GIMA

PROFESSIONAL MEDICAL PRODUCTS

MONITOR SPOT-CHECK PC-300
PC-300 SPOT-CHECK MONITOR
MONITEUR SPOT-CHECK PC-300
MONITOR SPOT-CHECK PC-300

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REF **35162**

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M35162-M-Rev.7-03.22

Instructions for User

Dear Customers,
Thank you for purchasing the PC-300 Spot-Check Monitor. Please read the following information before using the device.
These instructions describe the operating procedures which are to be strictly followed, read these instructions carefully before using the Spot-Check Monitor. Failure to follow these instructions can cause monitoring abnormalities, damage to the monitor and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues or any monitoring abnormalities, personal injury and equipment damage due to user's negligence of the operation instructions. The manufacturer's warranty service does not cover such faults.

Warnings:

- Do NOT use the device under flammable gas condition or in any environment that may lead to explosion.
- The device and accessories that should not be serviced or maintained while the device is in use.
- The doctor or patient is the intended operator.
- Do not modify this equipment without authorization from the manufacturer.
- The SpO_2, NIBP, Temperature, and ECG (optional) measurements are frequently used functions.
- The device is IP22 and is protected against solid foreign objects of 12.5mm or greater, and protected against vertically falling water drops when the enclosure is tilted up to 15.
- Please check the monitor before use to verify that the accessories can function safely and correctly.
- If the monitor is connected with other devices, the total leakage current may exceed the

limitation and as a result this can cause potential danger to the user.

- Although biocompatibility tests have been performed on all the applied parts, under exceptional circumstances, allergic patients may have anaphylaxis. Do NOT use the monitor on patient with anaphylaxis.
- All connecting cables and rubber tubes of the applied parts should be kept away from the patient's neck to prevent suffocation.
- As a standard, please only use the components provided by the manufacturer or those that are of the same model and specifications as the accessories.
- If the monitor falls off a surface accidentally, please do NOT operate it before its safety and technical performance have been tested, and positive results obtained.
- Do NOT open the device cover without authorization. The cover should only be opened by a qualified service personnel.
- When disposing of the monitor and its accessories, the national regulation should be followed.
- There are some electromagnetic or inductance circuit designed in the device, use during MRI environment could burns or adversely affect the MRI image or the device's accuracy. So the device is MR unsafe.
- The device and accessories are provided non-sterile.
- The device has no alarm and is intended only for spot-checking.

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Chapter 1 OVERVIEW

1.1 Features

- Small in size, light in weight, easy to carry and operate.
- Clear and large numeric display, segmented LCD panel, real-time clock display.
- Accurate blood pressure measurements can be activated or canceled by one shortcut button.
- Unique oximetry technique ensures quick and accurate SpO_2 & pulse rate measurements by smart sensors.
- Smart infrared temperature probe ensures quick and accurate measurements of body temperature.
- Blood pressure, oxygen saturation, pulse rate and temperature can be measured simultaneously.
- Blood Glucose meter option can be connected to the device.
- Up to 100 user ID can be marked.
- Data storage with recall, up to 999 groups of records can be stored and recognised by patient ID.
- Power management with power saving mode, auto power off and low battery indicator.
- Data upload to PC by USB cable and real-time data transmission to smart phones by wireless connections.
- Lifetime: 5 years.

1.2 Product Name and Model

Name: PC-300 Spot-Check Monitor
Model and Configuration:

Model	Configuration					Display LCD
	NIBP	SpO_2	Pulse rate	Temperature	Blood Glucose	
PC-300	√	√	√	√	--	√

NOTE: 1. Spot-Check Monitor can configure with ECG and blood glucose function, details see the User Manual for Easy ECG Monitor and Glucose Meter respectively.
2. "√" means function is available, and "--" means function is not available.

1.3 Intended Use

The Spot-Check Monitor is a device designed for spot-checking the user's physiological parameters, such as non-invasive blood pressure (NIBP), functional oxygen saturation (SpO_2), pulse rate (PR), and body temperature (TEMP). Additionally, the device can take measurements from the Blood Glucose Meter function, and ECG data from the Easy ECG Monitor (both Blood Glucose Meter and Easy ECG Monitor are certified separately). This device is applicable for use in clinical institutions and has no conditions or factors of contraindication.

1.4 Impact on the Environment and Resources

Low

Chapter 2
OPERATION INSTRUCTIONS

2.1 Appearance

2.1.1 The Front Panel

Description:

1/2. / up/down key: on the setup display screen, a short press will change the parameter value step by step press and hold to change the parameter values quickly; on the review display screen, short press to review the history data records, press and hold to recall the history data records quickly.

3. Memory key: on the measurement display screen, press and hold the key (for 3 seconds) to enter into the review display screen; once the review display screen, a short press will recall the history data records. On the setup display screen, all parameters

Figure 2.1

can be set in anticlockwise order by pressing and holding  , key, similarly, a short press of  key will set the parameters in clockwise order.

4.  Menu key: on the measurement display screen, press and hold the menu key to enter the setup screen; on the setup or review display screen, press and hold the  key to go back to the measurement display screen.

5.  Start/cancel button: on the measurement display screen, a short press of this button will activate or cancel the blood pressure measurement.

2.1.2 The Right and Upper Sides of the Device

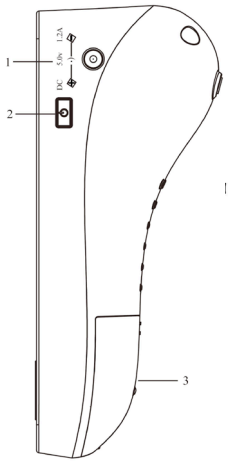


Figure 2.2

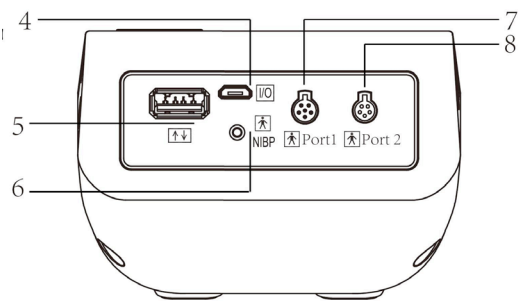
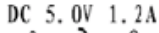


Figure 2.3A Vista lato superiore

The power switch and external DC power input socket are on the right side of the monitor as shown in figure 2.2.
The signal input/output ports are on the upper side of the monitor as shown in figure 2.3.

Description:

1. 

: External DC power input socket.

2.  **: Power switch:** = press and hold to turn on/off monitor.

3. Battery cover.

4. I/O **:** Charge / USB data interface.

5. **:** Connector to link with the blood glucose meter.

6. NIBP: Cuff connector.
7/8. Port 1/Port 2: Connector to link with the temperature probe or smart SpO_2 probe.
NOTE: Figure 2.3A is the upper-side-view for the previous version device, and Figure 2.3B is the upper-side-view for the current version device. The difference between the two versions is seen on the upper-side panel. The previous version device has only 2 ports, marked "PORT1" and "PORT2", which are the generic connectors capable of connecting any combination of temperature probe, smart SpO_2 probe or ECG accessory (for example Easy ECG Monitor). However, the current version device has 3 porte, contrassegnate ports, marked "SpO_2", "TEMP" and "ECG" respectively, which can be used only to connect the corresponding sensors or accessories.

