

This Manual is written for the current Spot-Check Monitor.

The Manual describes, in accordance with the Spot-Check Monitor's features and requirements, main structure, functions, specifications, correct methods for transportation, installation, usage, operation, repair, maintenance and storage, etc. as well as the safety procedures to protect both the user and equipment. Refer to the respective chapters for details.

The Manual is published in English and we have the ultimate right to explain the Manual.

Marks in the Manual:

-  **Caution:** must be followed to avoid endangering the operator and the patient.
-  **Attention:** must be followed to avoid causing damage to the Spot-Check monitor.
-  **Note:** contains some important information and tips about operations and application.

Instruction to User

Dear Customers,

Thank you for purchasing this quality product. Please read the following information very carefully before using this device.

Read these instructions carefully before using this Spot-Check Monitor. These instructions describe the operating procedures to be followed strictly. Failure to follow these instructions can cause monitoring abnormality, equipment damage and personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues and any monitoring abnormality, 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 the flammable gas condition or in any environment that may lead to explosion.
- ☠ The device and accessories that shall not be serviced or maintained while the device is in use.
- ☠ The doctor or patient is an intended operator.
- ☠ Do not modify this equipment without authorization of the manufacturer.
- ☠ The SpO₂, NIBP, Temperature, ECG(optional) measurements are frequently used functions.
- ☠ The device is IP22 with protection harmful solid objects and ingress of liquid. So that means the device is protected against solid foreign objects of 12.5mm and greater, and protected against vertically falling water drops when enclosure tilted up to 15°.
- ☠ Please check the monitor completely to verify that the accessories can function safely and normally.

- When the user is connected with other devices, the total leakage current may exceed the limitation and cause potential danger to the user as a result.
- All combinations of equipment must be in compliance with standard of IEC 60601-1-1 medical and electric system requirements.
- Although biocompatibility tests have been performed on all the applied parts, some exceptional allergic patients may still have anaphylaxis. Do NOT apply to those who have anaphylaxis.
- All the connecting cables and rubber tubes of the applied parts should be kept away from the patient' neck to prevent any possible suffocation of the patient.
- All the parts of the monitor should NOT be replaced at will. If necessary, please use the components provided by the manufacturer or those that are of the same model and specifications as the accessories along with the monitor which are provided by the same factory, otherwise, negative effects concerning safety and biocompatibility etc. may be caused.
- If the monitor falls off accidentally, please do NOT operate it before its safety and technical performance have been tested minutely and positive testing results obtained.
- Do NOT open the device cover without authorization. The cover should only be opened by qualified service personnel.
- When disposing of the monitor and its accessories, the local law should be followed.

Table of contents

CHAPTER 1 OVERVIEW	60
1.1 Features	60
1.2 Product Name and Model.....	61
1.3 Intended Use.....	61
1.4 Impact on the Environment and Resources.....	62
CHAPTER 2 OPERATION INSTRUCTION	62
2.1 Appearance.....	62
2.1.1 The Front Panel.....	62
2.1.2 The Right and Upper Sides of The Device.....	64
2.2 Installation.....	66
2.2.1 Power Supply.....	66
2.2.2 Starting the Monitor	67
2.2.3 Download the APP software for Android Smart Phone	67
2.3 Make Measurement	68
2.3.1 Blood Pressure Measurement.....	68
2.3.2 SpO ₂ Measurement	71
2.3.3 Temperature Measurement	73
2.3.4 Blood Glucose Measurement (Optional).....	75
2.3.5 ECG Measurement (Optional)	79
2.4 Pressure Accuracy Check Method	82
2.5 Symbols	84
CHAPTER 3 MONITORING SCREEN DISPLAY	86
3.1 Measuring Screen	86
3.2 System Setting Screen	88

3.3	History Data Review Screen	89
3.4	Data Uploading	91
CHAPTER 4 TECHNICAL SPECIFICATIONS		91
4.1	Blood Pressure Measurement.....	91
4.2	SpO ₂ Measurement	92
4.3	Pulse Rate Measurement.....	92
4.4	Temperature Measurement	93
4.5	Blood Glucose Measurement (Optional).....	93
4.6	ECG Measurement (Optional)	93
4.7	Others	93
	4.7.1 Operating Environment	93
	4.7.2 Classification.....	94
	4.7.3 Guidance and manufacturer's declaration - Electromagnetic compatibility	95
CHAPTER 5 TROUBLESHOOTING.....		99
CHAPTER 6 PACKING LIST		100
CHAPTER 7 MAINTENANCE AND SERVICE		101
7.1	Technical Maintenances.....	101
	7.1.1 Daily Examination.....	101
	7.1.2 Routine Maintenance	101
	7.1.3 Battery Maintenance.....	102
7.2	Cleaning and Disinfection of the Main Unit.....	103
7.3	Clean and Disinfection of the Accessories	104
7.4	Storage	105
7.5	Transportation	105

Chapter 1

OVERVIEW

1.1 Features

- Small in size, light in weight, easy to carry and operate;
- Clear and large numeric display by segment LCD panel, real-time clock display is available;
- Accurate blood pressure measurement can be activated or canceled by one shortcut button;
- Unique oximetry technique ensures quick and accurate SpO₂ & pulse rate measurement by smart sensor;
- Smart infrared temperature probe ensures quick and accurate measurement of body temperature;
- Blood pressure, oxygen saturation, pulse rate and temperature can be measured simultaneously;
- Blood Glucose meter can be connected to the device as well;
- Data storage with recall, up to 999 groups of records can be stored with label of patient ID.
- Power management with power saving mode, auto power off and low battery indication;
- Data upload to PC by USB cable and real-time data transmission to smart phone by wireless connection.

