-lead set, attach the electrodes to the positions as below Fig.7-1.
Electrode placement:
a.Red(R) electrode: be placed near the right shoulder, directly below the clavicle.
b.Yellow (L) electrode: be placed near the left shoulder, directly below the clavicle.
c.Black (N) electrode: be placed on the right hypogastrium.
d.Green (F) electrode: be placed on the left hypogastrium.
e.White(C) electrode: be placed on the chest.

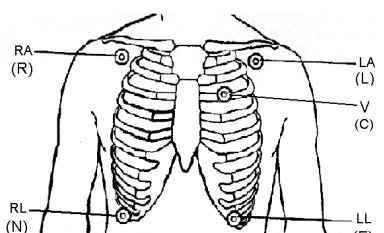


Fig. 4.2

Electrode's position, identification and color:

AHA		IEC		Position on body surface
Electrodes Identifier	Color Code	Electrodes Identifier	Color Code	
RA	White	R	Red	Right arm
LA	Black	L	Yellow	Left arm
LL	Red	F	Green	Left leg

RL	Green	N	Black	Right leg (neutral electrode)
V	Brown	C	White	Signal movable chest electrode

NOTE: To ensure patient safety, all leads must be attached to the right position or it will injure the patient or cause the wrong measurement.

II.Measuring

Press Start button, and then begin to measure the HR. You can obtain ECG I, II, &V and the value of HR. according the user needs to choose the type of leads. And then the result display on the screen as follows.

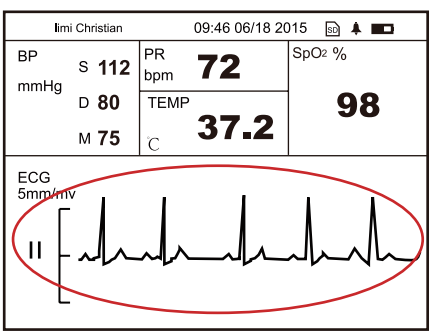


Fig. 4.3

Notes:

- In the measuring screen, short press the button 14 & 15 to change the ECG lead (I, II, &V).
- In the measuring screen, long press the button 15 to change the waveform scale （1mm/mv, 5mm/mv, 10mm/mv）
- In the measuring screen, long press the menu button to frozen the waveform.
- In the measuring screen, long press the button 12, in the ECG area, it will display 1mv waveform only for self-checking.

III.Maintenance and cleaning

Warnings!

- Before clean, make sure to take off the battery.
- If the ECG cable wears out, please replace the cable.

Cleaning

Clean the device with the soft cloth dampened with 70% alcohol

Sterilization

Avoid long-time use cause damage, we suggest that it is possible to sterilize the device. Before sterilize, you should clean the device firstly.

Recommend sterilize materials: 70% alcohol, 70% isopropyl alcohol.

Disinfection

Avoid long-time use cause damage, we suggest that it is possible to disinfect the device. Before disinfect, you should clean the device firstly.

4.4 BP

Measurement Principle

This device is intended for non-invasive measuring of an adult individuals' systolic, diastolic and mean blood pressure using the oscillometric method.

Warnings!

- Before starting a measurement, verify that you have selected a setting appropriate for your patient.
- Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.
- Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.
- Plug in the air hose and switch on the system.
- Too frequent measurements can cause injury to the patient due to blood flow interference.
- Do not apply the cuff over a wound, as this can cause further injury.
- Don't apply the cuff and its pressurization on the arm on the side of a mastectomy.
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring device on the same limb.
- Check the operation of the Automated sphygmomanometer does not result in prolonged impairment of the circulation of the blood of the patient.

- Any blood pressure reading can be affected by the measurement site, the position of the patient (standing, sitting, lying down), exercise, or the patient's physiologic condition.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- Apply the blood pressure cuff to the patient's arm as shown in Fig.4.4

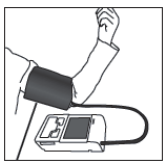


Fig. 4.4

Notes:

- Ensure that the cuff is completely deflated.
- Apply the appropriate size cuff to the patient, and make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.
- The width of the cuff should be either 40% of the limb circumference or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50~80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.
- Make sure that the cuff edge falls within the range of mark <->. If it does not, use a larger or smaller cuff that fits better.
- Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values.
- If the cuff is placed higher than the heart level, add 0.9 mmHg (0.10kPa) for each inch of different.
- If it is placed lower than the heart level, deduct 0.9 mmHg (0.10kPa) for each inch of different.
- The rated range of cuff pressure: 0mmhg~380mmhg.

