

GIMA ABPM PULSE RATE MONITOR WITH SPO2

Use and maintenance book

GIMA 35111



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IPX1



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Foreword

Please read the User Manual carefully before using this product. The User Manual which describes the operating procedures should be followed strictly. This manual detailed introduce the steps must be noted when using the product, operation which may result in abnormal, the risk may cause personal injury and product damage and other contents, refer to the chapters for details. Any anomalies or personal injury and device damage arising from use, maintain, store do not follow requirements of the User Manual, Our company is not responsible for the safety, reliability and performance guarantees! The manufacturer's warranty service does not cover such faults!

Our company has a factory record and user profile for each device, users enjoy free maintenance services for one year from the date of purchase. In order to facilitate us to provide you with a comprehensive and efficient maintenance service, please be sure to return the warranty card when you need repair service.

 **Note: Please read the User Manual carefully before using this product.**

Described in this User Manual is in accordance with practical situation of the product. In case of modifications and software upgrades, the information contained in this document is subject to change without notice.

The warning items

Before using this product, you should consider the safety and efficacy of the following described:

- The safety classification of this product is Type BF applied part (Internally powered).
- Described each measurement results combined with clinical symptoms by qualified doctors.
- The reliability and operation of using this product whether meets the operation of this manual relate to the maintenance instructions.
- The intended operator of this product may be the patient.
- Do not perform maintenance and service while the device is in use.

Responsibility of operator

- The operator must carefully read the User Manual before use this product, and strictly follow the operating procedure of the User Manual.
- Fully consider the security requirements during product design, but the operator should not ignore the observation for the patient and the state of machine.
- The operator has the responsibility to provide the use condition of the product to our company.

Responsibility for our company

- Our company have the responsibility to provide qualified product which conform to company standard of this product.

- Our company will provide the circuit diagram, calibration method and other information at the request of the user to help the appropriate and qualified technicians to repair those parts designated by our company.
- Our company have the responsibility to complete product maintenance according to the contract.
- Our company have the responsibility to respond the requirements of user in time.
- In the following case, our company is responsible for the impact on the safety, reliability and performance of the device:

Assembly, addition, debugging, modification or repair are carried out by personnel approved by our company.

The electrical facilities in the room are in compliance with the relevant requirements and the device is used in accordance with the User Manual.

The User Manual is written by our company. All rights reserved.

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Chapter 1 Introduction

- Operators do not need professional training, but should use this product after fully understanding the requirements in this manual.
- To prevent users from suffering damage or loss due to improper use, please refer to Safety Precautions and use this product properly.
- For an overall introduction to the monitor, please refer to General Information.
- For basic operating instructions, please refer to Button Function.
- For allocation of interface sockets, please refer to External Interfaces.

Safety Precautions



Warning



- If not use correctly, it exists the possibility of damage for personnel and goods.
- Good damage means the damage of house, property, domestic animal and pet.
- For severe blood circulation disorder or arrhythmia patients, please use the device under the guidance of a doctor. If the arm is squeezed during measurement, it may cause acute internal hemorrhage or inaccurate measurement results.
- You must not perform NIBP measurements on patients with sickle-cell disease or under

any condition which the skin is damaged or expected to be damaged.

- For patients with severe disturbances of blood coagulation, whether automatically measure the blood pressure should be based on the clinical evaluation, because limb friction with the cuff may cause the risk of hematoma.

 **Contraindication** 

No contraindications.

 **Warning** 

Do not use the device in the case of there are flammable anesthetic gasses mixing with the air or nitrous oxide.

Otherwise it may cause risk.

For children and the person who can't express oneself, please use the device under the guidance of a doctor.

Otherwise it may cause accident or dissension.

Self-diagnosis and treatment using measured results may be dangerous. Follow the instructions of your physician.

Please hand measurement results to the doctor who knows your health and accept diagnosis.

Please do not use for any other purpose except BP measurement.

Otherwise it may cause accident or holdback

Please use special cuff.

Otherwise it is possible that measurement result is incorrect.

Please do not keep the cuff in the over-inflated state for a long time.

Otherwise it may cause risk.

If liquid splashes on the device or accessories, especially when liquids may enter the pipe or device, stop using and contact the service department.

Otherwise it may cause risk.

Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

Otherwise it may cause harm to the environment or children.

Please use approved accessories for the device and check that the device and accessories are working properly and safely before use.

Otherwise the measurement result may be inaccurate or an accident may occur.

When the device is accidentally damp, it should be placed in a dry and ventilated place for a period of time to dissipate moisture.

Otherwise the device may be damaged due to moisture.

Do not store and transport the device outside the specified environment.

Otherwise it may cause measurement error.

It is recommended that you check if there is any damage on the device or the accessories regularly, if you find any damage, stop using it, and contact the biomedical engineer of the hospital or our Customer Service immediately. Do not disassemble, repair and modify the device without permission.

Otherwise it cannot be accurately measured.

This device can not be used on mobile transport platforms.

Otherwise it may cause measurement error.

This device can not be used on a tilted tabletop.

Otherwise there is a risk of falling.

Dispose of packaging materials, waste batteries and end-of-life products in accordance with local laws and regulations. The end-of-life products and materials are properly disposed of by the user in accordance with the authority's decree.

Replace accessories which not provided by our company may lead to the occurrence of errors.

Without our company or other approved maintenance organizations trained service personnel

should not try to maintain the product.

This device can only be used for one test object at a time.

If the small parts on the device are inhaled or swallowed, please consult a doctor promptly.

The device and accessories are processed with allergenic materials. If you are allergic to it , stop using this product.

Do not use a mobile phone near the blood pressure monitor. Excessive radiation fields generated by mobile phones can interfere with the normal use of the blood pressure monitor. The blood pressure monitor has slight electromagnetic radiation to the external environment, but does not affect the normal use of other equipment.

This device is suitable for occasions with electrosurgical equipment, but when used with electro-surgical equipment, patient safety must be given the highest priority.

The parts of the device that are in contact with the patient (cuffs, air pipes, enclosure, etc.) are made of insulating material and the device is protected against electric shock. When high frequency or defibrillation devices are applied to the patient, no special precautions need to be taken and the defibrillator discharge will not affect the device.

If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood

vessel.

This device is suitable for occasions with electrosurgical equipment, but when used with electrosurgical equipment, patient safety must be given the highest priority.

When the monitor is wetted, please stop using it and contact us.

After pressing the power button, if the device has display fault such as white screen, blurred screen or no display content, please contact our company.



Note



- The software was developed in accordance with IEC60601-1. The possibility of hazards arising from errors in the software program has been minimized.
- All analog and digital equipment connected to this device must be certified to IEC standards (such as IEC60950: Information technology equipment-Safety and IEC60601-1: Medical electrical equipment-Safety), and all equipment should be connected to in accordance with the requirement of the valid version of the IEC60601-1-1 system standard. The person connecting the additional equipment to the signal input and output port is responsible for whether the system complies with the IEC60601-1 standard.
- Refer to the following chapters for the minimum value of patient physiological signals. Operation of the device below the minimum value may result in inaccurate results.

- **The Monitor shall comply with the standard IEC 80601-2-30:Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers.**

1.1 General Information

General instruction:

The monitor not only measures the ambulatory blood pressure, but also monitors the parameters of NIBP and SpO₂.The monitor integrates parameter measuring modules function and display function in one device, features in compactness and lightweight, the monitor suitable for pregnant women.

The POWER switch is on the front panel. The RUN indicator and the PROMPT indicator at the bottom of the screen flash once when the device is powered on. The PROMPT indicator flashes when prompt occurs. The cuff and SpO₂ probe sockets are located on the top of the device. USB socket is at the bottom of the monitor.

This monitor has friendly operation interface, all operations can be finished by the buttons on the front panel. (Refer to "Button Functions" for details)

Ambulatory blood pressure measurement functions:

In this mode, the monitor can work 24 hours continuously. The monitor can upload the data to PC

for data editing, trend chart editing, statistic, information displaying, diagnosis information editing, various parameter settings, printing and other functions.