1.2 Product Name and Model

Name: Spot-Check Monitor

Model and Configuration:

Model	Configuration				LCD Display
	NIBP	SpO ₂	Pulse Rate	Temperature	
PC-301	√	--	--	--	√
PC-302	√	√	√	--	√
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 On Call Plus Glucose Meter respectively.

2. “√” means function available, and “--” means function unavailable.

1.3 Intended Use

The Spot-Check Monitor is a device designed for measuring the user’s physiological parameters, such as non-invasive blood pressure (NIBP), oxygen saturation (SpO₂), pulse rate (PR), and body temperature (TEMP). Besides, the device can receive measurement result from the Blood Glucose Meter, and the 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 no contraindication.

1.4 Impact on the Environment and Resources

Low

Chapter 2

OPERATION INSTRUCTION

2.1 Appearance

2.1.1 The Front Panel

Description:

1/2. : up/down key: on the setup display screen, short time press it to change the parameter value in step, longtime press it to change the parameter value quickly; on the review display screen, short time press it to review the history data records one by one, longtime press it to recall the history data records quickly.

3. : memory key: on the measurement display screen, longtime press this key (about 3s) to enter into the review display screen; on the review display screen,



Figure 2.1

short time press it to recall the history data records. On the setup display screen, all parameters can be set in the order

of anticlockwise by longtime pressing "" key, similarly, short time pressing "" key to set the parameters in the order of clockwise.

- : menu key: on the measurement display screen, longtime press menu key to enter the setup screen; on the setup or review display screen, longtime press "" key to go back to the measurement display screen.
- : start/cancel button: on the measurement display screen, short time press this button to activate or cancel the blood pressure measurement.

2.1.2 The Right and Upper Sides of The Device

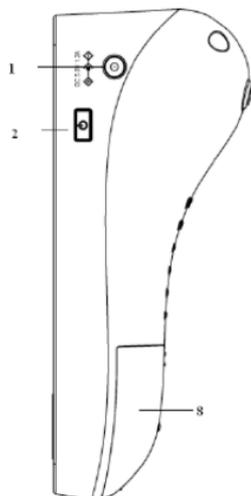


Figure 2.2

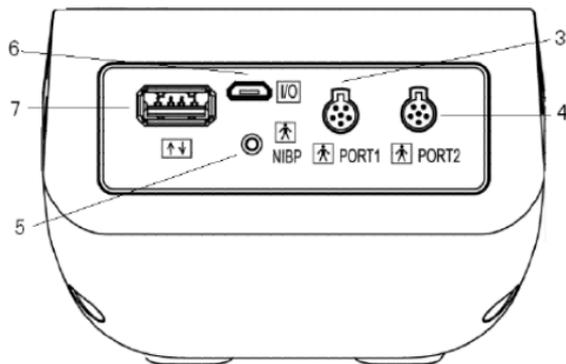


Figure 2.3A

The power switch and external DC power input socket are at the right side of the monitor as shown in figure 2.2.

The signal input/output ports are at the upper side of the monitor as shown in figure 2.3.

Description:

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

2.  : Power switch: long time press it to turn on/off the monitor.

3/4. Port 1/Port 2: Connector to link with temperature probe, smart SpO₂ probe or blood glucose meter.

5. **NIBP:** Cuff connector.

6.  : Charge / USB data interface.

7.  : Connector to link with other devices (reserved).

8. Battery cover.

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 SpO₂ probe or ECG accessory (for example Easy ECG Monitor). However, the current version device has 3 “” ports, marked “SpO₂”, “TEMP”

and “ECG” respectively, which can be used only to connect the corresponding sensors or accessories.

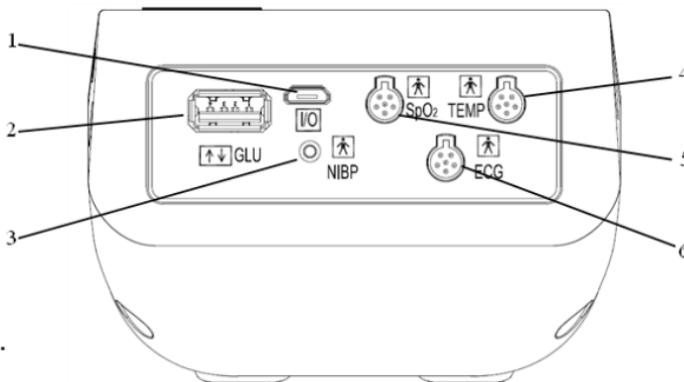


Figure 2.3B Upper-side view

Description:

1. : Charge / USB data interface.
2. : Connector to link to the blood glucose meter.
3. NIBP: Cuff connector.
4. TEMP: Temperature probe connector.
5. SpO₂: Smart SpO₂ probe connector.
6. ECG: Connector to link with ECG accessories.