Description:

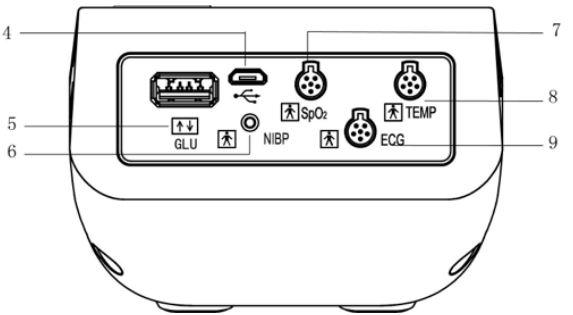


Figure 2.3B Upper-side view

1. DC 5.0V 1.2A : External DC power input socket.

2. : Power switch: = press and hold to turn on/off monitor.

3. Battery cover.

4. : Charge / USB data interface.

5. GLU : Connector to link to the blood glucose meter.

6. NIBP: Cuff connector.

7. SpO_2: Smart SpO_2 probe connector.

8. TEMP: Temperature probe connector.

9. ECG: Connector to link with ECG accessories..

2.2 Installation

2.2.1 Power Supply

1. Internal power supply to the built-in battery

When the battery indicator displays full grids, the built-in battery is fully charged. When it blinks, the battery voltage is low, and the user should charge the battery by connecting the device to the AC power adapter or a USB power source via USB cable. When the grids of the battery indicator are rolling circularly, the battery is being charged.

2. External power supply from the AC power adapter

Use the AC power adapter provided by the manufacturer. Make sure that the mains power supply is 110~240VAC with 50/60Hz.

3. External power supply from the USB cable

Use the USB data cable with micro-USB connector, connect one end of the data cable to the connector on the device marked I/O , and the other end to the USB power source with output capacity of 5Vdc/1.2A.

2.2.2 Starting the Monitor

By pressing and holding down the switch, the software version will be displayed after releasing the switch, the device will enter the measurement display screen automatically. The user can then begin to operate the monitor.

Note: Do not touch the 4 touch-keys during switching on the monitor, or the touch-keys may be out of work temporarily. If the touch-keys are not sensitive enough, do not operate them for over 8 seconds, then the touch-keys will resume to its normal sensitivity automatically.

- The monitor is powered by built-in Lithium battery, when the battery voltage is low, the measurement and wireless connection may be unstable.
- For electric safety, do not use the monitor during its battery is in charging.
- Please make measurement for a single person at a time

➔ If monitor fails to start by pressing the switch, please use the external power supply.

2.2.3 Downloading APP software onto Android smart phone

Terminal devices such as Android smart phones can be used to receive data from the Spot-Check Monitor in real-time, store the received data, and also review the stored data. To use this function, download the corresponding APP software onto the smart phone device.

For terminal devices with the Android system, please follow the procedure to download:

1. Install an APP software for scanning QR Codes with a smart phone.
2. Run the APP software to scan the QR Code image in Figure 2.4, please focus the QR Code frame while scanning.
3. When successfully scanned, a web link for downloading the APP software will be displayed.
4. Open the web link to download the APP software. Install the software when successfully downloaded.

   For terminal devices with the iOS system (such as iPhone, iPad), please follow this procedure to download:

   1. On the App Store of the device, enter "Shenzhen Creative" into the search function. **Note:** if you use an iPad to search, please select "iPhone only" when searching.
   2. Once the search results are listed, select the result with @Health icon 

, then download the corresponding APP software.

Instruction for Measurement

☞ Make sure the APP software successfully connects with the Spot-Check Monitor.

☞ Refer to the manual of the APP software for more detailed information for operation.

Figure 2.4 QR Code Image

2.3 Taking Measurement

2.3.1 Blood Pressure Measurement

1. An appropriate cuff should be selected according to the age and arm circumference of the patient. The cuff width should be 2/3 of the length of the upper arm. The inflatable part should be long enough to permit wrapping approximately 80% of the limb.
2. Applying the cuff: unfold the cuff and wrap it around the upper arm evenly to the appropriate tightness. The correct cuff position is shown in figure 2.5.
3. Connect the hose from the cuff to the connector on the upper-side of the device where marked “NIBP”.

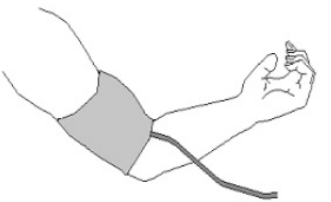
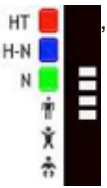


Figure 2.5 Cuff position

4. Long press menu key to enter the setup screen, select the proper patient category, for example, if you select "Child", then the indicator on the screen will focus towards "Child", shown as 

which means that the current patient type is set to Child. **Note:** refer to Section 3.2 for detailed setting operation.
5. Press the start/cancel button to begin the blood pressure measurement. The result will be displayed on the screen, and the corresponding blood pressure level will be indicated, shown

as 

, which means that the adult's blood pressure result is normal. Please refer to the form below for detailed blood pressure levels. **Note:** blood pressure level indication is only for "Adult" patient type.

Level	**Blood pressure range (Unit: mmHg)**
N (Normal)	SIS <130mmHg, and DIA <85mmHg
H-N (High normal)	130 mm Hg ≤ SIS <140mmHg, and 85mmHg ≤ DIA <90mmHg
HT (Hypertension)	SIS ≥140mmHg, or DIA ≥90mmHg

NIBP Measurement Principle

The NIBP measurement is based on oscillation technology. The measurement is started by inflating the cuff by a pump automatically after the cuff pressure is high enough to block the arterial blood flow within the upper arm, then the cuff pressure is deflated slowly, and all the change of cuff pressure in the deflation process is recorded to calculate blood pressure based on certain algorithm. The device will judge whether the quality of signal is good enough. If the signal is not good enough (such as sudden movement or touch of cuff while measurement), the device will stop deflating or re-inflating, or aborting this measurement and calculation.

Safety Instructions for blood pressure measurement

- Blood pressure measurement is prohibited to those who have severe hemorrhagic tendencies or with sickle cell disease, as partial bleeding maybe caused.
- Too frequent measurements or connection tube kinking may result in purpura, neuralgia and lack of blood.
- Wrap the cuff and operation of the start/cancel button  are the frequently used functions.
- Do NOT apply the CUFF over a wound, as this can cause further injury.
- Operation of the device does not result in prolonged impairment of PATIENT blood circulation.
- Do NOT wrap the cuff on limbs with transfusion tubes, intubation or skin lesions on the area, as damage may be caused to the limbs.
- The equipment can be used on pregnant or pre-eclamptic patients.
- The proper operating steps are needed to obtain accurate resting Blood Pressure reading routinely:
  - -- Patient position in normal state, including comfortably seated, legs uncrossed, feet flat on the floor, back and arm supported, middle of the cuff at the level of the right atrium of the heart.
  - -- The patient should be as relaxed as possible and should not talk during the measurement procedure.
  - -- 5 minutes should elapse before the first reading is taken.
- The user needs to check the operation of this equipment does not result in prolonged impairment of patient blood circulation.
- Readings can be affected by the measurement site, the position of the patient(standing, sitting, lying down), exercise, or the patient's physiological condition.
- The performance of the equipment can be affected by extreme temperature, humidity and altitude.