Measuring

Press the Start button; enter into the measuring interface. Press the shortcut button (button 12), the user feel the cuff inflation. After that, the device will automatically deflate. Finally, the screen will display the results: Systolic Blood Pressure, Diastolic Blood Pressure and Mean Blood Pressure. The interface is as shown in Fig.4.5

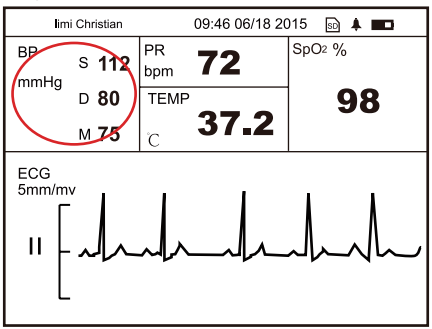


Fig. 4.5

WARNINGS!

- If any abnormality is observed, stop the blood pressure measurements.
- If you suspect the accuracy of the value, please adopt other method to further check.
- If the liquid splashes on the device or accessories, especially liquid enter into the device, please connect the local service center.
- Inaccurate measurements may result from such causes:

a. Limb's twitch and tremble will cause inaccuracy or prolonged the cycling of measurement; serious tremble will lead to the failure of measure.
b. Placing the cuff too loosely or tightly on the patient.
c. Leaky cuff or hose
d. Insure the NIBP and pulse rate within the range of this monitor.
e. Excessive patient motion will cause the inaccuracy, patient should be relax and avoid movement.
f. Arrhythmia lead to irregular heart beat

g. Use the artificial heart-lung machine
h. The patient is in shock or low temperature.

Pressure Safety Protection

- Automatic deflation will be activated when the cuff pressure exceed 280 mmHg under the adult mode.
- Automatic deflation will be activated when the continuous inflation last more than 30 seconds.
- If there is no value when measurement time exceeds 120 seconds under the adult mode, the measurement will be canceled.
- You can press the START (NIBP) button to cancel a NIBP measurement when necessary.

Maintenance and Cleaning

WARNINGS!

- Do not squeeze the hose of cuff.
- Do not allow liquid to enter the connector socket when cleaning the monitor.
- Do not wipe the inner part of the connector socket when cleaning the monitor.
- When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

IV.NIBP cuff disinfection

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use this method. The cuff should not be dry-cleaned.

The cuff can also be machine-washed or hand-washed; the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag, and for machine-washing, close the Velcro fastening. Allow the cuff to dry thoroughly after washing, and then reinsert the rubber bag.

To obtain accurate routine resting BLOOD PRESSURE measurements for the condition hypertension including;

– adjustment of the pressure reduction rate, if applicable,
– patient position in normal use, including
1) comfortably seated

2) legs uncrossed
3) feet flat on the floor
4) back and arm supported
5) middle of the cuff at the level of the right atrium of the heart
– a recommendation that the patient relax as much as possible and not talk during the measurement procedure,
– a recommendation that 5 min should elapse before the first reading is taken;
– operator position in normal use

How to enter static pressure measurement interface?

1. Turn on the device, press the menu button enter into the main menu.
2. Select and enter the software version.
3. Under the software version interface, press the return button, then press the up button twice times, press the down button twice times, then long press the return button enter into the static pressure measurement interface.

4.5 SpO_2

What is SpO_2 Monitoring

SpO_2 plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97%. The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

Measurement principle

Principle of the oximeter is as follows: A mathematical formula is established making use of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in glow and near-infrared zones. Operation principle of the instrument: Photoelectric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm glow and 905nm near infrared light) can be focused onto a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the

oximeter's display through process in electronic circuits and microprocessor.