Monitoring function:

NIBP systolic pressure(SYS), diastolic pressure(DIA), mean pressure(MAP)

SpO₂ oxygen saturation(SpO₂), pulse rate(PR), SpO₂ PLETH

 **Note** 

In this mode, the length of working time continuously is decided by the interval of measurement set by the user.

It is useful that the software at the state of monitoring as the ambulatory blood pressure.

Refer to Software Functions for details.

1.2 Button Functions

User can switch the interface by the buttons to achieve the functions of parameter setting, blood pressure measuring, SpO₂ measuring and result checking, the detailed functions for each button are as followings:

-  Power button

ON/OFF: long press it to turn on/off the device.

Shortcut function: in any interface, short press it to return to the main interface quickly.



 **Note** 

When the battery power is low, the prompt occurs. The battery's frame becomes red, and ceaseless flash.

-  MENU button

In any interface, press it to execute the selected function

-  UP button

Main interface: if the prompt sound is "ON" ( displays on the top left corner), short press it to switch between prompt and silence ( displays on the top left corner).

Other interfaces: select upward items or page turning.

-  DOWN button

Select downward items or page turning.

-  Measure button

Press it to inflate the cuff for blood pressure measuring. During measuring, press it to stop measuring and deflate.

 **Note** 

The yellow rectangular mark that moves along with the selection of the UP and DOWN buttons on the interface is the cursor, and all the places where the cursor can stay can be operated. When selecting contents by the menu button, the cursor turns to red, then press the UP/DOWN to select, press the MENU button again to exist from the selected state and complete the parameter setting.

 **Note** 

Plug in USB to carry on upload and download data when no battery. That the topside of the screen displays USB symbol shows the instrument triumphantly connects with the computer. NIBP key is invalidation when plug in USB line.

1.3 External Interfaces

For the convenience of operation, the different kinds of interfaces are in different parts of the monitor.

(1)At the top is the Socket for SpO₂ Sensor and socket for NIBP cuff.

 **Note** 

NIBP airway tube has been fixed to the Socket for NIBP cuff.

- ① the Socket for NIBP cuff
- ② the Socket for SpO₂ Sensor

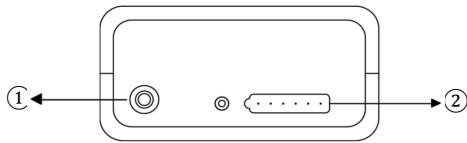


Figure 1.3.1 Top

(2) At the bottom is the USB socket

- ① USB socket

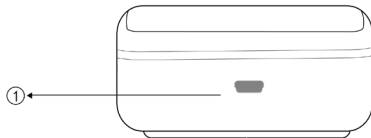


Figure 1.3.2 Bottom

1.4 Accessories

- 1) a cuff for adult
- 2) a USB data line
- 3) a SpO₂ probe
- 4) a pouch
- 5) a user manual

 **Warning** 

Please use the accessories supplied by the manufacturer or replace the accessories according to the requirements of the manufacturer in order to avoid making harms to patients.

 **Note** 

The width of the cuff should be 40% of the limb circumference(50% for the newborn) or 2/3 of the length of the upper arm.The length of the inflated part of the cuff should be sufficient to surround 50% to 80% of the limb. Unsuitable cuffs can produce erroneous readings. If there is a problem with the size of the cuff, use a larger cuff to reduce the error.

Reusable Cuff for adult:

Patient type	Limb circumference	Width of the cuff	Length of inflatable tube
Adult 1	25~35cm	14cm	1.5m or 3m

Adult 2	33~47cm	17cm	
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 **Warning** 

Please use the special accessories supplied by the manufacturer or replace the accessories according to the requirements of the manufacturer in order to avoid making harms to patients.

 **Note** 

■ The cuff is a consumable. Calculate by measuring 6 times a day(3 times each morning and evening), the service life of the cuff is about 1 year.(using our experimental conditions) In order to correctly measure blood pressure, please replace the cuff in time;

■ If the cuff leaks, please contact our company to buy a new one. The cuff purchased separately does not include the BP extension tube. Please give an explanation if you need to buy a BP extension tube at the same time. If you do not want to buy a BP extension tube, please do not throw the BP extension tube away when replacing the cuff, install it on the new cuff.

■ Pouch is convenient for patients to carry the monitor. It is not necessary to replace it when the backpack has a slight wear. Patients can according to the actual situation, contact our company to buy a new backpack when the original backpack can not carry the monitor.

 **Note** 

When the product and accessories described in this manual are about to exceed the period of use, they must be disposed according to relevant product handling specification. If you want to know more information, please contact our company or representative organization.

Chapter 2 Installation

2.1 Open Package and Check

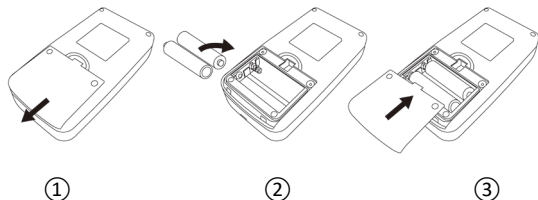
Open the package and take out the monitor and accessories carefully. Keep the package well for possible future transportation or storage. Check the components according to the packing list.

- **Check whether there is any mechanical damage.**
- **Check all the cables, connect some accessories.**

If there is any problem, contact the distributor immediately.


2.2 Battery Installation

The device is powered by two 'AA' alkaline batteries or high-capacity batteries. Before using the device, install two batteries in the battery compartment on the back of the Monitor. Specific steps are as follows:



- ① Demount the battery cover in the direction of the arrow.
- ② Install two "AA" batteries according to \oplus \ominus polarities
- ③ Slide to close the battery cover.

⚠ Note ⚠


Icon "": the batteries power will exhaust, the device prompts "Low battery" at the same time. Replace with two new batteries (the same sort) at this time. Test while low power may cause data deviation and other problems.

⚠ Cautions ⚠

- Turn the unit off before replacing the batteries.

- Please use 2 "AA" size manganese or alkaline batteries, do not use batteries of other types. Otherwise it may cause fire.
- New and old batteries, different kinds batteries can not be put off. Otherwise it may cause battery leakage, heat, rupture, and damage to the monitor.
- "+" and "-" polarities of the batteries must match the polarities of the battery compartment as indicated. When the batteries power exhausts, replace with 2 new batteries at the same time.
- Please take out the batteries when you do not use the device for a long time (more than ten days). Otherwise it may cause battery leakage, heat, rupture, and damage to the monitor.
- If electrolyte of battery gets in your eyes, immediately rinse with plenty of clean water. Contact a physician immediately. Otherwise it will cause blindness or other hazards.
- If electrolyte of the batteries immodestly glues on the skin or the clothes, please immediately flush with plenty of clean water. Otherwise it may hurt the skin.
- Dispose of the exhausted batteries according to applicable local regulations about environmental. Otherwise it will cause environmental pollution.
- The monitor is internally powered equipment, can be connected to the public grid.

2.3 Power on

Turn on the power switch , the indicator will flash once, the system will enter the main interface successfully. The backlight is always light in monitoring and blood pressure mode. In ABPM mode, the backlight will be turned off according to the backlight time when there is no button operation, press any button to lighten the screen.

Warning

If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or our Customer Service Center immediately.

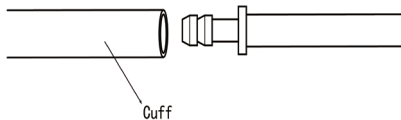
The device can be used normally after it is turned on ,without waiting for the device to be prepared.

Note

Check all the functions that may be used to monitor and make sure that the monitor is in good status.

2.4 Connect SpO₂ Probe

Connect the required sensor to the monitor and the patient's monitoring area. For blood pressure measurement, insert one end of the cuff into the NIBP cuff socket and wear the other end on the patient's upper arm. For SpO₂ measurement, insert one end of the sensor into the SpO₂ socket and the other end grip the finger. As shown below:



Chapter 3 Function Interface

3.1 Main Interface

Turn on the power switch, the indicator will flash once, the system will enter the main interface successfully.

In ABPM mode, if there is no button operation within the time set in the BACKLIGHT TIME item, the monitor will turn off LCD and enter standby mode. RUN indicator light flashes once every 2 seconds, indicating the monitor is under working mode. The information "Ambulatory Blood Pressure Monitor" displays in the bottom of the main interface.