- Avoid compressing or restricting the connection tubing.
- The patient should be comfortably seated with their legs uncrossed and feet flat on the floor. The patient's back and arm should be supported, and the middle of the cuff should be level with the right atrium of the heart.
- The environment or operational factors which can affect the performance of the device and/or its blood pressure reading (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion diabetes, age, pregnancy, pre-eclampsia, renal diseases, patient motion, trembling, shivering).
- Measurements should be taken at appropriate intervals. Frequent measurements with short intervals may lead to pressed arm, reduced blood flow, low blood pressure, and result in an inaccurate reading.
  It is recommended that the measurements are taken in intervals of more than two minutes.
- Before use, empty the cuff until there is no residual air inside.
- Do NOT allow the cuff to twist or bend.
- Do NOT twist the cuff hose or put heavy things on it.
- Please hold the connector of the hose while connecting and disconnecting it to the device.
- If arrhythmia or auricular fibrillation occurs, take measurement again.
- The patient should sit or lay down with calm condition and make the cuff and the patient's heart on the same level to get accurate measurement. Other positions may lead to inaccurate measurement.

2.3.2 SpO_2 Measurement

Operation procedures:

1. Connect the smart SpO_2 probe to the connector on the upper-side of the device marked "SpO_2" ("PORT1" or "PORT2" for previous versions of the device). When disconnecting the

connector, be sure to hold the head of the connector firmly and pull.
2. The red blinking light inside the clip of the SpO_2 probe indicates a successful connection.
3. Insert one finger (index finger is preferred, the nail should be not too long) into the clip of the probe according to the finger mark shown as below.
4. The device will begin to take the measurement.

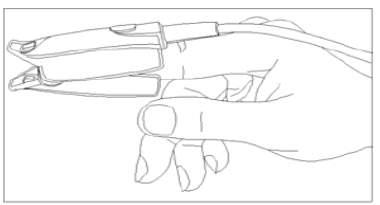


Figure 2.6 demonstration for SpO_2 probe

SpO_2 Measurement Principle

SpO_2 measurement is based on dual wavelength opto-plrthysmometry technology, a unique hardware and software design.

By use of red and infra-red light emitting through the patient's finger, the photo-detector at the other side senses the transmitted light and converts to current for later amplification and filtering. The acquired light intensity signals (plethysmogram) are digitalized and further processed with proprietary algorithm to determine the SpO_2 and pulse rate value.

Safety instructions for SpO_2 measurements

- Continuous use of the SpO_2 probe may result in discomfort or pain, especially for those with microcirculatory problems. It is recommended that the probe should NOT be applied to the

same place for over two hours, change the measurement site periodically and when necessary.

- Do NOT place the SpO_2 probe on a finger with edema or fragile tissue.
- When the ambient temperature is over 35°C, please change the measuring site every two hours; when the ambient temperature is over 37°C, please do NOT use the SpO_2 sensor, as using in high temperatures can cause burns.
- Do NOT put the SpO_2 probe and pressure cuff on the same limb, otherwise the blood pressure measurement may affect the SpO_2 measurement.
- The device is calibrated to display functional oxygen saturation.
- Do NOT allow the sensor cable to twist or bend.
- Check the SpO_2 sensor and cable before use. Do NOT use a damaged SpO_2 sensor.
- When the temperature of the SpO_2 sensor is abnormal, do not use it further.
- Remove nail polisher or other cosmetic products from the fingernail.
- The fingernail should be of normal length.
- The SpO_2 sensor cannot be immersed into water, liquid or cleanser.
- The SpO_2 sensor can be repeatedly used. Please clean and disinfect before reuse.
- The SpO_2 sensor can be repeatedly used. Please clean and disinfect before reuse.
- Anemia or low hemoglobin concentrations, intravascular dyes, carboxyhemoglobin, methemoglobin, and dysfunctional hemoglobin may effect the SpO_2 accuracy. If the patient has such situation, do not rely on the measured result for diagnostic decision, and it's recommended for the patient to consult with the doctor.
- **PORT1 or PORT2** can be connected with either temperature probe, smart SpO_2 probe, or Easy ECG Monitor, but not any other devices or probes. Do NOT connect two probes or devices with the same type (e.g. two temperature probes, or two smart SpO_2 probes, or two Easy ECG Monitors) to both PORT1 and PORT2.

2.3.3 Temperature Measurement

The infrared temperature probe is a delicate transducer. To operate please follow these steps and procedures. Failure to accurately operate may cause damage to the probes

1. The infrared temperature probe

Please place the infrared temperature probe in a stable ambient temperature for 30 minutes before taking a measuring.

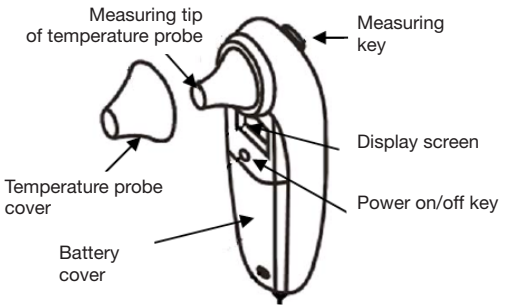


Figure 2.7A sonda per la temperatura a infrarossi

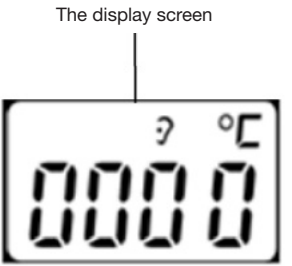


Figure 2.7B

Operation procedure:

1. Connect the infrared temperature probe to the connector on the upper side of device marked "TEMP" ("PORT1" or "PORT2" for previous versions of the device). When the LCD screen

displays  , this indicates that the probe is successfully connected.

2. When the screen shows as figure 2.7B and the temperature unit "°C" is blinking, the user can begin to take the measurement.
3. Insert the tip of the temperature probe into the earhole and press the measuring key to start the measurement. A short beep means the measurement has finished and the result will be displayed on the screen.

Note:

➔ If the temperature probe detects a hardware failure, the display screen on the infrared temperature probe will show "Err" and will not enter into measuring mode.

➔ The infrared temperature probe will switch to stand by automatically if there is no operation for 1 minute. If a further measurement is needed, please press the measuring key and repeat step 2 and step 3.

Normal body temperature varies depending on the position/area the measurement is taken from. The following table shows the varying temperature = ranges of the different body positions.

Temperature varying range at different body positions:

Arm	34.7 ~ 37.3°C
Oral	35.5 ~ 37.5°C
Rectal	36.6 ~ 38.0°C
Ear	35.8 ~ 38.0°C

Besides, each person has his/her own normal temperature value, and the normal temperature value also changes at different time within a day. Therefore, it's recommended to report your doctor not only the temperature value, but also the measuring position, if possible you may provide your own normal temperature range to your doctor for reference.

➔**Press and hold the power on/off key can shift the temperature unit**.