2.2 Installation

2.2.1 Power Supply

1. 1. Internal power supply from built-in battery

When the battery indicator "" displays with full grids, it means the built-in battery is fully charged. When it blinks, that means battery voltage is low, and the user should charge the

battery in time by connecting the device to the AC power adapter or USB power source via USB cable. When the grids of the battery indicator are rolling circularly, it means the battery is being charged.

2. External power supply from 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 USB cable

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

2.2.2 Starting the Monitor

Long time press and hold the switch, the operator can view the software version, at this time, release the switch, the device enters the measurement display screen automatically. Then the user can begin to operate it.

➤ If fail to start the monitor by pressing the switch, please try to use external power supply.

2.2.3 Downloading the APP software for Android smart phone

The terminal devices such as Android smart phone can be used to receive data from the Spot-Check Monitor in real-time, and store the received data, review the stored data as well. You have to download the corresponding APP software on the smart phone. Please follow the procedure to download:

1. Install an APP software for scanning QR Code by smart phone, such as QuickMark,

I-Nigma, Bee Tagg etc.

2. Run the APP software to scan the QR Code image in Figure 2.4, please focus the QR Code frame while scanning.
3. If successful scanned, then the scanning result, that is a web link for downloading the APP software “PC-300. Apk” will be displayed on the smart phone.
4. Open this web link by a web browser to download the APP software “PC-300.apk”. Install this APP software if successful 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 is successful to connect with the Spot-Check Monitor.
- ☞ Refer to the manual of this APP software for detail operating.

2.3 Take Measurement

2.3.1 Blood Pressure Measurement



Figure 2.4 QR Code image

1. When putting on the cuff, spread the cuff and wrap it around the upper arm evenly to appropriate tightness. The correct cuff position refers to figure 2.5.
2. Connect the hose from the cuff to the connector on the upper-side of the device with the mark of "NIBP".
3. Pressing start/cancel button  to start blood pressure measurement.

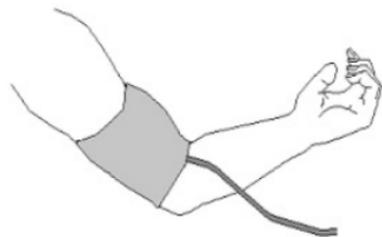


Figure 2.5 Cuff position

Safety Instructions for blood pressure measurement

- Blood pressure measurement is prohibited to those who have severe hemorrhagic tendency or with sickle cell disease, for partial bleeding may cause.
- Appropriate cuff should be selected according to the age and arm circumference of the subject. Its width should be 2/3 of the length of the upper arm. The inflatable part should be long enough to permit wrapping appropriately 80% of the limb. See the table below for the dimensions:

Cuff Model	Arm Circumference
Child cuff	17cm~22cm
Small-sized Adult Cuff	22cm~30cm
Middle-sized Adult Cuff	30cm~42cm
Large-sized Adult Cuff	42cm~48cm

- 📖 Continuous measurements may result purpura, neuralgia and lack blood.
- 📖 Do NOT wrap the cuff on limbs with transfusion tube or intubations or skin lesion area, otherwise, damages may be caused to the limbs.
- 📖 The equipment is intended for pregnant or pre-eclamptic patient, but not neonatal patients.
- 📖 The need to check that operation of the equipment does not result in prolonged impairment of patient blood circulation.
- 📖 The patient relax as much as possible and not talk during the measurement procedure.
- 📖 5 min should elapse before the first reading is taken.
- 📖 Any reading can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic condition.
- 📖 The performance of the equipment can be affected by extremes of temperature, humidity and altitude.
- 📖 The need to avoid compress or restriction of the connection tubing.
- 📖 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.
- 🔔 The measurement should be taken at appropriate intervals. Continuous measurement at too short intervals may lead to pressed arm, reduced blood flow and lower blood pressure, and resulting inaccurate reading of blood pressure. It is recommended the measure be taken at intervals of more than two minutes.
- 🔔 Prior to use of the cuff, empty the cuff until there is no residual air inside it to ensure accurate measurement.

- 🔔 Do NOT allow the cuff to be twisted or bended.
- 🔔 Do NOT twist the cuff hose or put heavy things on it.
- 🔔 Please hold the connector of the hose while pulling out or plugging in it to the device.
- 🔔 It's recommended that the patient should take measurement again when arrhythmia or auricular fibrillation occurs.
- 🔔 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 SpO₂ Measurement

Operation procedure:

1. Connect the smart SpO₂ probe to the connector on the upper-side of the device with mark of "PORT1" or "PORT2". When unplugging the connector, be sure to hold the head of the connector and pull it out.
2. Red light blinking inside the clip of SpO₂ probe means 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 on the probe, shown at the side.
4. The device begins to make measurement.