Monitoring mode and BP mode: "BACKLIGHT TIME" setup is invalid. The information "SpO₂ Sensor is off!" displays in the bottom of the main interface, "PM" displays in the bottom.

Under BP mode, "BACKLIGHT TIME" setup is invalid, the backlight is always bright. The information "SpO₂ Sensor is off!" displays in the bottom of the main interface. As shown below:

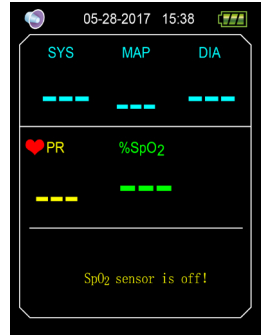
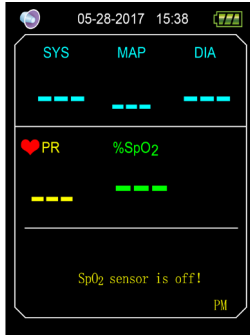
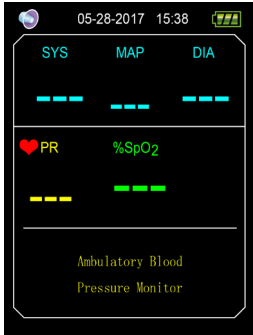


Figure 3.1.1 ABPM Main Menu

Figure 3.1.2 Monitoring Main Menu

Figure 3.1.3 BP Main Interface

After measuring, patient's measurement results will be displayed, the details are as follows:

SYS: systolic pressure

MAP: mean pressure

DIA: diastolic pressure

PR: pulse rate

%SpO₂: oxygen saturation

Pressure values can be compared in this interface: connect the device with the NIBP Simulator, long press "Measure" button for 5 seconds to enter the real-time pressure comparison mode to compare the pressure values measured by the device and the NIBP Simulator.

3.2 System Menu

Under the main interface, press the "MENU" button to enter the "SYSTEM MENU" interface. You can perform option operations by using UP and DOWN buttons.

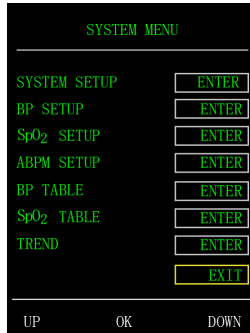


Figure 3.2 System Menu

"ABPM SETUP" in monitoring mode and BP mode is unavailable, it is gray font, switch current working mode to ABPM mode to change ABPM setup.

3.2.1 System Setup



Select the "SYSTEM SETUP" item in the "SYSTEM MENU" interface, press the middle button to enter "SYSTEM SETUP" interface:

"TIME SETUP": set the system time.

"LANGUAGE": switch the current system language.

"DEFAULT": select "YES" in the "DEFAULT" item to restore to the factory default.

"NEW PATIENT": after selecting "YES", the "Clear the last value ?" dialog box will appear. Select "YES" again to delete the measurement record of the last patient. Then select "NO" to return to the "SYSTEM SETUP" menu, the monitor does not perform any operations. Please pay attention to this function.

"PROMPT SOUND": after selecting "ON" in the "PROMPT SOUND" item, the loudspeaker is turned on and prompt monitoring is performed.  will display in the monitoring main interface. On the other hand, after selecting "OFF", the loudspeaker is turned off,  will display in the monitoring

main interface. When you change the settings, the password input box will appear, enter the correct password "8015" to change. The inputting method of password: move the cursor to the password display area, press the middle button, when the rectangle frame turns to red selected state, adjust the number by the "Up" and "Down" button, then press the middle button again to exit the selected state after adjusting. After entering the 4-bit password, move the cursor to "CONFIRM", then press the middle button, the prompt setting can be changed if the password is correct.

"FUNCTION SELECT": switch among PM, ABPM and BP modes.

"BACKLIGHT TIME(s)": under ABPM mode, users can set the backlight time, range is 5~120s, the adjustment step is 5s.

3.2.2 BP SETUP

Select "BP SETUP" in the "SYSTEM MENU" to enter its sub-menu :

"AUTO MEASURE": When users select "ON" in the "AUTO MEASURE" item, the device will measure blood pressure according to the time selected in the "INTERVAL(min)" item, and manual measure is also available. When selecting "OFF", it is the manual measure mode, "INTERVAL(min)" item becomes gray, which indicates that the setting can not be performed.

"INTERVAL(min)": 5, 10, 15, 20, 30, 45, 60, 90 minutes.

The prompt is set according to the high and low limits set, When the pressure is higher than the high limit or lower than the low limit, the prompt will occur. SYS PROMPT and DIA PROMPT can perform over-limit prompt.

Adjustable prompt range:

"SYS HIGH": higher than the low limit of systolic pressure prompt, ≤ 270 mmHg

"SYS LOW": lower than the high limit of systolic pressure prompt, ≥ 40 mmHg

"DIA HIGH": lower than the high limit of systolic pressure prompt, higher than the low limit of diastolic pressure prompt.

"DIA LOW": lower than the high limit of diastolic pressure prompt, ≥ 10 mmHg

3.2.3 SpO₂ SETUP

Select "SpO₂ SETUP" in the "SYSTEM MENU" to enter its sub-menu.:

Select "ON" in "PULSE SOUND" item, then there is pulse sound when measuring the SpO₂. Otherwise there is no pulse sound.

"SpO₂ PROMPT": according to the set high and low limits, when the SpO₂ is higher than the high limit or lower than the low limit, the prompt occurs.

"PR PROMPT": according to the set high and low limits, when the PR is higher than the high limit or lower than the low limit, the prompt occurs.

Adjustable prompt range:

"SpO₂ HIGH": higher than the low limit of SpO₂ prompt, ≤ 100%

"SpO₂ LOW": lower than the high limit of SpO₂ prompt, ≥ 85%

"PR HIGH": higher than the low limit of PR prompt, ≤ 250 BPM.

"PR LOW": lower than the high limit of PR prompt, ≥ 30 BPM.

3.2.4 ABPM SETUP

Select "ABPM SETUP" in the "SYSTEM MENU" to enter its sub-menu shown as below.

The screenshot shows a terminal-style interface for the "ABPM SETUP" menu. The title "ABPM SETUP" is at the top. Below it are seven rows of settings, each with a label on the left and a value in a box on the right. The values are: Asleep Time (01:00), Asleep Interval (90), Awake Time (17:00), Awake Interval (120), Special Start (23:00), Special End (04:00), and Special Interval (45). At the bottom right is a yellow-bordered "EXIT" button. At the very bottom are three navigation options: "UP", "OK", and "DOWN".

Setting	Value
Asleep Time	01:00
Asleep Interval	90
Awake Time	17:00
Awake Interval	120
Special Start	23:00
Special End	04:00
Special Interval	45
EXIT	

UP OK DOWN

Figure 3.2.4 ABPM SETUP

Adjustment increment for "Asleep Time" and "Awake Time" is 30 minutes, adjustment range is 00:00~23:30.

Adjustment increment for "Special Start" and "Special End" is 30 minutes, adjustment range is 00:00~23:30 and "NONE".

"Asleep Interval", "Awake Interval" and "Special Interval": 5, 10, 15, 20, 30, 45, 60, 90, 120 minutes and NONE. When one of "Special Start" and "Special End" is set "NONE", "Special Interval" is invalid.

3.2.5 BP TABLE

Select "BP TABLE" in "SYSTEM MENU" to enter its sub-menu shown as below.

BP TABLE			
Number	SYS	MAP	DIA
12	122	96	82
11	121	96	82
10	102	79	67
9	102	78	66
8	102	78	66
7	102	79	67
6	121	95	82
5	149	118	103
4	102	78	66
3	122	96	82

UP OK DOWN

Figure 3.2.5 BP TABLE

Display the corresponding blood pressure data according to current working mode, press UP/DOWN button to turn page.

3.2.6 SpO₂ TABLE

Select "SpO₂ TABLE" in "SYSTEM MENU" to enter its sub-menu shown as below.