Safety Instruction for Temperature Measurement

- This device meets requirements established in ASTM Standard (E1965-98).
- Do NOT use the infrared temperature probe when the subject temperature and ambient temperature are outside the operating ranges specified by the manufacturer.
- Performance of the device may be adversely affected when one or more of the following occur:
  A. Operation outside of the manufacturer specified subject temperature range.
  B. Operation outside of the manufacturer specified operating temperature and humidity ranges.
  C. Storage outside of the manufacturer specified ambient temperature and humidity ranges.
  D. Mechanical shock.
- Manufacturer defined soiled or damaged infrared optical components.
- Do NOT take a measurement when the patient is moving.
- Patients with tympanitis and otitis problems should NOT use this device for measuring.
- When the infrared temperature probe is connected to the device, the probe will consecutively be at power-on status, therefore pressing the power on/off key on the temperature probe will not take effect.

2.3.4 Blood Glucose Measurement (Optional)

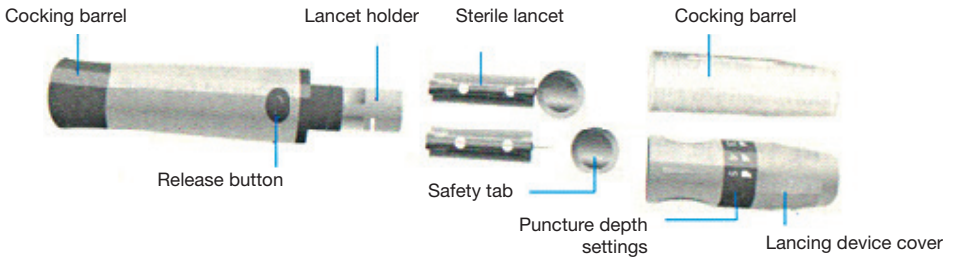
Using the optional link cable for the On Call Plus Blood Glucose Meter, connect the Glucose Meter to the connector on the right side of the Spot-Check Monitor marked "GLU" ↑↓.

Appearance and key functions of the On Call Plus Blood Glucose:

1. Test strip: the strip with chemical reagent attachment used for the meter to measure glucose concentration in blood.
2. Test strip slot: a test strip is inserted into the slot to perform a test.
3. LCD display: display the test result and help you go through the testing process.
4. M key: recall previous test results from the meter memory and performs other menu selection functions.
5. S key: select meter setting, perform other menu selection functions. Please refer to the User Manual of "On Call Plus Blood Glucose Monitoring System" for detailed function descriptions.
6. Data interface: used to connect to the Spot-Check Monitor for data transmitting.

Figure 2.8 Appearance of the On Call Plus Glucose Meter

Operations for the Lancing Device and Blood Lancet



1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancet holder and push it until the lancet comes to a complete stop in the lancet holder.
2. Hold the lancet firmly in the lancet holder and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.
3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.
4. Adjust the puncture depth by rotating the lancing device cover. There are five puncture depth settings.
5. Pull the cocking barrel back to set the lancing device. You may hear a click. The device is now ready for obtaining a drop of blood.

Refer to figure 2.9A.

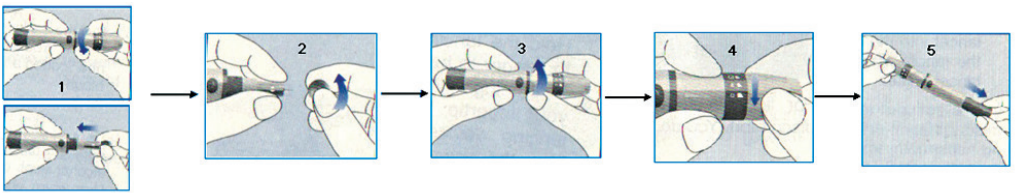


Figure 2.9A Operation for Lancing Device and Blood Lancet

Quick operation procedure for On Call Plus Glucose Meter:

1. Insert a new test strip into the strip slot, contact bars end first and facing up, to turn on the meter and display all the display segments. If the audio option is on, the meter will beep, signaling the meter is turned on.
2. The blinking test strip and blood drop icon will indicate that the test strip is inserted correctly and a drop of blood can be added.
3. Touch the blood sample to the sample tip at the end of the test strip. If the audio option is turned on, the meter will also beep to indicate the sample is sufficient and the measurement is started.
4. The meter will count down from 9 to 1 and then display the measurement results.
   The meter will also beep to indicate that measurement is complete.

Refer to Figure 2.9B.

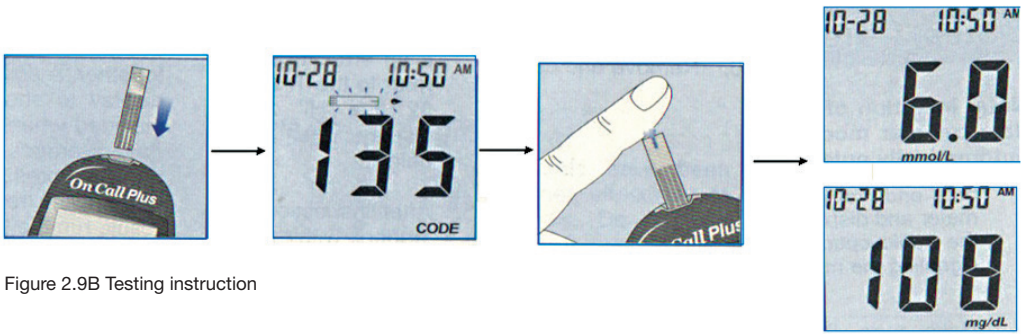
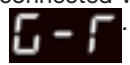


Figure 2.9B Testing instruction

Refer to the provided User Manual of the "On Call Plus Blood Glucose Monitoring System" for further detailed instructions.

Safety Instruction for Blood Glucose Measurement

- The provided test strips should be used with the On Call Plus Glucose Meter.
- Do NOT clean or disinfect finger with iodine.
- The calibration code must be the same with what on the packaging.
- The On Call Plus Glucose Meter will automatically switch to stand-by mode if a test strip is not inserted for 1 minute.
- The testing strip will suck blood at one end automatically, do not make it sucking at both ends.

- Do NOT press or scrape the bleeding finger.
- The testing strip should be used as soon as possible after unpacking, and the unused strips should be kept in the bottle with airproof condition.
- Take measurement only once within 1 min.
- If the monitor is connected with both temperature probe and the blood glucose meter, the screen will show  .
- The blood-collect pinhead is a disposable item. It's recommended to insert it back to the plastic cover and throw it into the specific dustbin.

2.3.5 ECG Measurement (Optional)

1. Connect the Easy ECG Monitor to the connector on the upper side of device marked "ECG" ("PORT1" or "PORT2" for previous version of the device).
2. Choose one of the methods (refer to figure 2.10B/C/D/E) to take the ECG measurement.
3. When the Easy ECG Monitor and Spot-Check Monitor are successful connected, press the "Start" button on the Easy ECG Monitor to activate the ECG measurement.
4. When "ECG" appears on the display screen of the Spot-Check Monitor, it means the Easy ECG Monitor has begun to take the ECG measurement.
5. 30 seconds later, the result will display on the screen of the terminal device, and the measurement will terminate.