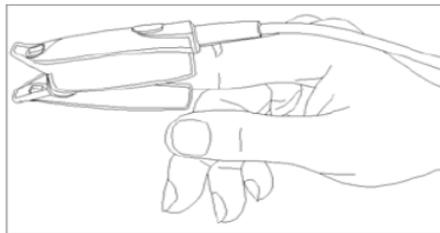


Figure 2.6 demonstration for SpO₂ probe

Safety instruction for SpO₂ measurement

- Continuous use of SpO₂ probe may result in discomfort or pain, especially for those with microcirculatory problem. It is recommended that the probe should NOT be applied to the same place for over two hours, change the measuring site periodically if necessary.
 - When the ambient temperature is over 35°C, please change the measuring site every two hours if necessary; when the ambient temperature is over 37°C, please do NOT use SpO₂ sensor, for long time using in high temperature will cause burns.
 - SpO₂ measuring site must be examined more carefully for some special patient. Do NOT place the SpO₂ probe on the finger with edema or fragile tissue.
 - Do NOT put the SpO₂ probe and pressure cuff on the same limb, otherwise the blood pressure measurement may affect the SpO₂ measurement.
 - The device is calibrated to display functional oxygen saturation.
 - 🔔 Do NOT allow the sensor cable to be twisted or bended.
 - 🔔 Check the SpO₂ sensor and cable before use. Do NOT use the damaged SpO₂ sensor.
 - 🔔 When the temperature of the SpO₂ sensor is abnormal, do not use it any more.
 - 🔔 Please do NOT use nail polisher or other cosmetic product on the nail.
 - 🔔 The fingernail should be of normal length.
 - 🔔 The SpO₂ sensor can not be immersed into water, liquor or cleanser.
 - 🔔 The SpO₂ sensor can be repeatable used. Please clean and disinfect it before using.
 - 🔔 **Connectors with the label “SpO₂” can only be connected with the smart SpO₂ probe.**
- Note:** The ECG and SpO₂ functions cannot be used simultaneously. If the device is successfully connected to both the ECG accessory and the smart SpO₂ probe, one function will take precedence over the other, for example of the user presses “Start” on the ECG accessory, the SpO₂ probe will be temporarily disabled until the ECG measurement is terminated.

2.3.3 Temperature Measurement

The infrared temperature probe is a delicate transducer. Please follow the steps and procedures in operation. Failure to operate it may cause damage to the probes.

1. The infrared temperature probe

Please place the infrared temperature probe to a stable ambient temperature for 30min before measuring. If the patient sweats, please wipe the sweat. Please begin to take measurement when the temperature is stable.

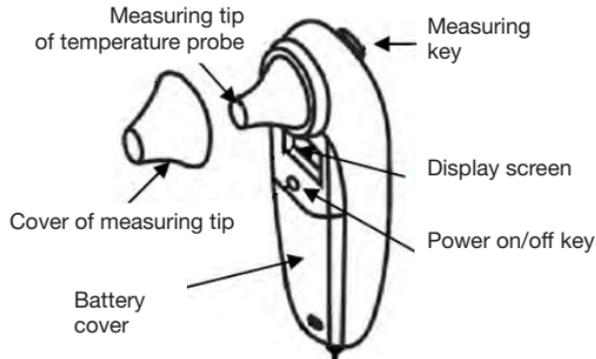


Figure 2.7A the infrared temperature probe

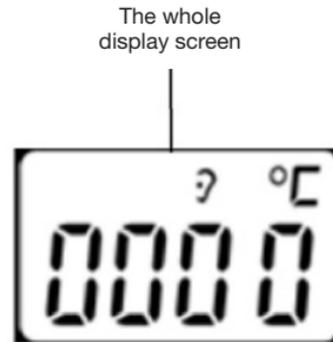


Figure 2.7B

Operation procedure:

1. Connect the infrared temperature probe to the connector on the upper side of device

with mark of “PORT1” or “PORT2”. When LCD screen displays , it means that the probe is connected successfully.

2. When the screen shows as figure 2.7B and the temperature unit °C is blinking, then the user can start to take measurement.
3. Insert the measuring tip of temperature probe into the earhole and press the measuring key to start the measurement. A short beep means the measurement is 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 stand by automatically if no operation for 1 min. If you need to make a measurement once more, please press the measuring key and repeat step 2 and step 3.

Normal body temperature varies in a range. The following table shows the temperature varying range at different body position, so it is meaningless to simply compare the temperature readings from different position.

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

Safety Instruction for Temperature Measurement

-  Do NOT take measurement when the subject is moving.
-  The patient with tympanitis and otitis problem should NOT use this device for measuring.
-  When the infrared temperature probe is connected to the device, the infrared temperature probe will be always at power-on status, so 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" ().

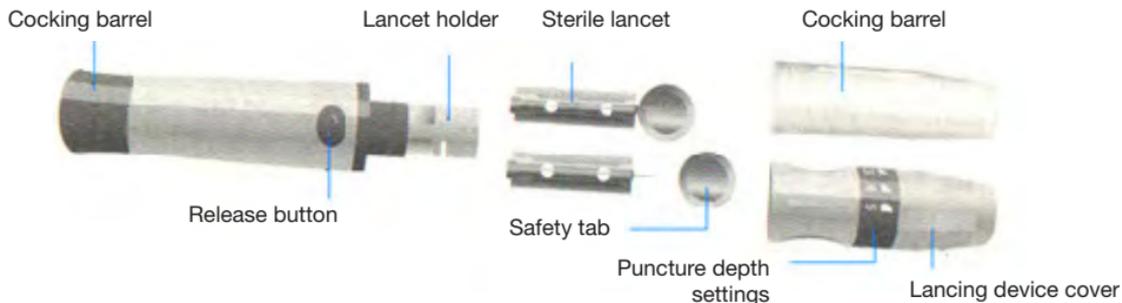
Appearance and key functions of the On Call Plus Blood Glucose:

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.