SpO ₂ TABLE		
Number	%SpO ₂	PR
317	95	81
316	95	91
315	95	80
314	95	80
313	95	80
312	96	80
311	96	80
310	96	80
309	96	80
308	96	80

UP OK DOWN

Figure 3.2.6 SpO₂ TABLE

Display the corresponding SpO₂ data according to current working mode, press UP/DOWN button to turn page.

3.2.7 DEMO

Select "DEMO" in "SYSTEM MENU" to enter its sub-menu. In DEMO interface, press "MENU" button to return to trend graph interface, as shown below:

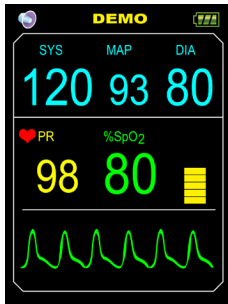


Figure 3.2.7 DEMO Interface

⚠ Note ⚠

In clinical application, this function is forbidden because the DEMO will mislead the medical staff to treat the DEMO waveform and parameter as the actual data of the patient, which may result in the delay of treatment or mistreatment.

Chapter 4 SpO₂ Monitoring

4.1 What is the SpO₂ Monitoring

SpO₂ Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97 % hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO₂ oxygen saturation of 97 %. The SpO₂ numeric on the monitor will read 97 %. The SpO₂ numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO₂/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

How the SpO₂/PLETH Parameter Works

- **Arterial oxygen saturation is measured by a method called pulse oximeter. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.**
- **The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is**

pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.

- The SpO₂ value and the PLETH waveform can be displayed in the main screen.
- Please read the measured value when the waveform on screen is equably and steady-going. The measured value is optimal value. And the waveform at the moment is the standard one.

Optical sensor: Red light (wavelength about 660nm, optical output power less than 6.65mW), infrared light (wavelength about 880nm, optical length less than 6.75mW). Optical sensor belongs to light-emitting component, which will cause interference to other medical equipment using this wavelength range. This information may be useful to clinicians on optical treatment.

Note:

◎The patient monitor adopts integrated SpO₂ probe (the measuring part is integrated with the probe).

◎The service life of integrated SpO₂ probe is 3 years.

 **Warning** 

ES (Electrosurgery) equipment wire and SpO₂ cable must not be tangled up.

 **Warning** 

Do not put the sensor on extremities with arterial catheter or venous syringe.

 **Note** 

Do not perform SpO₂ measuring and NIBP measuring on same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO₂ value.

4.2 Precautions during SpO₂/Pulse Monitoring

 **Note** 

- ◎Make sure the nail covers the light. The probe cable should be on the backside of the hand. Improper probe placement or improper contact with the test site will influence the measurement.
- ◎SpO₂ value always displays in the fixed place.
- ◎The test site shall not use external coloring agent (such as nail polish, dyestuff or color skin care products, etc.), otherwise it will affect the measurement.
- ◎The fingers which are too cold or too thin may affect the measure accuracy, please insert the thicker finger such as thumb or middle finger deeply enough into the probe.
- ◎The SpO₂ probe is suitable for children and adults (not suitable for infants and newborns). The

- device may not applicable for all patients. If you are unable to achieve stable readings, stop using it.
- ◎Data averaging and signal processing will delay the SpO₂ displaying and data values transmitting. The update time of measurement data is less than 30 seconds, when signal attenuation, weak perfusion or other interference appears, it will result in time increasing of dynamic data averaging, which depends on the PR value.
 - ◎The PLETH waveforms are not normalized, which is used as the indicator for signal incompleteness. So the accuracy of the measured values may decrease when the waveform does not tend to smooth and stable. When the waveform tends to smooth and stable, the reading is optimal value, and the waveform at the moment is the most standard one..
 - ◎The temperature for the contact surface of the device with the body is less than 41°C, and this temperature value is measured by a temperature measuring device.
 - ◎The device does not provide over-limit alarm function, so it is inapplicable for using in places where need such function.
 - ◎The SpO₂ probe has been calibrated before leaving factory. It does not need to be calibrated during maintenance.
 - ◎SpO₂ probe is calibrated to show functional oxygen saturation.
 - ◎The SpO₂ probe and photoelectric receiving tube should be arranged in a way with the subject's

arteriole in a position there between. Make sure the optical path is free from any optical obstacles like rubberized fabric, to avoid inaccurate measurement.

©As the measure is taken on the basis of arteriole pulse, substantial pulsating blood flow of subject is required. For a subject with weak pulse due to shock, low ambient/body temperature, major bleeding, or use of vascular contracting drug, the SpO₂ waveform (PLETH) will decrease. In this case, the measurement will be more sensitive to interference.

©The accuracy of the readings under weak perfusion has been verified using signals from the patient simulator. The SpO₂ and pulse rate values vary within the measurement range due to various weak signal conditions and are compared to the actual SpO₂ and pulse rate values of the known input signals.

©The claim for SpO₂ accuracy should be supported by clinical research measurements covering the entire spectrum. By artificially inducing to different stable oxygen levels, make it in the range of 70% ~ 100% of SpO₂. Use secondary standard SpO₂ measuring equipment for comparison to collect SpO₂ values together with the tested product, compose paired data groups for accuracy analysis.

©Clinical report records data of 12 healthy volunteers, including 6 females and 6 males. Volunteers' age ranges from 21 to 29. Skin color is distributed from dark to light, including 3 dark black skins, 2

medium black skins, 5 light skins, 2 white skins.

©When using the device, please keep it away from the instruments that can generate strong electric or magnetic field. Use the device in an inappropriate environment may cause interference to the surrounding radio equipment or affect its working.

©If necessary, please log on our company's official website to download the list of SpO₂ probes and extension cords that can be used in conjunction with this device.

 **Warning** 

©Check if the cable of SpO₂ probe is in normal condition before measuring. After unplugging the SpO₂ probe cable from the socket, "SpO₂%" and "bmp" on the screen will disappear.

©Do not use the SpO₂ probe once the package or the probe is found damaged. Instead, you shall return it to the vendor.

©The supplied SpO₂ probe is only suitable for use with this device. This device can only use the SpO₂ probe described in this manual. It is the responsibility of the operator to check the compatibility of the device and the SpO₂ probe (and extension cable) before use. Incompatible accessories may result in device performance decreasing or cause injury to the patient.

©SpO₂ probe is a medical product that can be used repeatedly.

©The measured value may be normal seemingly for the testee who has anemia or dysfunctional

hemoglobin (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulphaemoglobin (SuHb)), but the testee may appear hypoxia, it is recommended to perform further assessment according the clinical situations and symptoms.

©Pulse oxygen has only reference significance for anemia and toxic hypoxia, as some patients with severe anemia still show better pulse oxygen measurements.

©Measurement accuracy can be affected by the interference of electrosurgical equipment.

©Do not install the SpO₂ probe on an extremity with arterial catheter or receiving intravenous injection.

©Do not perform SpO₂ measuring and NIBP measuring on same limb at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO₂ value.

©Excessive movement (active or passive) of the subject or severe activity can affect the measurement accuracy.

©Excessive ambient light may affect the measuring results, such as surgical light (especially xenon light sources), bilirubin lamp, fluorescent lamp, infrared heater and direct sunlight, etc. In order to prevent interference from ambient light, make sure to place the probe properly and cover the probe with opaque material.

©The measured value may be inaccurate during defibrillation and in a short period after defibrilla-

tion, as the SpO₂ probe not have defibrillation-proof function.

©The person who is allergic to silicone, PVC, TPU, TPE or ABS can not use this device.

©For some special patients, it should be a more prudent inspecting in the measurement part. The probe can not be clipped on the edema and tender tissue.

©Do not stare at the luminescent component directly when the device is turned on (infrared light is invisible), even if for maintenance purpose, or it may have bad influence to the eyes.

©Uncomfortable or painful feeling may appear if using the SpO₂ probe ceaselessly, especially for the microcirculation barrier patients. It is recommended that the measurement should not be taken at the same position for over 2 hours. Continuous, long measurements may increase the risk of unwanted changes in the skin characteristics, such as exceptionally sensitive, reddish, blistering or oppressive necrosis, especially for neonates or the patients with perfusion disorder and change or immature skin form. It should be paid special attention to check the placement position of the probe according to the skin quality change, correct optical alignment and attachment method. Check the attachment position periodically and change it when the skin quality decreases. A more frequent check may be required due to the difference of patient's state.