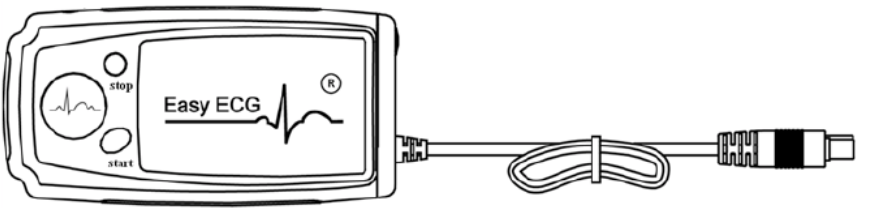


Figure 2.10A Easy ECG Monitor

➔ **Start / Stop: Start/Stop ECG measurement.**

Figure 2.10B
Palm measurement

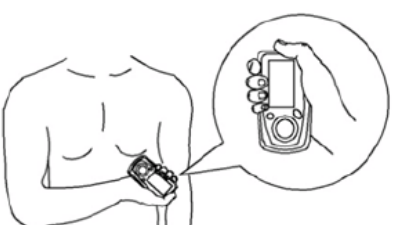


Figure 2.10C
Chest measurement

Figure 2.10D
Leg measurement

To obtain a clear and high quality ECG signal, the lead wire measurement can be used. Connect the lead wire firmly to the lead wire socket of the device. Place the electrodes and connect the lead wires as shown in Figure 2.10E to obtain the Lead II ECG signal. If you want to measure Lead I and Lead III ECG signal, connect the lead wires to the electrodes (**Note:** lead wire is optional) as detailed in table below.

➔ Safety Instructions for ECG Measurement

1. Check the device to make sure that there is no visible damage that may affect the user's safety and the measurement performance. If there is obvious damage, stop using the unit.
2. Do NOT make a diagnosis of oneself according to the measurement and measurement results, always consult a doctor if abnormal information is presented frequently.
3. Do NOT use the device in a bathroom or humid environments.

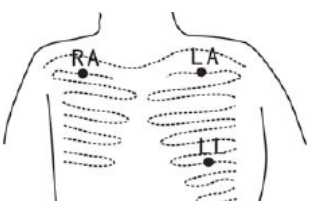


Figure 2.10E Lead wire measurement

Table 1 ECG Leads Configuration and Electrodes Location Table

Electrode Name & Color / Lead / Electrode Location	Lead I	Lead II	Lead III
The intersection between the centerline of the right clavicle and Rib 2.	R (Red)/ RA (White)	R (Red)/ RA (White)	L (Yellow)/ LA (Black)
The intersection between the centerline of the left clavicle and Rib 2.	F (Green)/ LL (Red)	L (Yellow)/ LA (Black)	R (Red)/ RA (White)
Between the left edge of the breast bone and Rib 5.	L (Yellow)/ LA (Black)	F (Green)/ LL (Red)	F (Green)/ LL (Red)

2.4 Blood Pressure Accuracy Check Method

Operation procedure:

1. Unscrew the M3x6 screw from the battery compartment on the back of the Spot-Check Monitor, as shown in figure 2.11.
2. Take a NIBP connector plug from the battery cover, as shown in figure 2.12. (**Note:** there are two plugs but you will only need one.)
3. Air Path Connection: Take a piece of air tube (0.5~1m long, Φ8.0mm/Φ4.0mm diameter). Attach the NIBP connector with a connector plug on to one end of the air tube. Connect the other end to the 3-way connector. Connect the other 2 ends of the 3-way connector to a Mercury Sphygmomanometer as shown in Figure 2.13.

4. Connect the NIBP connector end to the NIBP port on the Spot-Check Monitor as shown in figure 2.14.
5. Turn on the Spot-Check Monitor. Press the menu button to go to the settings. Press and hold the large NIBP measurement button to enter the Pressure Check Mode.
6. Start pumping, and check if the pressure reading on the Spot-Check Monitor matches the mercury pressure reading.

Figure 2.11

Figure 2.12

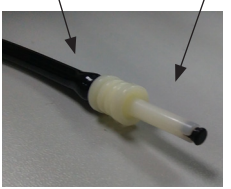


Figure 2.13

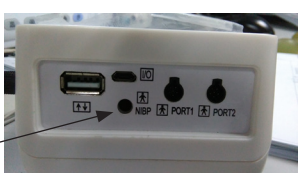
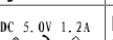


Figure 2.14

Figure 2.15

2.5 Symbols

Symbol	Description	Symbol	Description	Symbol	Description
	Wireless		Keep in a cool, dry place		External DC power input
	Alarm		Keep away from sunlight		Charger or USB Data interface / Connector to link with blood glucose meter
	Memory icon		Date of manufacture		Follow instructions for use
	Power on/off switch		WEEE disposal		Product code
	Type BF applied parts		Pulse rate (unit: bpm, beat per min)		Lot number
	Serial number		Battery voltage indicator		Medical Device complies with Directive 93/42/EEC
	Manufacturer		USB icon		Caution: read instructions (warnings) carefully
	Class II applied		No SpO_2 Alarms		

Chapter 3
MONITORING SCREEN DISPLAY
3.1 Measuring Screen

Screen Description:

1. USB connection icon

2. wireless transmission icon;

: means that the wireless transmission function is on; when the icon is blinking, the wireless connection set up is unsuccessful; when this icon is steady, the wireless connection set up is successful;; ×; the wireless transmission function is off.

3. **:** Beep sound indicator; : pulse beep is on; × : pulse beep is off.

4. Battery voltage indicator. When the battery is full, the battery voltage indicator displays a full grid.

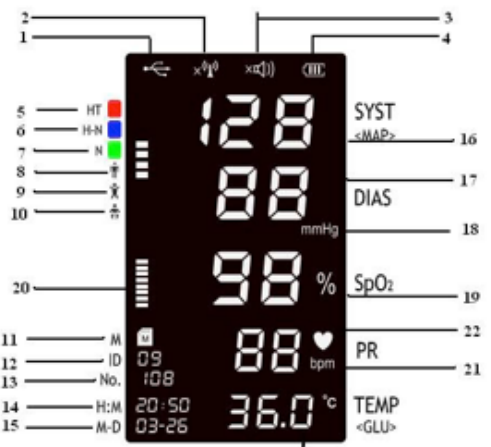


Figure 3.1 Measuring screen

When the indicator is blinking, it means the battery voltage is low and the user should charge the battery. Please connect the device to the external power supply to ensure the correct use of the monitor, and the battery will be charged. During charging, the grids in the battery indicator with roll circularly.

5.~7.  : means the inflation pressure during cuff inflation. When displaying the measurement result, the indicator  appears on the corresponding blood pressure level, such as N (Normal), H-N (High normal), and HT (hypertension).

8~10: Indicates the NIBP measurement mode, the indicator  appears on the corresponding patient type,,  for Adult, for Child, and for Infant.

11. M: memory
12. ID: the patient ID, which can be set from 0 to 99.
13. NO.: the number of stored data, ups to 999 records can be stored for each ID.
14. H:M: the time stamp (hour: minute). The time can be set in the system setup screen.
15. M-D: the time stamp (month-day). The date can be set in the system setup screen.
16. SYST: systolic pressure
17. DIAS: diastolic pressure
18. kPa/mmHg: unit of blood pressure, 1kPa=7.5mmHg.
19. SpO_2: the value of SpO_2 with unit of %.
20. **:** pulse bar-graph.
21. PR: pulse rate with unit of bpm.