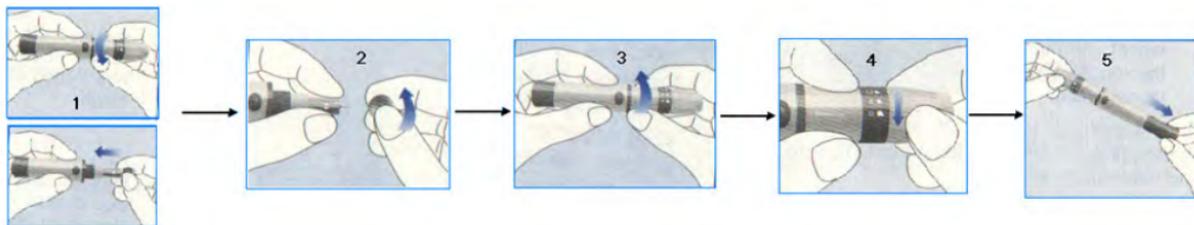


Figure 2.9A Operation for Lancing Device and Blood Lancet

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.

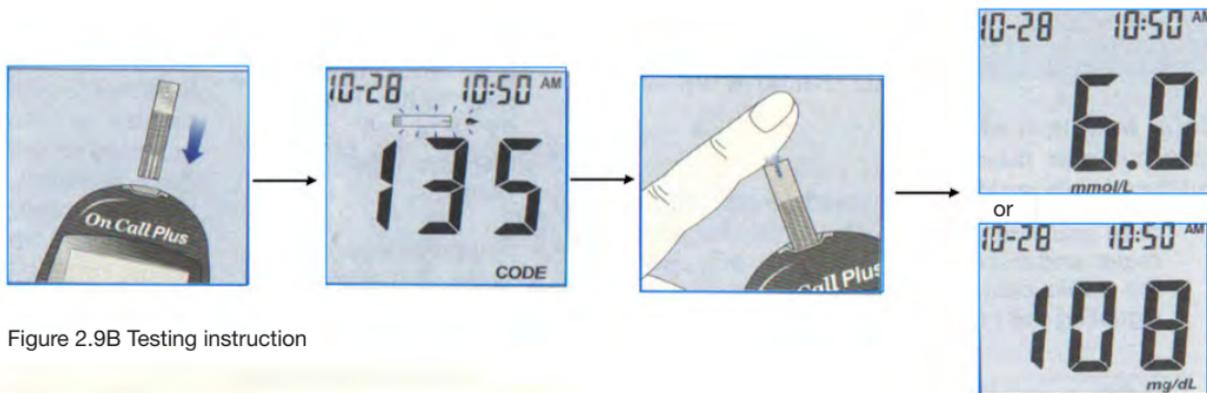
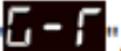


Figure 2.9B Testing instruction

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 with mark of "PORT1" or "PORT2".
2. Choose one of the methods (refer to figure 2.10B/C/D/E) to make ECG measurement.
3. When Easy ECG Monitor and Spot-Check Monitor are successful connected, press "Start" button on the Easy ECG Monitor to activate the ECG measurement.
4. When "ECG" appears on the display screen of Easy ECG Monitor, it means the Easy ECG Monitor begins to make measurement.
5. 30 seconds later, the measuring result will be displayed on the screen, and the measurement terminates.

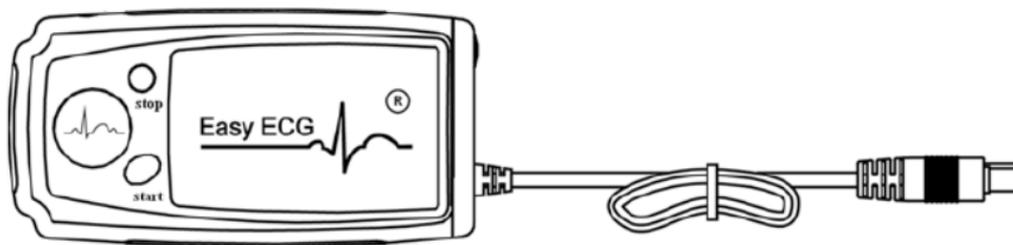
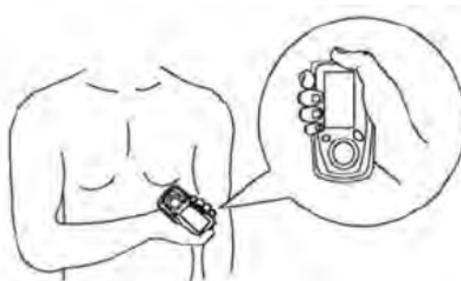


Figure 2.10A ECG accessory

Start / Stop: Start/Stop ECG measurementFigure 2.10B
Palm measurementFigure 2.10C
Chest measurementFigure 2.10D
Leg measurement

To obtain 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 Figure 2.10E to obtain the Lead II ECG signal; if you want to measure Lead I and Lead III ECG signal, according to the following table to connect the lead wires to the electrodes (**note**: lead wire is optional).

Safety Instruction for ECG Measurement

1. Check the device to make sure that there is no visible damage that may affect user's safety and measurement performance. Stop using the unit, when there is obvious damage.
2. Do NOT make diagnosis oneself by the measurement and measurement results, always consult the doctor if abnormal information is presented frequently.
3. Do NOT use the device in the bathroom or moist circumstance.