Measuring

a.Power on the device

b.Before starting a measurement, verify that you have selected a suitable size sensor for the patient.

c.Connect the end of sensor to the device, the other end to the patient measured finger, as shown in Fig.4.6

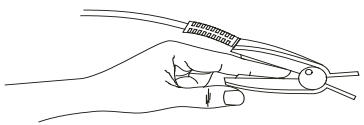


Fig.4.6

Press the start button, enter into the measuring interface. Serial minutes later, the result will display on the screen as shown in Fug.4.7

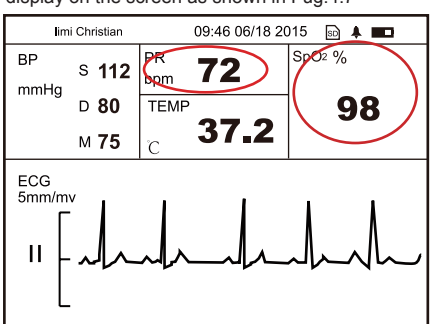


Fig.4.7

Inaccurate measurements may be caused by

- Significant levels of dysfunctional hemoglobin (such as carbonyl - hemoglobin or methemoglobin);
- Intravascular dyes such as indocyanine green or methylene blue;
- High ambient light. Shield the sensor area if necessary;
- Excessive patient movement;

- High-frequency electrosurgical interference and defibrillators;
- Venous pulsations;
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line;
- The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia;
- The patient is in cardiac arrest or is in shock;
- Fingernail polish or false fingernails;
- Weak pulse quality (low perfusion);
- Low hemoglobin.

Maintenance and Cleaning

WARNINGS!

- Disconnect the AC power before cleaning the monitor or sensor.
- Do not immerse sensor completely in water, solvents, or cleaning solutions because the sensor and connector are not waterproof.
- Do not sterilize SpO_2 sensors by irradiation, steam, or ethylene oxide.
- Do not soak the sensor in the detergent liquid; if any abnormity of the sensor or cable is detected, stop using it immediately.

Cleaning:

Moisten the soft cloth or gauze with alcohol and use it to wipe the surface of sensor, and then use the clean cloth to dry it. The same method can be used to clean the light source and photo detector.

Cables can be disinfected by 3% of hydrogen-peroxide or 7% of isopropyl alcohol. Do not immerse the connector into the liquid.

Probe LED Specifications

	Wavelength	Radiant Power
RED	660±3nm	3.2mw
IR	905±10nm	2.4mw

Note: The information about wavelength range can be especially useful to clinicians.

Note:

1. The pulse oximeter equpment is calibrated to display functional oxygen saturation.
2. Pulse oximeter monitor, the pulse oximeter probe and probe cable

extender have been validated and tested for compliance with this international standard.

3. Please use the probe and cable that provided by our company.

4. Please Verify the compatibility of the monitor, probe, and cable before use, otherwise patient injury can result.

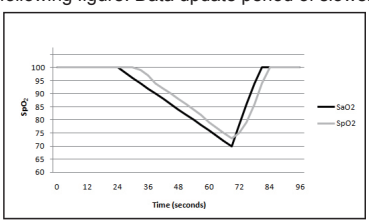
5. All the waveforms have been uniformed.

6. Functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

7.Alarm condition without delay, alarm signal delay, data averaging and other signal processing have no effect of SpO_2 and PR.

Equipment data update period

As shown in the following figure. Data update period of slower average is 8s.



4.6 Power off

After measurement, please take off your finger and press and hold the power button to turn off the device.

CHAPTER 5 MAINTENANCE

5.1 Examination

Before use the device, please check the following things

- Whether the device has mechanic damage
- Check all the cables and accessories
- Check the device functions

Do not use the damage device, or it will injure the patient. Please connect the local consumer service center. The device needs to repair by the professional man.

5.2 Cleaning and Disinfection

Customer should responsible for periodic maintaining of the device and its accessories. Be sure to disconnect power line to the device before cleaning and inspecting.

Warnings!

- Do not use the strong solvents. Such as acetone.
- Do not sterilize the device using autoclaving, ethylene oxide sterilizing.
- Before using the detergent, please follow the manufacturer's instructions to dilute the detergent.
- Do not use the material easy to wear. Such as steel wool and silver polishing agent.
- Do not spray water or cleaning liquor over the product, neither allows any liquid to flow into power switch, connector or other intake.
- Do not leave any detergent in the surface of the device.