22. the heart beat symbol which flashes with heart beat.

23. TEMP/GLU: the current displayed temperature with an option of °C for Celsius, or °F for Fahrenheit.
When the optional GLU (Blood glucose) is chosen, the blood glucose value will be displayed with the default unit of mmol/L.

3.2 System Setting Screen

On the measurement display screen, press and hold the menu key to setup the display screen, as shown in figure 3.2. The user can choose the settings for the wireless function, pulse beep, blood pressure unit, temperature unit, date and time.

Operation Instruction:

1. Press and hold the key, and release after hearing one beep, to enter into the setup screen. When the patient ID blinks, the setup function is available.

2. A short /long press of the key to cycle select the setting item, the item will be blinking if selected.
For example, if NIBP patient type is selected, then NIBP indicator will be blinking. (All parameters can be set

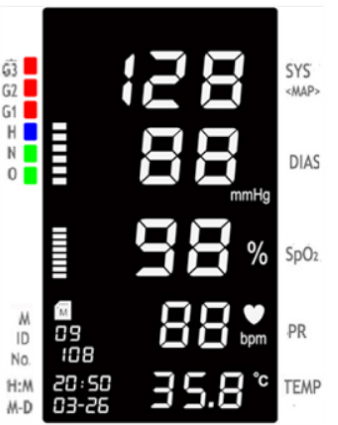


Figure 3.2 Setup display screen

in the order of anti-clockwise by pressing and holding the , key, the order will be: ID → Minute → Hour → Day → Month → Year → TEMP → NIBP unit → Alarm sound → Wireless transmission function → NIBP mode).

3. A short press of the / key sets the detailed item. For example, if you want to choose Child type, then press up/down key to move the indicator on the label of "Child".

4. A short press of the key confirms the setting

5. Press and hold the key brings the screen display back to the measurement display screen. The monitor will also switch back to the measurement display screen as well if there has been no operation for 30 seconds.

Note: 1. On the setup display screen, all parameters can be set in anticlockwise order by pressing and holding the key.

2. For setting the date, the century is fixed to be 20, i.e. “13y” indicates the year 2013.

Please see the following example for the date and time: 11:14", March 23, 2013.

3.3 History Data Review Screen

On the measurement display screen, press and hold key to recall the stored data records, as shown in figure 3.3.

Operation instructions:

1. Press and hold the , key, release the key after hearing one beep. The memory mark" " will appear (i.e. entering to review display screen). The patient's ID number will blink at the same time.
2. A short press of the / key will browse the patient's ID number.
3. A short press of the key will confirm the setting, and the recorded number (No.) will blink.
4. A short press of the / key will set the recorded number to be recalled. The data displayed on the screen is for the specific record of the patient that you selected.
   Note: when selecting the patient ID, the screen only displays patients with history data records.

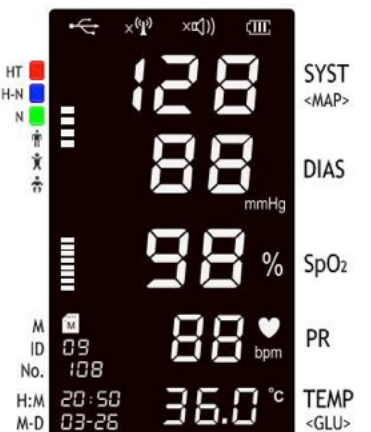


Figure 3.3 History data review screen

3.4 Data Uploading

1. When the wireless transmission function is on, the monitor can communicate with a host device such as a PC, smart phone or other wireless enabled devices for real-time data transmission.
2. When connected to a USB cable, the history data can be uploaded to a PC for viewing and management.

Chapter 4
TECHNICAL SPECIFICATIONS

4.1 Blood Pressure Measurement

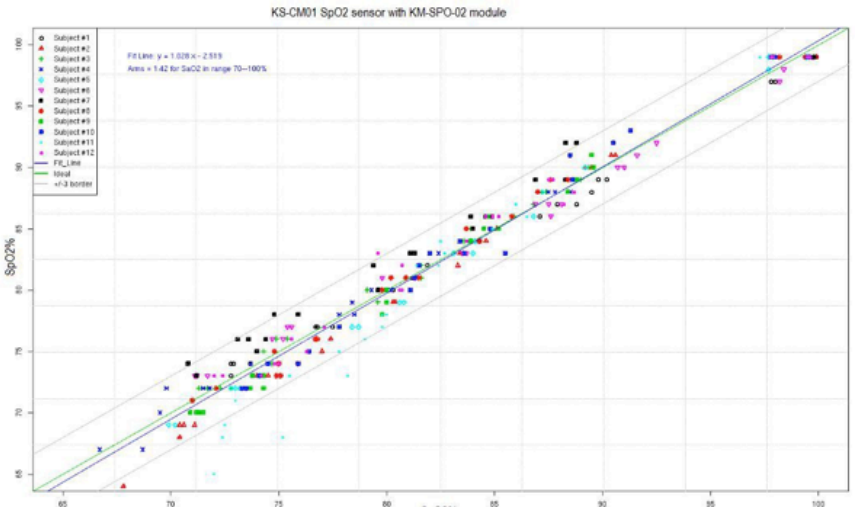
1. Technique: Oscillometric
2. Pressure measuring range: 0mmHg~300mmHg
3. Cuff inflation time:<20 seconds (typical adult cuff)
4. Overpressure protection limit
   Adult: 300mmHg (39.9kPa); Child: 240mmHg; Infant: 150mmHg
5. Blood pressure measurement range:
   SYST: 30mmHg~270mmHg DIAS: 20mmHg~235mmHg MAP: 10mmHg~220mmHg
6. Blood pressure measuring accuracy:
   Maximal mean difference: ≤ ±5mmHg (0.67kPa)
   Maximal standard deviation: ≤8mmHg (1.067kPa)

4.2 SpO_2 Measurement

1 Technique: optical with dual-wavelength
LED wavelength: Red light: 663nm,
Infrared light: 890nm
Maximal optical output power: less than 2mW maximum average
2. SpO_2 display range: 0%~100%
3. SpO_2 measuring accuracy: Arms is not greater than 3% for SpO_2 range from 70% to 100%, undefined during range 0%~70%
Note: Arms is defined as root-mean-square value of deviation according to ISO 80601-2-61 / ISO 9919
4. Measuring mode: spot-checking
5. SpO_2 display update: every second
6. SpO_2 averaging: Averages the recent eight seconds value falling within the acceptable limits
7. The table with measured SpO_2 accuracy specification in the discrete SpO_2 ranges:

SpO_2 range	**Arms**
70%~80%	1,62
80%~90%	1,09
90%~100%	1,58
70%~100%	1,42

8. The graphical plot of all sampled data points:



9. **Note:** The data is obtained from UP-7000 (K123711), which has the same technology as the PC-300, through a controlled, induced hypoxia study, which was conducted with healthy adult volunteers. The device uses the same SpO_2 measurement technology provided in the subject device.