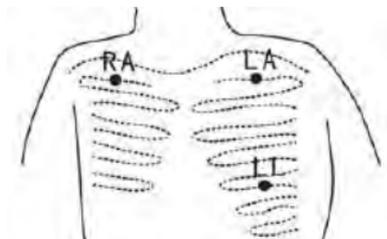


Figure 2.10E
Lead wire measurement

Table 1 ECG Leads Configuration and Electrodes Location Table

Lead	Lead I	Lead II	Lead III
Electrode Location	Electrode Name& Color		
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, Ø8.0mm/Ø4.0mm 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.

M3x6 Screw



Figura 2.11

NIBP Connector Plug



Figura 2.12

Air tube

NIBP Connector

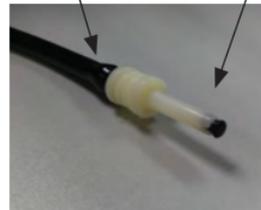


Figura 2.13

NIBP Port

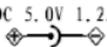


Figura 2.14



Figura 2.15

2.5 Symbols

Symbol	Description	Symbol	Description
	Wireless		Battery voltage indicator
	Alarm		USB icon
	Memory icon	bpm	Unit of pulse rate
	Pulse strength bar graph	kPa/mmHg	Unit of blood pressure
°C/°F	Unit of temperature	DC 5.0V 1.2A 	External DC power input
	Power on/off switch		Charger or USB data interface
	Type BF applied parts	SN	Serial Number
	Pulse rate (unit: bpm, beat per min)		Refer to manual

Symbol	Description	Symbol	Description
TEMP	Connector for temperature probe		No SpO ₂ Alarms
NIBP	Connector for cuff		Date of manufacture
ECG	Connector for ECG accessory		Attention, read the warning notices
	Manufacturer information		Keep dry
	Connector to link with blood glucose meter		Keep away from sunlight
	Follow WEEE regulations for disposal	CE 0476	CE mark according to the Directive 93/42/EEC and further amendments
SpO ₂	Connector to smart SpO ₂ probe		
	Battery cover		

Chapter 3

MONITORING SCREEN DISPLAY

3.1 Measuring Screen

Screen Description:

1.  USB connection icon

2.  wireless transmission icon;

"": means that the wireless transmitting function is on; when this icon is blinking, it means that the wireless connection is set up unsuccessful; when this icon is steady, it means that the wireless connection is set up successful;

"" means that the wireless transmitting function is off.

3.  beep sound indicator;  pulse beep is on;  pulse beep is off.

4.  battery voltage indicator. When the battery is full, battery voltage indicator displays full grid. When the indicator is blinking, it means the battery voltage is low and the user should



Figure 3.1B measuring screen

charge the battery. Please connect the device to the external power supply in time to ensure the normal use of the monitor, and the battery will be charged. During charging, the grids in the battery indicator are rolling circularly.

5. : it means the inflation pressure of the cuff during cuff inflation. Meanwhile,

on displaying the measured result, the description for the pressure will be displayed, such as O (optimal), N (normal), H (high), G1 (grade 1 hypertension), G2 (grade 2 hypertension), and G3 (grade hypertension).

11. **M**: Memory.

12. **ID**: the patient ID, can be set from 0 to 99.

13. **NO.:** the record number of stored data, up 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. **SYS**: Systolic pressure.

17. **DIAS**: Diastolic pressure.

18. **kPa/mmHg**: unit of blood pressure, 1kPa=7.5mmHg.

19. **SpO₂**: the value of SpO₂ with unit of %.

20. : pulse bar-graph.

21. **PR**: pulse rate with unit of bpm.

22. : the heart beat symbol. It flashes with heart beat.

23. **TEMP/BG**: the currently displayed temperature which unit is °C or °F. °C is Celsius, and °F is Fahrenheit. When the optional BG is chosen, blood glucose value will be displayed with the default unit of mmol/L.

3.2 System Setting Screen

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

Operation Instruction:

1. Longtime press "", please release the key after hearing one beep, and enter into setup screen. When the patient ID blinks, it means the setup function is available.
2. Short time press "/" key to enable or disable the wireless transmission function.
3. Short time press "" key to confirm the setting.

And the beeping mark  is blinking.

4. Short time press "/" key to enable or disable the pulse beep.
5. Short time press "" key to confirm the setting. And the "kPa" (blood pressure unit) is blinking.



Figure 3.2 setup display screen

The functions of wireless transmission, beep, blood pressure unit, temperature unit, date and time can be set by following the above steps.

6. Longtime press  key to bring the screen display back to the measurement display screen. The monitor will switch back to the measurement display screen as well if there is no operation for 30 seconds.

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

2. For setting the date, the century of year is fixed to be 20, i.e. “13y” means the year of 2013. Please see the following example for the date and time: 11:14”, March 23, 2013.



13y
11:14
03-23

3.3 History Data Review Screen

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



Figure 3.3 History data review screen

Operation instruction

1. Longtime press  key, and release the key after hearing one beep. Then the memory mark  will appear (i.e. Entering to review display screen). The patient's ID number is blinking at the same time.
2. Short press  /  key to browse the patient's ID number.