The following detergent can be used:

- Ammonia (diluted)
- Sodium hypochlorite bleacher (diluted)
- isopropyl alcohol

5.3 Troubleshooting

- No display after power on

Check the power connections, the power adapter.

- ECG wave is not correct when monitoring the patient

Check the LEAD wire and the electrodes position.

- No SpO_2 wave and pulse rate display when monitoring

Check the probe connection and the finger temperature

- Cuff inflation lacked when measuring blood pressure.

Cuff too loose or leak, Check the connections of tube.

- When measuring the BP, inflation unfinished but begin to deflate.

Check the battery quantity, if the battery quantity less than 30%, please replace the battery. If still have this problem, please check the BP cable whether it be pressed.

5.4 Warranty and Repair

5.4.1 Warranty and repair content

- Repair response time: AM9:00 to PM17: 30 on Monday to Friday except legal holiday.

Repair time: AM9:00 to PM17: 30 on Monday to Friday except legal holiday.

- Repair service: Including telephone support, field inspecting, fittings replacement.
- Telephone support: we can give guidance to customer's engineer to inspecting the instrument when you dial our service line. Professional repair engineer online provides technical support.
- Field inspecting: we will send engineers to repair the instrument if necessary. Certified engineers of our company or local repair team trained by our company provide this service.
- Fittings replacement: if necessary, we will replace the damaged fittings according to contract. The damaged fittings should be returned to us expect for special reason.
- Spare machine for repair: it is used to replace the damaged machine for customer using, customer should send the damaged machine to us to repair.
- Repair for sponsoring and contributing machine: customer should send the machine to us to repair.
- Updating software is free.

5.4.2 Exemption and restriction:

- Warranty does not apply to the damage or loss sustained due to well-known act of god, such as fire, earthquake, flood, thunder, cyclone, hail, electrical storm, blast, building collapse, commotion, etc.

- Non-service items:

a. The cost and insurance of dismantling and testing, overhauling, reinstall, transfer, moving the instrument or parts.

b. Damage or loss sustained due to inspected or repaired by other institute that is not certified

c. Damage or alteration by anyone other than our company authorized service personnel.

- The damage or lose sustained due to connection to peripheral equipment (such as printer, computer etc.), that are not provided by our company are not covered by the warranty.
- Obligation restriction: In the duration of warranty, if the operators use other fittings that are not provided by us, we reserve the right to cancel warranty.

5.4.3 Customer guarantees:

- Read the user manual in details before operation.
- Operation and maintenance according to the user manual, and guarantee the requests of power and environment.

5.4.4 Non-warranty and Non-replacement Policy

- The work environment is not eligible. For example, if the relative humidity exceeds 70%, circuit boards of the instrument may be damaged due to condensate.
- If voltage of power supply is fluctuant and exceeds 240VAC, the power adapter may be damaged.
- There is smear or marks that are not belong to the instrument and cannot be removed from the outside surface of the instrument.
- The instrument or its fittings are mechanically damaged.
- The circuit is short and damaged due to liquor or other stuff flow in the instrument or its fittings.
- All probe and its accessories are not free replacement.
- Leakage of air cell of blood pressure sleeve due to improper storage or operation is not free replacement.
- The malfunction with result from improper repair by anyone other than our company authorized service personnel.
- The malfunction with result from improper use.
- If any code label of parts is damaged or missing, this warranty shall

become null and void. For example of code label.

5.4.5 Customer special warranty period

Due to we stipulate the warranty period according to the relevant electronic regulation of country, which we stipulate is on year, accessory is three months. When customer requires to extending the warranty period, you should consider whether it is reasonable. Because electronic product quickly replace, as to the warranty period over three years, purchased accessories may be out of stock. In this case, we will adopt to entirely upgrade or replace the old, you should pay the minimum acceptable cost of renewed device.

5.4.6 Repackaging

Remove all the detectors, leads and accessories and put them into the plastic bag.