©Some models of functional tester or patient simulator can measure the accuracy of the device that reproduces the calibration curve, but it can not be used to evaluate the accuracy of this device.

- ©please refer to related medical literature for detailed clinical restrictions and contraindications,
- ©This device is not used for treatment purpose.
- ©Do not use the SpO₂ probe during MRI and CT scanning, as the induced current may cause burns.
- ©When the device is ON, if power interrupt for more than 30s, the SpO₂ probe needs no operation after the power is restored, after the device is turned on, ensure that the SpO₂ probe can be used normally.
- ©The probe can be used before/after sport, but not recommended to use during exercising.

4.3 Monitoring Procedure



SpO₂ display range: 0 % ~ 100 %, PR display range: 30 bpm (beats/min) ~ 250 bpm (beats/min)

If the SpO₂ works abnormally, after connecting the SpO₂ probe to the device, the device will not display any data under the SpO₂ interface.

SpO₂ plethysmogram measurement

- 1.Switch on the patient monitor.
- 2.Attach the sensor to the appropriate site of the patient finger.
- 3.Plug the connector of the sensor extension cable into the SpO₂ socket, please pay attention to the

connection direction of the socket.

4. Please pull out the sensor when measurement is over.

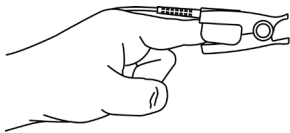


Figure 4.3 Mounting of the Sensor

Measurement Limitation

During operation, the accuracy of SpO₂ readings can be affected by:

- High-frequency electromagnetic interference such as interference from electrosurgical apparatus connected to the system.
- Intravenous dyestuff.
- Excessive patient movement.
- External light.
- Improper SpO₂ probe installation or incorrect contact position of the patient.
- Temperature of SpO₂ probe(optimal temperature range: 28°C ~ 40°C).
- Place the SpO₂ probe on an limb that has a blood pressure cuff, arterial catheter, or intravascu-

lar line.

- Concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin(CO₂Hb) and methemoglobin(MetHb).
- SpO₂ is too low, Bad circular perfusion of the part being measured.
- Intravascular staining agents (such as indocyanine green or methylene blue), skin pigmentation.
- It is required to use SpO₂ probe which is provided by our company, contact with our sale department when necessary.

Chapter 5 NIBP Monitoring

5.1 Introduction

- The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method .It is that: using the blade to block artery blood, checking the oscillometric wave during degassing for sure that it was not affected by the operator's subjective factors or the disruption of the environmental noise.
- There are two modes of measurement available: manual and automatic .Each mode displays the diastolic, systolic and MAP blood pressure and pulse rate.
- ◇ “Manual” mode:only one measurement is conducted for each time.
- ◇ “Auto” mode: The measurement is started automatically the device reaches the automatic measuring point.

Warning

Prolonged non-invasive blood pressure measurements in Auto mode may be associated with purport, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

 **Warning** 

You must not perform NIBP measurements on patients with sickle-cell disease or under any condition which the skin is damaged or expected to be damaged.

For a thrombasthenia patient, it is important to determine whether measurement of the blood pressure shall be done automatically. The determination should be based on the clinical evaluation.

5.2 NIBP Monitoring

 **Note** 

- Do not speak or move during measuring.
- Do not use mobile devices such as cellphone near the device when measuring.
- Measurement results may be different due to different cuff position.
- Do not touch the device, cuff or extension tube during measuring.
- Refer to the Safety Precautions for the contraindications of NIBP measurement.
- Please use the device under proper temperature and humidity (refer to related chapters), otherwise measured result may not accurate.

⚠ Warning ⚠

The minimum value of the patient's physiological signal is the lower limit that the device can measure. The measured result may be inaccurate if the device runs below the minimum amplitude or minimum value of patient's physiological signal.

Prolonged non-invasive blood pressure measurements may be associated with purpura, ischemia and nerve injury in the limb wearing the cuff. When monitoring a patient, examine the color, warmth and sensitivity of the distal part of the limb frequently. If any abnormality is observed, stop the measurement immediately or replace the cuff location.

Do not twist or tangle the airway tube, otherwise it will cause continuous pressure in the cuff, then causing blocked blood flow and serious injury to the patient.

Do not use the cuff on the injured area, otherwise it will cause more serious damage to the injured area.

Do not use the cuff on the site where intravascular treatment is being performed or with catheter connection, otherwise it may cause temporary blockage of blood flow and then cause injury to the patient.

Do not use the cuff on the side of the mastectomy;

The pressure by the cuff may cause temporary weakness of some functions of the body. So do not

use monitoring medical electrical equipment on corresponding arm.

Do not move during measuring, because it will have a delayed effect on the patient's blood flow.

The device needs 2 hours recovery time to reach its performance of intended use after taking out from the lowest storage temperature.

The device needs 4 hours recovery time to reach its performance of intended use after taking out from the highest storage temperature.

1. Plug the air hose to the cuff socket on the device, and connect the device to power supply.

2. Apply the cuff to the patient's upper arm following the instructions below.

- ◆ Ensure the cuff is completely deflated.
- ◆ Apply the appropriate size cuff to the patient, and make sure that the symbol "ϕ" is over the appropriate artery. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.

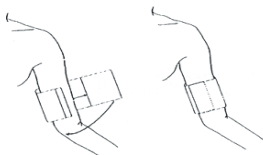


Figure 5.2 Cuff applying

3. Connect the cuff to the airway tube. The limb wearing a cuff should be placed at the same level as the patient's heart. Otherwise amend the measurement results by the following methods

☒ If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each inch of difference.

☒ If it is placed lower than the heart level, minus 0.75 mmHg (0.10 kPa) for each inch of difference.

4. Press the NIBP button on the front panel to start inflating and measuring.

Measurement Limitations

The oscillometry method has some limitations depending on the patient's condition. This measure is based on the regular pulse wave generated by arterial pressure. In the case where the patient condition makes such a detection method difficult, the measured value becomes unreliable and the

measuring time increases. The user should be aware that the following conditions will make the measurement unreliable or measurement time extended. In this case, the patient's condition will make the measurement impossible:

- Patient Movement

Measurement will be unreliable or may be impossible if the patient is moving, shivering or having convulsions. As these conditions may interfere the detection of the arterial pressure pulsation, and the measurement time will be prolonged.

- Cardiac Arrhythmia

Measurement will be unreliable and may be impossible if the patient has irregular heartbeat arisen from cardiac arrhythmia, and the measurement time will be prolonged.

- Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

- Pressure Change

Measurement will be unreliable and may be impossible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulsation are being analyzed to obtain the measurement values.

- Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since the decrease of the blood flow to the peripheries will cause the reduction of artery pulsation.

- Heart Rate Extremes

Measurements can not be made at a heart rate of less than 40 bpm or higher than 240 bpm.

- Obesity patient

The thick fat layer under the limb will decrease the measurement accuracy, as the vibration from artery can not arrive to the cuff, which is arisen from the fat damping.

The following conditions may also cause changes in the blood pressure measurement value

- After eating (within 1h), or having drinks containing alcohol or caffeine, or after smoking, taking exercises or bathing;
- Using incorrect posture such as standing or lying down, etc.;
- The patient speaks or moves his body during measurement;
- When measuring, the patient is nervous, excited, or in unstable emotion;
- The room temperature rise or fall sharply, or the environment of measurement often changes;
- Measuring in a moving vehicle;
- The position of cuff applied (higher or lower than the heart level);

5.3 Error messages and causes

Error message	Meaning	Possible causes
00	No error	
02	Self-test failure	Possible sensor or A/D sampling error
03	No error	
04	Low battery	
05	Cancel measuring	
06	Loose cuff	Cuff is not connected, or it is too loose.
07	Air leakage	Air leakage in the valve or airway.
08	Atmospheric pressure error	Valve can not open.
09	Weak signal	The pulse of measured subject is too weak or the cuff is loose.
10	Over range	The NIBP value of measured subject exceeds measurement range.
11	Excessive movement	Movement may result in too much interference in the signal during measuring process.