3. Short time press  key to confirm the setting, the record number (No.) is blinking at the same time.
4. Short pres   key to set the record number to be recalled. The data displayed on the screen is for the specific record of specific patient that you selected.
Note: when selecting patient ID, the screen only displays the patient who has the history data records

3.4 Data Uploading

1. When the wireless transmission function is on, the monitor can communicate with the host device such as PC, smart phone or other wireless enabled devices for real-time data transmission.
2. When connecting with USB cable, the history data can be dumped to 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. Accuracy of pressure measurement: ± 3 mmHg
5. Overpressure protection limit
Adult: ≤ 300 mmHg (39.9kPa)
6. Blood pressure measuring range:
SYS: 60mmHg~240mmHg DIA: 30mmHg~180mmHg
7. Blood pressure measuring accuracy: Maximal mean difference: ± 5 mmHg
8. Maximal standard deviation: 8mmHg

4.2 SpO₂ 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. SpO₂ measuring range: 35%~100%
3. SpO₂ measuring accuracy: Arms is not greater than 3% for SpO₂ range from 70% to 100%
Note: Arms is defined as root-mean-square value of deviation according to ISO 9919
4. Low perfusion performance: the above declaration is still attained while the amplitude modulation ratio is as low as 0.6%.

4.3 Pulse Rate Measurement

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

4.4 Temperature Measurement

1. Measuring range: 32.0°C~43.0°C
2. Measuring accuracy: $\pm 0.2^{\circ}\text{C}$ is for TEMP range from 35.0°C to 42.0°C, and $\pm 0.3^{\circ}\text{C}$ is for the rest.
3. Response time: $\leq 5\text{s}$

4.5 Blood Glucose Measurement (Optional)

1. Technique: Amperometric, glucose oxidase
2. Measuring range: 1.1mmol/L~33.3mmol/L (20~600mg/dL)
3. Minimum sample size: 1ul.
4. Measuring time: 10 seconds

4.6 ECG Measurement (Optional)

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

4.7 Others

4.7.1 Operating Environment

1. Operating temperature: 5°C~40°C; Relative humidity: 15%~93%;
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, so as to prevent overheating inside of the equipment.
 3. Do not use this equipment in combination with any equipment other than those expressly permitted in the user manual.
 4. The device should be stored and used in specified temperature, humidity and atmospheric pressure range, or it may cause damage to the device or inaccurate measurement results.
 5. If the device gets wet by accident, the operator should NOT power it on directly until it has been air-dry enough to avoid any damage to it.
 6. Do not use this equipment in an environment with toxic or inflammable gas.
 7. Monitor a single person at a time.

Warning: Don't use other adapter than provided by the Creative.

4.7.2 Classification

1. The type of 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, SpO₂ 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

4.7.3 Guidance and manufacturer's declaration electromagnetic compatibility

Guidance and manufacturer's declaration - electromagnetic emissions

The device Monitor PC-300 is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it's used in such an environment.

Emission Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

The device Monitor PC-300 is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

IMMUNITY Test	test level IEC 60601	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	± 1kV differential mode ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (> 5% dip in U_T) for 0,5 cycle	<5% U_T (> 95% dip in U_T) for 0,5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is

	<p>40 % U_T (6% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (> 95% dip in U_T) for 5 s</p>	<p>40% U_T (60% dip in U_T) for 5 cycles</p> <p>70% U_T (30% dip in U_T) for 25 cycles</p> <p><5% U_T (> 95% dip in U_T) for 5 s</p>	<p>recommended that the device be powered from an uninterruptible power supply or a battery.</p>
<p>Conducted RF EN 61000-4-6</p>	<p>3Vrms 150kHz to 80MHz (for non life-sup- porting devices)</p>	<p>$V_1 = 3 \text{ V rms}$</p>	<p>The portable and mobile RF communication devices, including cables, must not be used closer to the device Monitor PC-300, than the separation distance calculated by the equation applicable to the transmitter frequency.</p>
<p>Radiated RF EN 61000-4-3</p>	<p>3V/m 80MHz to 2.5GHz (for non life-sup- porting devices)</p>	<p>$E_1 = 3 \text{ V / m}$</p>	<p>Recommended separation distance:</p> $d = \left[\frac{3,5}{V^1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E^1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E^1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$

Where P is the maximum nominal output voltage of the transmitter in Watt (W) depending on the manufacturer of the transmitter and d is the recommended separation distance in meters (m).

The intensity of the field from the fixed RF transmitters, as determined by an electro-magnetic study of the site (a) could be lower than the level of conformity of each frequency interval (b). It is possible to check for interference in proximity to devices identified by the following symbol:



Note 1: At 80 MHz and 800 MHz the interval with the highest frequency is applied.

Note 2: These guide lines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field intensity from fixed transmitters such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Chapter 5

TROUBLESHOOTING

Trouble	Possible reason	Solution
Can 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 others 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 well inserted to NIBP jack	Insert the windpipe to the NIBP jack
No SpO ₂ result	SpO ₂ probe is not plugged to Port1 or Port2	Plug SpO ₂ probe to Port1 or Port2
No TEMP result	Temperature probe is not well plugged to Port1 or Port2	Plug temperatur2 probe to Port1 or Port2
	Make measurement before "READY" appears on the temperature probe screen	Do not make measurement until "READY" appears on the temperature probe screen

Chapter 6

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	Optional
7	Temperature probe	One piece	
8	Smart SpO ₂ probe	One piece	
9	On Call Plus Glucose Meter	One set	
10	Blood glucose test strips	One pack	
11	ECG accessory	One piece	
12	ECG lead wire (snap)	One piece	
13	Disposable adhesive ECG electrodes	Six pieces	

Chapter 7

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 read and follow the operating instructions, important information and maintenance measures.