4.3 Pulse Rate Measurement

1. PR measuring range: 30bpm~240bpm
2. Pulse rate measuring accuracy: ±2bpm or ±2%, which is greater

4.4 Temperature Measurement

1. Measuring range: 32.0°C~43.0°C
2. Measuring accuracy: ±0.2°C is for TEMP range from 36.0°C to 39.0°C, and ±0.3°C is for the rest; ±0.4°F is for TEMP range from 96.8°F to 102.2°F, and ±0.5°F is for the rest.
3. Response time: ≤5s

4.5 Blood Glucose Measurement (Optional)

1. Technique: Amperometric, glucose oxidase
2. Measuring range: 1.1mmol/L~33.3mmol/L (20~600mg/dL)
3. Measuring time: 6 seconds

4.6 ECG Measurement (Optional)

1. Heart Rate measuring range: 30bpm~240bpm
2. Heart Rate measuring accuracy: ±2bpm or ±2% whichever is greater
3. Display scale: 5.0mm/mV±10%
4. Common-mode rejection ratio (CMRR): ≥60dB

4.7 Others

4.7.1 Operating Environment

1 Operating temperature: 5°C~40°C;
Relative humidity: 30%~80%;
Atmospheric pressure: 70.0kPa~106.0kPa;
Power supply: a.c. 110V-240V AC, 50/60Hz;
Internal power supply: d.c.3.7V (rechargeable Lithium battery);
Input: 15VA

2. The device should be situated in a place protected against direct sunlight, to prevent overheating inside of the equipment.
3. Do not use this equipment in combination with any equipment other than those approved in the user manual.
4. The device should be stored and used in a specified temperature, humility and atmospheric pressure range, or damage maybe caused to the device and as a consequence, record inaccurate results.
5. If the device gets wet by accident, the operator should NOT turn on the power until it has been thoroughly air dried.
6. Do not use this equipment in an environment with toxic or inflammable gas.
7. Only monitor a single person at a time.
8. Do not expose the device to a magnetic resonance (MR) environment.
   - The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.
   - Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning.
   - The device may generate artifacts in the MR image.

- The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

Warning: Do not use any other adapters than those provided.

9. RF parameter
   - Receiver bandwidth: 2.402 GHz – 2.480 GHz
   - Transmitter bandwidth: 2.402 GHz – 2.480 GHz
   - Effective radiated power: 8 dBm

4.7.2 Classification

1. Protection against electric shock: Class II equipment and internally powered equipment
2. The degree of protection against electric shock: Type BF applied part
3. Define apply part: cuff, SpO_2 probe, temperature probe, ECG lead wires (optional).
4. The degree of protection against harmful ingress of liquid: The equipment is IP22 with protection against ingress of liquid
5. Electro-magnetic Compatibility: Group I, Class A

Chapter 5
TROUBLESHOOTING

Trouble	Possible reason	Solution
Ca not turn on the device	The built-in battery is drained	Recharge by connecting the power supply adapter
	Battery is not installed	Install the Lithium battery
	Some parts provided by other manufactures are inserted to the connector	Remove the related parts and try again
No blood pressure result	The cuff is wrapped around the arm incorrectly	Wrap the cuff around the arm correctly
	The windpipe is not correctly inserted to the NIBP jack	Insert the windpipe to the NIBP jack
No SpO_2 result	The SpO_2 probe is not plugged into the "SpO_2" connector (or Port1 or Port2)	Plug the SpO_2 probe into the "SpO_2" connector (or Port1 or Port2)
No TEMP result	The temperature probe is not correctly plugged into "TEMP" connector (or Port1 or Port2)	Plug the temperature probe into "TEMP" connector (or Port1 or Port2)
	Taking measurements before "READY" appears on the temperature probe screen	Do not take a measurement until "READY" appears on the temperature probe screen

Chapter 6
ERROR MESSAGE INTERPRETING

Error code	Description
ERR 01	Fails to inflate pressure to 30mmHg within 7 seconds (The cuff is not well-wrapped)
ERR 02	Cuff pressure is over 295mmHg (Overpressure protection)
ERR 03	No valid pulse is detected
ERR 04	Excessive motion artifact
ERR 05	Invalid measured result
ERR 06	Air leakage is detected
ERR 07	Self-test fail
ERR 08	Pneumatic system error
ERR 09	Signal saturation
ERR 10	Air leakage check fail
ERR 11	Hardware fault
ERR 12	Measurement timeout (the max. measurement time for adult is 120 seconds when the pressure is over 200mmHg, 90 seconds when the pressure is less than 200mmHg, and 90 seconds for neonate.)

Chapter 7
PACKING LIST

Item	Description	Quantity	Check
1	Spot-Check Monitor	One piece	OK
2	Handbag	One piece	OK
3	User Manual	One piece	OK
4	Cuff	One piece	OK
5	USB cable	One piece	OK
6	Charger (with USB socket)	One piece	Option
7	Temperature probe	One piece	
8	Smart SpO2 probe	One piece	
9	Glucose Meter (with lancing device and link cable)	One set	
10	Blood glucose test strips (with blood lancets)	One pack	
11	Spot-Check Monitor Data Manager Software	One set	
12	Easy ECG Monitor	One piece	
13	ECG lead wire (snap)	One piece	
14	Disposable adhesive ECG electrodes	Six pieces	

Chapter 8
MAINTENANCE AND SERVICE

The Spot-Check Monitor should be properly maintained to ensure its maximum performance and long service life. In addition to the warranty period, the company also offers long-term service for each customer.
It is important that the user reads and follows the operation instructions, important information and maintenance measures.

8.1 Technical Maintenances

8.1.1 Daily Examination

Before using the monitor, the following checks should be carried out:
- Check the monitor for any mechanical damage;
- Inspect the exposed parts and the inserted parts of all the leads, and the accessories;
- Examine all the functions of the monitor that are likely to be used for patient monitoring, and ensure that it is in good working condition.

If there is any indication of damage, or if damage is accurately proven, do not use the device. Contact your supplier for advice and to reach a satisfaction solution.

8.1.2 Routine Maintenance

- If the hospital fails to carry out a satisfactory maintenance program on the monitor, it may cause harm to the patient.
- If there is any indication of cable and transducer deterioration or damage, please do not use.

- The SpO_2 function has been adjusted before vending. If the user needs to adjust the SpO_2, adjust by using the simulator mode FLUKE INDEX2.
- The adjustable units in the monitor such as the potentiometer cannot be adjusted without permission so to avoid unnecessary failures that may affect the normal application.
- It is recommended to use the battery once a month to ensure a strong power supply capacity and long service life, and recharge once the power has completely run out..

8.1.3 Battery Maintenance

- Please pay attention to the polarity of the battery, do NOT insert into the battery compartment with reversed polarities.
- In order to avoid damaging the battery, do NOT use other power supply device to charge the battery.
- After use, dispose of the battery according to local regulations, do NOT throw into fire.
- Do NOT hit or strike the battery with force.
- Do NOT use this battery in other devices.
- Do NOT use this battery below -20°C or above 60°C.
- In order to maintain the battery supply and prolong the battery lifetime, please charge the battery routinely. Regularly, charge the battery every 3 months even if the device has not been used.
- Only use a battery with the specification recommended by the manufacturer.
- Whether the monitor is on or off, the built-in battery will charge as long as the monitor is connected to an AC adapter and the AC power is on. When the battery is full, it will stop charging to avoid causing any damage. If the monitor is connected to an AC adapter and the AC power is on, it will use the AC power, but when the AC power is off, the battery power will be used. Priority of using the AC power and the power switch between the AC and battery is automatic and seamless.