12	Overpressure	The cuff pressure exceeds the range, maybe the cuff is blocked or extruded.
13	Saturated signal	Movement or other factors may lead to too big signal amplitude.
14	Air leakage	System airway leakage is found in leakage detection.
15	System failure	Possible failure caused by pump, A/D sampling, pressure sensor error or software operation error.
19	Time out	The measuring time is longer than specified, adult and pediatric: 150 s, neonate: 90 s
---	Display error	Check if the battery is installed correctly.

Chapter6 Maintenance and Cleaning

***Please do obey the precautions and correct operating methods in this user manual. Otherwise, we will not responsible for any fault.**



Warning



- Remove the batteries before cleaning the device or peripheral equipment. The accessories and main unit must be separated for cleaning.
- Do not squeeze the rubber tube on the cuff.

Cleaning:

- Do not soak the device and accessories in liquid.
- If any damage or deterioration of the device and accessories is found, please do not use it.
- Do not let water or cleaning agent flow into the sockets to avoid device damage.
- Do not use gasoline, volatile oil, diluent, etc. to wipe the device.

Maintenance:

- Clean the device and accessories regularly. It is recommended to clean them every one month. When it gets dirty, use a dry and soft cloth to wipe. If the device, accessory or the peripheral equipment is very dirty, it is available to dip the soft cloth into water or mild detergent, and wring

out, then use the cloth for cleaning. Do not clean the inner parts.

■ The device should be inspected and calibrated periodically or obey the requirements of the hospital(the recommended period is 1 year). It is available to inspect in the state specified inspection institution or by professional personal. Please contact our company's after-sales personnel if you need to enter the static pressure detection mode for inspection.

Reusable Blood Pressure Cuff

The cuff can be sterilized by means of conventional autoclaving, gas, or radiation sterilization in hot air ovens or disinfected by immersion in decontamination solutions, but remember to remove the rubber bag if you use these methods. The cuff should not be dry-cleaned. It can be machine-washed or hand-washed, the latter method may prolong the service life of the cuff. Before washing, remove the latex rubber bag. Allow the cuff to dry thoroughly after washing, then reinsert the rubber bag in the cuff.

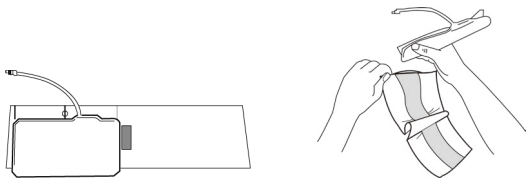


Figure 6.1 Replace the rubber bag

To insert the rubber bag in the cuff, first place the bag on top of the cuff so that the rubber tubes line up with the large opening on the long side of the cuff. Now roll the bag lengthwise and insert it into the opening on the long side of the cuff. Hold the tubes and the cuff and shake the cuff until the bag is in position. Thread the rubber tubes from inside the cuff, and out through the small hole under the internal flap.

Disposable Blood Pressure Cuffs

Disposable cuffs are intended for one-patient use only. Do not use the same cuff on any other patient. Do not sterilize or use autoclave on disposable cuffs. Disposable cuffs can be cleaned using soap solution to prevent infection.

⚠ Note ⚠

For protecting environment, the disposable blood pressure cuffs must be recycled or disposed properly.

Storage:



Do not expose the device in direct sunlight for long time, otherwise the display screen maybe damaged.

The basic performance and safety of the device are not affected by the dust or cotton wool in home environment, while the device shall not be placed where with high temperature, humidity, dusty or corrosive gases.

Aged cuff may result in inaccurate measurement, please replace the cuff periodically according to the user manual.

To avoid device damage, keep the device out the reach of children and pets.

Avoid the device close to extreme high temperature such as fireplace, otherwise the device performance may be affected.

Do not store the device with chemical medicine or corrosive gas.

Do not place the device where there is water.

Do not place the device where with slope, vibration or impact

Chapter 7 Requirements of Hardware

Processor: Basic frequency 2.5G or more

Operation System: Windows XP or higher

EMS memory: 1GB and more

Hard Disk: 250G or more

Display: Resolution ratio 1024*768 or higher

USB: 2 or more

Resolution of printer: 600 DPI

Chapter 8 Software Functions

8.1 User Register

Double-click the software icon, then the dialog box shown as below appears.

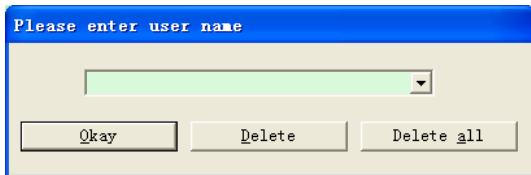


Figure 8.1.1 User Register

Enter the user name, click "Okay", then the "Configuration Set" dialog box shown as Figure 8.1.2 will appear. Click "Delete" to delete the configuration information of the user. "Delete all" is used to delete the configuration information of all users.

If you are a new user, then the following dialog box will appear.

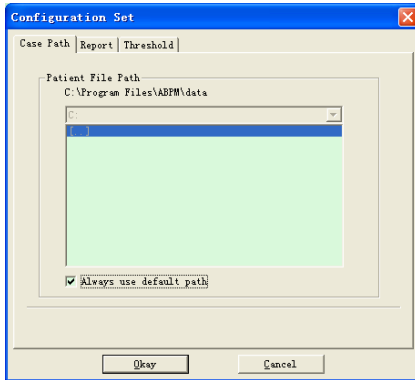


Figure 8.1.2 Configuration Set

"Case path": select the default storage path for case, after getting the data from the device, the case file will be saved in this path.

If you select "Always use default path", then the case file will be automatically saved in the installation path.

8.2 Main Interface

The device will enter to the main interface(shown as below) after setting the configuration information.



Figure 8.2 Main Interface

8.3 Wear



After clicking the shortcut key **Wear**, the following figure appears. Before using the device, please read "Matters need" carefully, and wear the device according the following figure.

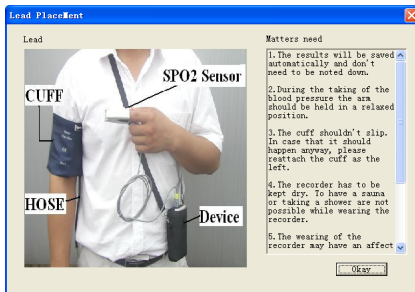


Figure 8.3 Wear

8.4 Setting for Collection Plan



Click the shortcut key **U** or "Upload" from menu, after selecting the connection mode, the dialog box "Select the status of the device" will appear.

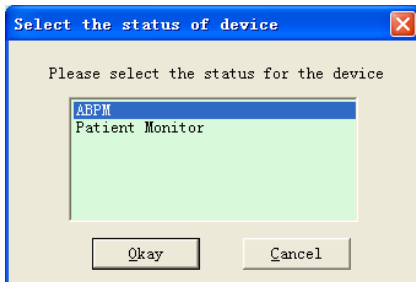


Figure 8.4.1 Select the Device Status

If you choose "ABPM", the following dialog box will appear.

Time Periods	Time	Interval
Awake	07:00	30mins
Asleep	22:00	60mins
Special Start	None	None
Special End	None	

Figure 8.4.2 Set the Collection Plan

The doctor can set the parameters according to patient's status and diagnosis requirements, after correct settings and communicating, the device will perform the collection task. Parameters descriptions are as followings:

Patient Name: patient's name.

Patient ID: patient's ID number, it is used to identify the patient, it is unique.

Current Time: the time displayed in the computer, it is used to update the device system time.

Start Key: whether support to collect by the manual operation.

Parameters settings for Time Periods:

Awake: start time of awakening

Asleep: start time of sleep

Special and Special End: optional items, they are used to set the data collection plan in special time.