7.1 Technical Maintenances

7.1.1 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.

In case of any indication of damage about the function of the monitor is detected and proven, it is not allowed to apply it to the patient for any monitoring. Please contact the local dealer or our company, and we are to offer the best solution as soon as possible for your satisfaction.

7.1.2 Routine Maintenance

The designed life of this monitor is 5 years. In order to ensure the measuring precision, it is recommended to adjust the monitor every year. As for the adjustment, it can be performed

in the specific instruction or contract our company directly. After each maintenance or the yearly maintenance, the monitor can be thoroughly inspected by qualified personnel, including function and safety examinations.

- If the hospital fails to carry out a satisfactory maintenance program about the monitor, it may be disabled and cause harm to the patient.
- If there is any indication of cable and transducer damage or they deteriorate, they are prohibited from any further use.
- The SpO₂ function has been adjusted before selling. So it is unnecessary to adjust again. If the user need to adjust SpO₂ during using, please adjust by using the simulator mode FLUKE INDEX2.
- 🔔 The adjustable units in the monitor such as potentiometer are not allowed to adjust without permission to avoid unnecessary failures that affect normal application.
- 🔔 It's recommended to use the battery once a month to ensure its strong power supply capacity and long service life, and recharge it after run out of the power volume.

7.1.3 Battery Maintenance

- Please pay attention to the polarity of battery, do NOT insert it into battery compartment with reversed polarities.
- Do NOT use the battery manufactured by other companies, if being inserted, the device may be damaged.
- In order to avoid damaging the battery, do NOT use other power supply device to charge the battery.
- After battery aging phenomenon occurring, do NOT throw the battery into fire to avoid explosion risk.

- Do NOT hit or strike it with force.
- Do NOT use this battery on other devices.
- Do NOT use this battery below -20°C or above 60°C .
- 🔔 In order to maintain battery supply and prolong battery lifetime, please charge the battery routinely. Generally, charge the battery every 3 months if the device has not been used for more than 3 months.
- 🔔 Only use the battery with the specification recommended by the manufacturer.
- 🔔 Whether the monitor is on or off, the built-in battery will be charged as long as the monitor is connected to an AC adapter and AC power is on. When the battery is full, it will stop charging for protecting from damage. If the monitor is connected to an AC adapter and AC power is on, it will use AC power, but when AC power is off, the battery power will be used. Priority of using AC power and power switch between AC and battery is automatic and seamless.
- 🔔 If the battery is damaged, please replace it with the 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.

7.2 Cleaning and Disinfection of the Main Unit

- 🔔 Switch off the monitor and disconnect the power cord before cleaning.
- 🔔 Keep the monitor from dust.
- 🔔 It is recommended to clean the outer shell and screen of the monitor to keep it clean. Only non-corrosive cleanser such as clear water is permitted.

-  Wipe the surface of the monitor and transducers with an alcohol impregnated wipe, and dry it with clean cloth or just air-dry.
-  Dilute the cleaner.
-  Do NOT use the scrub materials.
-  The monitor can be disinfected. Please clear the monitor first.
-  Do not let the liquid cleaner flow into the connector jack of the monitor to avoid damage.
-  Clean the exterior of the connector only.
-  Do NOT let any liquid flow into the shell or any parts of the monitor.
-  Do NOT let the cleaner and disinfectant stay on its surface.
-  Do NOT perform high pressure sterilization to the monitor.
-  Do NOT put any parts of the monitor or its accessories in the liquid.
-  If the monitor is accidentally wetted, it should be thoroughly dried before use. The rear cover can be removed by qualified service technician to verify absence of water.
-  Do NOT pour the disinfectant on its surface while disinfecting.

7.3 Cleaning and Disinfection of Accessories

It is recommended to clean and disinfect the accessories (excluding SpO₂ probe) with a piece of gauze which has been soaked in 75% Alcohol or 70% Isopropanol before using.

-  Do not use damaged accessories.
-  Accessories can not be entirely immersed into water, liquor or cleanser.
-  Do NOT use radiation, steam or epoxyethane to disinfect accessories.
-  Wipe off the remained alcohol or isopropanol on the accessories after disinfection, for good maintenance can extend life of accessories.

- 🔔 Disinfect the temperature sensitive probe with alcohol.
- 🔔 Wipe the thermometer clean with a mild cloth if it is dirtied.
- 🔔 Wipe the thermometer clean and keep it in the packaging for maintenance after using.

7.4 Storage

If the equipment will not be used for long time period of time, wipe it clean and keep it in the packaging, which shall be kept in a dry good ventilation place free from dust and corrosive gases.

Storage environment:	Ambient temperature:	-20°C~60°C
	Relative humidity:	≤93%
	Atmospheric pressure:	53.0kPa~106.0kPa

7.5 Transportation

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



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. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.

Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed. The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.