Try to use the original packaging case and materials. Any damage due to the improper packaging during the transportation shall be responsible by the user. If you are still within the period of warranty, please present the warranty card and one copy of the invoice or receipt.

Please present a written note detailing all the troubles when repairing the instrument.

5.4.7 Storage and Transportation

Storage: Temperature: -20℃～ 55℃ , Humidity: ≤93%

Transportation: Transportation: via road, rail or aviation after properly insured and packaged.

CHAPTER 6 SPECIFIVATIONS

NOTES:

- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional personal authorized by our company.
- The illustrations used in this manual may differ slightly from the appearance of the actual device.
- The maximum application time for each type of probe at a single site is 4h.
- The equipment has been calibrated , users do not to calibrate. In order to ensure the accuracy of the probe, please change the probe once a year. Make sure that the type of probe need to be specified.
- The equipment is guaranteed for 5 years from the date of purchase.
- The required of the App:

The App should match with the communication protocol. If you need the protocol, please connect with the manufacturer.

Display

The screen dimension: 3.5inch; 76mm×54mm;

The screen resolution: 240×320

Dimension: 167mm ×103mm × 48mm

Displayed parameters: ECG waveform, HR, %SpO_2, Temperature, BP (systolic, diastolic and mean)

ECG

Standard lead: I, II, V

Scan speed: 25mm/s

Gain: 1mm/mv, 5mm/mv, 10mm/mV

Sampling rate：250Hz/s

Bandwidth：0.67Hz ～ 40Hz(-3dB)

CMRR：89dB

Heart rate range: 15bpm ～ 300bpm

Accuracy：15bpm ～ 99bpm,±1bpm; 100bpm ～ 300 bpm, ±2%.

Resolution：1bpm

The maximum T-wave amplitude: 1.2mV

Heart rate averaging: Using recent period between 8 RR, remove the minimum and maximum values, calculate the average from the rest of the RR period, the calculation results is the heart rate value
the updating rate: 1s
Heart rate meter accuracy and response to irregular rhythm: bigeminy:80bpm slowly varying bigeminy：60bpm
Response time of heart rate meter to change in heart rate:
80bpm ~120bpm: ＜ 12s; 80bpm~40bpm: ＜ 13s
Sweep speeds: 25mm/S
The minimum input impedance: 5MΩ

NIBP

Measuring range：
Systolic 30mmHg ~ 255mmHg
Mean 20mmHg ~ 235mmHg
Diastolic 15mmHg ~ 220mmHg
Resolution：1mmHg
Accuracy：Max.±3 mmHg
Maximum standard deviation: 8 mmHg
Measuring mode: manual / auto

SPO_2

Display range：0%~100%
Measurement range：70~100%
Resolution：1%
Accuracy：70%~100%：±2%；<70% no definition

PR

Display range：0bpm ～ 255bpm；
Measurement range： 30bpm ～ 250bpm;
Resolution：1bpm；
Accuracy：±2bpm or ±2%

TEMP

Display range：3℃～ 49.9℃ ;
Measurement range: 25℃～ 45℃ ;
Resolution：±0.1℃；
Accuracy：25℃～ 45℃ ±0.2℃

Alarm

Hear rate	
Default	upper limit：120bpm，lower limit：50bpm
upper limit range:11bpm ～ 300bpm, continuously adjust, step: 1bpm lower limit range：10bpm ～ 299bpm,continuously adjust, step: 1bpm	
Blood Pressure	
Systolic/default	upper limit:160 mmHg，lower limit:90mmHg
Diastolic/default	upper limit:95 mmHg，lower limit:60mmHg
Mean/default	upper limit:110 mmHg，lower limit:60mmHg
Systolic: upper limit:16mmHg ～ 295mmHg，lower limit:15mmHg ～ 294mmHg Diastolic:upper limit:11mmHg ～ 285mmHg，lower limit:10mmHg ～ 284mmHg Mean: upper limit:11mmHg ～ 285mmHg，lower limit:10mmHg ～ 284mmHg	
TEMP Default：upper limit:38.0℃ , lower limit:35.0℃ upper limit:35.0℃～ 45.0℃，continuously adjust, step: 0.5℃ lower limit：32.0℃～ 40.0℃，continuously adjust, step: 0.5℃	
PR Default：upper limit:120bpm,lower limit:50bpm upper limit:11bpm ～ 235bpm lower limit：10bpm ～ 234bpm	
SpO_2 Default：upper limit:100%,lower limit:85% upper limit:86% ～ 100%,continuously adjust, step: 1% lower limit：85% ～ 99%,continuously adjust, step: 1%	

Note: the upper limit must greater than the lower limit.