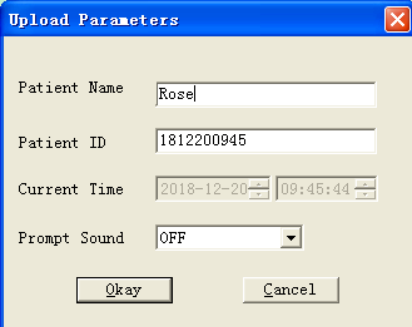
Interval: acquisition time interval, taking the effect of minimizing the impact on the patient's sleep into account, the interval during sleep is generically set longer.

Take the above figure as an example, Awake time zone is 7:00-22:00, Asleep time zone is 22:00 - 7:00 the next day. "Interval" in "Awake" is 5 minutes, "Interval" in "Asleep" is 30 minutes.

Asleep time zone, Awake time zone, special measurement time zone will be displayed in the bottom right in the graphical form, which is convenient for parameters setting.

"PROMPT SOUND": after selecting "ON" in the "PROMPT SOUND" item, the loudspeaker is turned on and prompt monitoring is performed. On the other hand, after selecting "OFF", the loudspeaker is turned off.

If you choose "Patient Monitor", the following dialog box will appear.



Upload Parameters

Patient Name

Patient ID

Current Time

Prompt Sound

Figure 8.4.3 Parameters Setting

Parameters descriptions are as followings:

Patient Name: patient's name

Patient ID: patient's ID number, it is used to identify the patient, it is unique.

Current Time: the time displayed in the computer, it is used to update the device system time.

After setting, click "OK" to set this plan to the device.

"Prompt Sound": after selecting "ON" in the "Prompt Sound" item, the loudspeaker is turned on and prompt monitoring is performed. On the other hand, after selecting "OFF", the loudspeaker is turned off.


8.5 Data Download

Before you download the measurement data from device, please make sure that:

1. The device is correctly connected to the computer properly.
2. The device is turned on.
3. Disconnect the device from patient before connecting it to the computer.

The downloaded patient data will be saved in case storage path set. If you want to change the storage path, select "Set file path", the dialogue box (Figure 8.1.2) will appear, then you can change the path.



Click the shortcut key  or "Download" from menu to select the data in which status is to be obtained, then start to download the data.

8.6 Open Data File

Click "Open Data" to open the case interface shown as below:

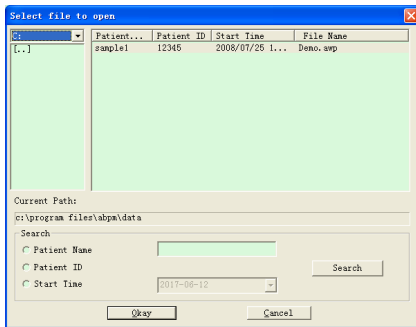


Figure 8.6 Case Selection

In this interface, you can operate the drive and folder selection on top left part to load the specified disk and folder content, if case file exists in this folder, the basic information of these case files will be displayed in the form of list, contents including: patient name, patient ID, start time and file name. Click to select the case file to be opened, then click "Okay" to open and load the case file information.

When there are many case data, select one inquiry item, enter the key information, then click

"Search" to query.

8.7 Delete Data File

If you feel some patient data are not necessary, you can delete them. Select "Delete Data" from menu to enter its sub-menu shown as below.

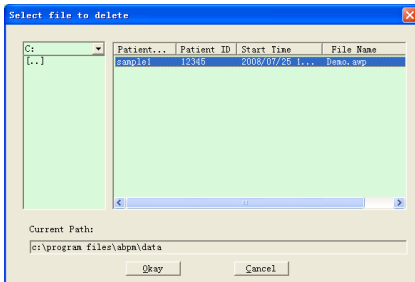


Figure 8.7 Data File Delete

Many files can be deleted at the same time. Push "Ctrl" and click the file you want to delete at the same time, click "Okay", to delete the case file selected. Click "Cancel" to cancel deleting.

8.8 Data File Backup

The software has the function of case backup. Select "Copy data" from menu, then the following figure will appear.

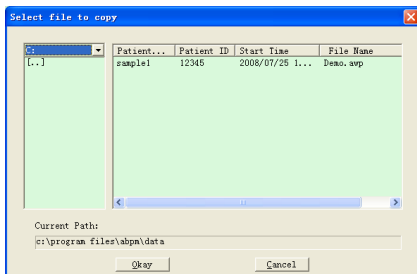


Figure 8.8.1 Data File Copy

After selecting files, click "Okay", then a dialog box which is used to set the storage files of backup files appears. After setting, click "Okay" to save. The destination directory interface is shown as below:

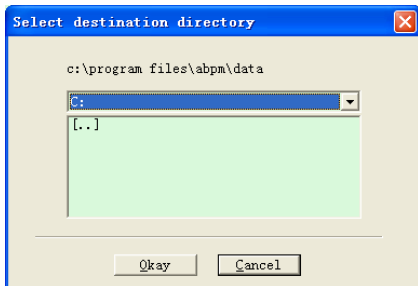



Figure 8.8.2 Backup Path Settings

8.9 Edit IP Data

After opening the case file, blood pressure data can be edited. Click the shortcut key  or select "Bp data" from menu to enter the interface shown as below:

* = 5/192 (2.6%)								
Number	Time	Date	BP (mmHg)	PR (BPM)	MAP (mmHg)	PP (mmHg)	SpO ₂ ...	TC
1	14:45	25-07-2008	116/71	70	82	45	---	3/0
2	14:50	25-07-2008	113/69	75	85	44	---	3/0
3	14:55	25-07-2008	121/77	81	95	44	---	3/0
4	15:00	25-07-2008	124/74	75	87	50	---	3/0
5	15:05	25-07-2008	113/71	72	81	42	---	3/0
6	15:10	25-07-2008	106/72	72	83	34	---	3/0
7	15:15	25-07-2008	111/76	74	88	35	---	3/0
8	15:20	25-07-2008	107/64	65	75	43	---	3/0
9	15:25	25-07-2008	123/67	73	96	56	---	3/0
10	15:30	25-07-2008	132/68	75	79	64	---	3/0
11	15:35	25-07-2008	109/62	72	74	47	---	3/0
12	15:40	25-07-2008	102/64	75	75	38	---	3/0
13	15:45	25-07-2008	98/58	74	72	40	---	3/0
14	15:50	25-07-2008	107/63	68	74	44	---	3/0
15	15:55	25-07-2008	98/62	76	76	36	---	3/0
16	16:00	25-07-2008	112/64	66	76	48	---	3/0
17	16:05	25-07-2008	110/72	71	82	38	---	3/0
18	16:10	25-07-2008	105/68	64	79	37	---	3/0
19	16:15	25-07-2008	101/65	62	75	36	---	3/0
20	16:20	25-07-2008	108/64	68	77	44	---	3/0

Figure 8.9 Data Edit Interface

All the BP readings are shown in the above dialog box.

*=5/192(2.6 %): 192 represents the data sum, 5 represents the data amount deleted, 2.6 % is the percentage of data deleted in all collection data.

Number: stands for data collection serial number.

Time: stands for collection time.

Date: stands for collection date.

BP(mmHg): systolic pressure/diastolic pressure, unit is mmHg.

PR: pulse rate, unit is BPM

MAP: mean pressure, unit is mmHg.

PP: pressure difference between systolic pressure and diastolic pressure, unit is mmHg.

SpO₂(%): oxygen saturation, unit is %.

TC: error code /measurement mode(refer to chapter 5)

Comment: add comment information to the BP data.

These data can also be performed exclusion operation. The symbol "*" indicates to delete the data(not be displayed in the trend graph, and not be recorded in statistics). You can click the location area of the first column to add or delete "*". And in the comment field, you can annotate the data, and the comment information will be displayed in the trend graph and report.

8.10 Trend Graph

8.10.1 BP Trend Graph

After selecting case file, the BP trend curve will be displayed in the screen automatically. Click the



shortcut key to its sub-menu. Two graph types: color filling trend and dotted line trend.

The trend graph is shown as below.