- If the battery is damaged, please replace it with a battery with "CCC" or "CE" mark. The model and specifications of the battery should be the same as the original battery. The user must ensure that the battery meets all applicable safety codes. The user can also contact the distributor for service.

8.2 Cleaning and Disinfection of the Main Unit

- Switch off the monitor and disconnect the power cord before cleaning.
- Keep the monitor free from dust.
- It is recommended to regularly clean the outer shell and screen of the monitor. Only use a non-corrosive cleanser such as clear water.
- Wipe the surface of the monitor and transducers with an alcohol impregnated wipe, and dry with a clean cloth or just air-dry.
- Dilute the cleaner.
- Do NOT use scrubbing materials.
- The monitor can be disinfected. Please clear the monitor first.
- To avoid damage do not let liquid cleaner flow into the connector jack of the monitor.
- Clean the exterior of the connector only.
- Do NOT let any liquid flow into the shell or any other parts of the monitor.
- Do NOT leave any residue liquid or disinfectant on the surface of the monitor.
- Do NOT perform high pressure sterilization on the monitor.
- Do NOT immerse any parts of the monitor or its accessories in the liquid.
- If the monitor accidentally becomes wet, it should be thoroughly dried before use. The rear cover can be removed by a qualified service technician to verify the absence of water.
- Do NOT pour disinfectant on the monitor's surface while disinfecting.

8.3 Cleaning and Disinfection of Accessories

It is recommended to clean and disinfect the accessories (excluding the SpO_2 probe) with a piece of gauze soaked in 75% Alcohol or 70% Isopropanol.

- Do not use damaged accessories.
- Accessories cannot be entirely immerged into water, liquid or cleanser.
- Do NOT use radiation, steam or epoxyethane to disinfect accessories.
- Wipe off any remaining residue of alcohol or isopropanol after disinfection.
- To prevent cross infection, the user wipes the temperature sensitive probe with 75% alcohol before and after use, then wipes the residue clean with clean dry cloth.
- Disinfect the temperature sensitive probe with alcohol.
- Wipe the thermometer clean with a mild cloth if it becomes dirty.
- Wipe the thermometer clean and return to packaging after use.

8.4 Storage

If the equipment will not be used for a long time period of time, wipe it clean and return it to the packaging.

Store in a dry well ventilated place free from dust and corrosive gases.

Storage environment: Ambient temperature: -20°C~60°C
Relative humidity: 10%~95%, non-condensing
Atmospheric pressure: 53.0kPa~106.0kPa

8.5 Transportation

The monitor should be transported by land (vehicle or railway) or air in accordance with the contractual terms. Do NOT hit or drop with force.

Chapter 9
EMC Compliance

Essential Performance

The monitor has the following essential performance in an environment of electromagnetic environment specified below:
Operating mode, accuracy, function

Warnings

- Use of the spot-check monitor 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 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 the spot-check monitor could result in increased electromagnetic emissions or decreased electromagnetic immunity of the spot-check monitor and result in improper operation.
- 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 spot-check monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of the spot-check monitor could result.

Electromagnetic compatibility
Levels of compliance with the EN 60601-1-2:2015 standard

- ESD immunity 15kV for air discharge 8 kV for contact discharge (EN 61000-4-2)
- 2kV/100kHz burst immunity (EN 61000-4-4) power supply/1kV signals
- Surge immunity (EN 61000-4-5): 1kV common/2kV differential
- Magnetic field (EN 61000-4-8): 30A/m
- Dip Immunity: 0% 0.5 cycles; 0% 1 cycle; 70% 25 cycles (50Hz) and 30 cycles (60Hz); Breaks: 250 cycles (50Hz); 300 cycles (60Hz)
- Immunity to RF currents in the range 150kHz-80MHz (EN 61000-4-6) 3V modulation 80% 1kHz 6V modulation 80% 1kHz for the following frequency ranges: 6.765 MHz ÷ 6.795 MHz 13.553 MHz ÷ 13.567 MHz 26.957 MHz ÷ 27.283 MHz 40.66 MHz ÷ 40.70 MHz
- CISPR 11 class A emissions
- EN 61000-3-2 class A Harmonic currents
- PST, DT, DC Flickers

RF field immunity (EN 61000-4-3):		
Field (V/m)	**Frequency**	**Modulation**
3	80MHz ÷ 2700MHz	1kHz AM 80%
27	380MHz ÷ 390MHz	18Hz PM 50%
28	430MHz ÷ 470MHz	18Hz PM 50%
9	704MHz ÷ 787MHz	217Hz PM 50%
28	800MHz ÷ 960MHz	18Hz PM 50%
28	1700MHz ÷ 1990MHz	217Hz PM 50%
28	2400MHz ÷ 2570MHz	217Hz PM 50%
9	5100MHz ÷ 5800MHz	217Hz PM 50%

WARNINGS:
Even though it complies with EN 60601-1-2, the medical device (DEVICE NAME) may interfere with other appliances nearby. The device should not be used next to or stacked with other equipment. Install the device away from other equipment which radiates high frequencies (short waves, microwaves, electrosurgical units, mobile phones).

The use of this device near to or placed on other appliances should be avoided, as this can lead to its incorrect operation. In these cases, the device and the other equipment should be kept under observation to verify their normal operation.
Transportable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no less than 30 cm (12 inches) away from any part of the [EM EQUIPMENT or EM SYSTEM], including the cables specified by the MANUFACTURER. Otherwise, performance degradation of this equipment may occur.

The device is designed to operate in an electromagnetic environment in which RF radiated disturbances are under control. The customer or the operator can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable RF communication devices (transmitters) and the medical device, as recommended below, in relation to the maximum output power of the radio communication devices.

Rated maximum output power of transmitter (W)	**Distance (m) of separation according to the frequency of the transmitter**		
	from 150kHz to 80MHz $d = 1.2\sqrt{P}$	**from 80MHz to 800MHz** $d = 1.2\sqrt{P}$	**from 800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
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

For transmitters whose rated maximum output power is not listed above, the recommended separation distance d in metres (m) can be calculated using the equation applicable to the transmitter frequency, where P is the rated maximum power transmitter output in Watts (W) according to the transmitter manufacturer.

Notes:

(1) The highest frequency range must be applied at 80 MHz and 800 MHz

(2) These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and by the reflection from structures, objects and people.

Appendix I
Classification of Blood Pressure Level

Category	SYS (mmHg)	DIA (mmHg)
Optimal	<120	<80
Normal	<130	<85
High normal	130~139	85~89
Grade 1 hypertension (Mild hypertension)	140~159	90~99
Grade 2 hypertension (Moderate hypertension)	160~179	100~109
Grade 3 hypertension (Severe hypertension)	≥180	≥110
Isolated systolic hypertension	≥140	<90

Reference:
The 1999 WHO-ISH Guidelines for the Management of Hypertension

***Disposal**: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

GIMA WARRANTY TERMS
The Gima 12-month standard B2B warranty applies.