Alarm level

High(Level 1)	SpO_2 exceeds the limit
Medium(Level 2)	BP exceeds the limit
	HR exceeds the limit
	Temp exceeds the limit
	Systolic exceeds the limit
	Diastolic exceeds the limit
	Mean exceeds the limit
	The battery less than 5%

Low(Level 3)	SpO_2 probe off
	No finger
	ECG cable off
	error measurement of BP

Environment Requirements

Operation Temperature：5℃～40℃

Storage/ Transport Temperature：-20℃～+55℃

Ambient Humidity：≤80% no condensation in operation; ≤93% no condensation in storage/transport

Atmosphere pressure：86kPa ～ 106kPa

Power supply

DC 7.4V，one rechargeable lithium battery；

Operating time：24 hours continuous working

power adapter: MENB1030A0900F02; Output: 9V DC, 3A

Fuse

3A/32V

WiFi

Frequency range: 2412.00~2497.00MHz

Occupied bandwidth: ≤20MHz

Effective radiated power: ≤11 dBm

max radio-frequency power transmitted:

+15dbm

Classification

According to the type of protection against electric shock: internal powered equipment.

According to the degree of protection against electric shock: type BF and Defibrillation CF applied part

According to the degree of protection against ingress of water: IPX1

According to the mode of operation: continuous operation

Applied part

SpO_2 probe

Electrode plate

Temperature probe

NIBP cuff

Note: All the applied part contains temperature probe, cuff, electrode plate and SpO_2 probe are compliance with the biological compatibility Standard.

List of accessories

Accessories	Mode	Type	Quantity
SpO_2 probe	M-50E013CS09	9 pin(round), 0.9m	1 piece
SpO_2 patch cord		9 pin convert to DB9 pin, 2 m	1 piece
NIBP cuff for adult	RNC0001A -013B	27CM-35CM	1 piece
NIBP extended line		1.5M	1 piece
ECG cable	TJ-003-0428	7 pin, Euro-standard	1 piece
Temperature probe	TYT-3.5	¢3.5	1 piece
Power adapter	MENB 1030A0900F02	Input: 100 – 240V AC 1.0A; Output: 9V DC, 3A	1 piece
Power cord		1.5M	1 piece
Charger	BR-6000C	Input: 100 – 240V AC; Output: 8.4V DC, 600mA	1 piece
Rechargeable Lithium battery	GS-248	7.4V 3050mAh	2 pieces
ECG electrode for single use	7.4V, 3300mAh	2153	1 pack
Hang bag			1 piece
User manual			1 piece
Quick operation guide			1 piece

CHAPTER 7 COMPLIANCE LEVEL FOR EMC

Table 1 Electromagnetic emission level

Electromagnetic emission	
Electromagnetic requirements of this RF generator are given below and it is the responsibility of end user to meet these requirements.	
Emission test	Compliance
CISPR 11 Conducted emission	Group 1, Class A*
CISPR 11 Radiated emission	
IEC61000-3-2 Harmonic emission	Class A
IEC61000-3-3 Voltage fluctuation / flickering emission	Conform
*The RF generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.	

Table 2 ENCLOSURE PORT

Phenomenon	Basic EMC standard	Immunity compliant levels
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 2 Hz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 5
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3 Input a.c. power PORT

Phenomenon	Basic EMC standard	Immunity compliant levels
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2Hz
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycle

Table 4 PATIENT coupling PORT

Phenomenon	Basic EMC standard	Immunity compliant levels
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 2Hz

Table 5 The specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13,17	Pulse modulation 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 – 5800	WLAN 802.11a/n	Pulse modulation 217 Hz	9
5500				
5785				