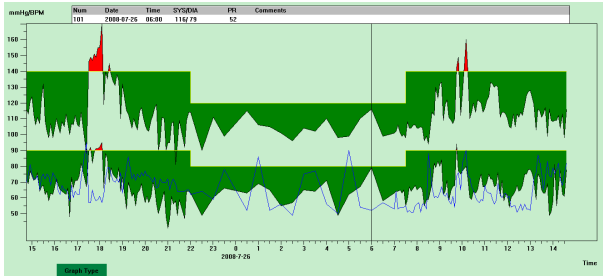


Figure 8.10.1 Color Filling Trend Ggraph

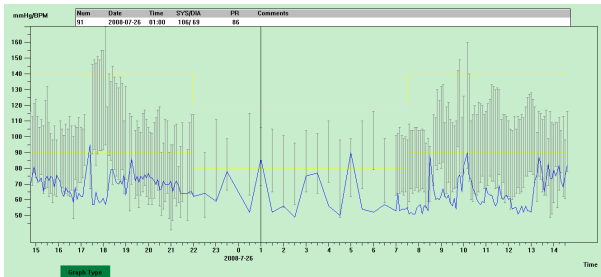


Figure 8.10.2 Dotted Line Trend Graph


You can switch the two trend graph types by "Graph Type" button in the bottom of the software interface. When you move the mouse on the trend area, the detail data information on this location will display in the top of the trend area, including the data serial number, collection time and collection date, high/low blood pressure value, pulse rate, comment, etc. Press mouse' left button to delete or add the data point to be shown.

8.10.2 SpO₂ trend graph

When you open the case file with SpO₂ data, click "SpO₂ Trend" to enter SpO₂ trend interface.



Figure 8.10.3 SpO₂ Trend Graph

4 buttons  are used to set the time length of one page, that is how long data will be visible at the same time in the window area from left to right.

1

current screen displays 1-minute trend graph.

10

current screen displays 10-minute trend graph.

60

current screen displays 1-hour trend graph.



one dialog box will appear after pressing this button, then you can set the time length according to requirements.



Four buttons are used to move the trend back or front.

Select "Parameters Set" to enter its sub-menu shown as below.

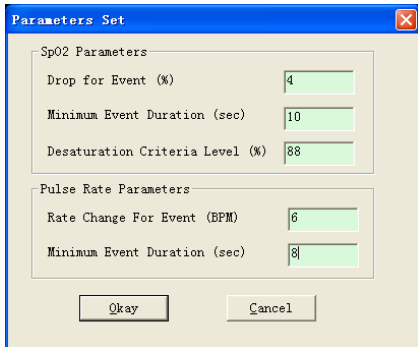


Figure 8.10.4 Analysis Parameters Settings

The setup in the dialog box above indicates:

SpO₂ (desideration) event: the SpO₂ value reduces at least 4%, whose continuous time is at least 10 seconds.

Pulse Rate event: the pulse rate fluctuates at least 6bpm, whose continuous time is at least 8 sec-

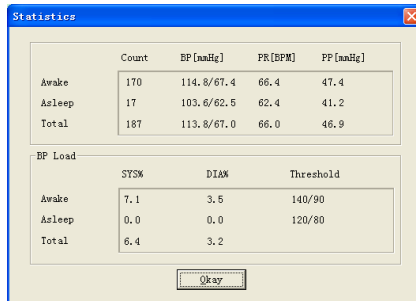
onds.

8.11 Display of Statistics Information



Press the shortcut key **Stati...** or select "Report" from menu to enter its sub-menu shown as

below.



The screenshot shows a window titled "Statistics" with a blue border and a close button in the top right corner. The window contains two tables of data.

	Count	BP [mmHg]	PR [BPM]	PP [mmHg]
Awake	170	114.8/67.4	66.4	47.4
Asleep	17	103.6/62.5	62.4	41.2
Total	187	113.8/67.0	66.0	46.9

	SYS%	DIAS%	Threshold
Awake	7.1	3.5	140/90
Asleep	0.0	0.0	120/80
Total	6.4	3.2	

At the bottom of the window is an "Okay" button.

Figure 8.11 BP Statistics Information

The upper half part of the figure shows the average of blood pressure data and the measurement number under "Awake" and "Asleep" state. The lower part shows the percentage of warning value data, 140/90, 120/80 represent blood pressure warning value of the systolic and diastolic pressure under "Awake" and "Asleep" state, the unit is mmHg.

8.12 Patient Information Settings

Select "Patient Data" from the menu to enter its sub-menu shown as below. Patient information including: patient information, current medications, diagnose information and physician information.

The screenshot shows a 'Patient info set' dialog box with four tabs: 'Patient Info', 'Current Medications', 'Diagnose Information', and 'Physician Info'. The 'Patient Info' tab is selected. The form contains the following fields:

Patient ID	12345	Age	30
Patient Name	sample	Male/Female	Male
Address		Height (cm)	180
		Weight (kg)	75
Out Patient No.		Race	
Admission No.		Date of Birth	1987-12-30
Bed No.		Telephone	
Department No.		Email	

At the bottom of the dialog box are two buttons: 'Okay' and 'Cancel'.

Figure 8.12 Edit Patient's Information

Recent medication information of patient can be entered in "Current Medications" column. Blood pressure data description and diagnosis information can be entered in "Diagnose Information" column.

Doctor name and doctor advice can be entered in "Physician Info" column.

8.13 Sleep Time Setting

Awake and Asleep time can be set by manual mode, after setting, the software will calculate the data again under "Awake" and "Asleep" state, then update the trend graph and calculate the statistic data automatically. The interface shown as below will appear after selecting "Sleep Period" from menu.

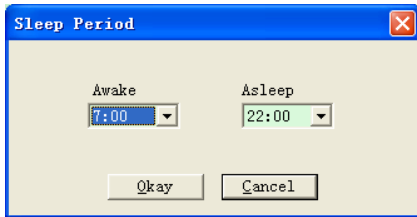


Figure 8.13 Sleep Time Setting

8.14 BP Threshold Setting

The BP threshold can be changed by manual mode, after changing, the corresponding trend graph

and analysis data will be automatically renewed. Select "Threshold" to enter its sub-menu shown as below.

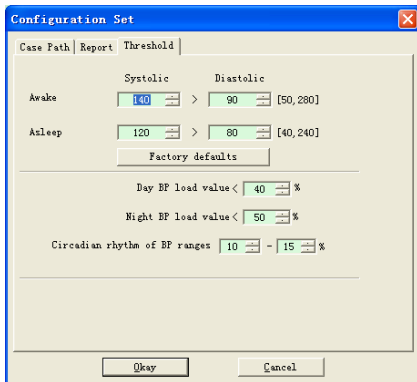


Figure 8.14 BP Threshold Setting

The default recommended thresholds for calculating Blood Pressure Load are 140/90 for wake periods and 120/80 for sleep periods. These are the default values when you select the Factory

Defaults button.

8.15 Histogram



Press the shortcut key **Hi sto...**, the following interface will appear.

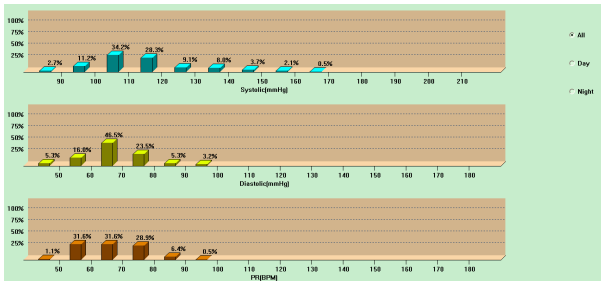


Figure 8.15 Histogram

"All", "Day" and "Night" can respectively display the analysis values in each period.

8.16 Pie Chart



Press the shortcut key **Pie c...**, the following interface will appear:

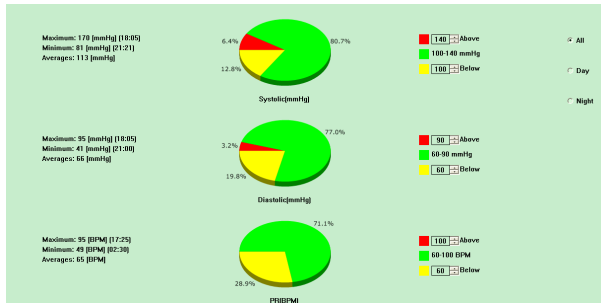


Figure 8.16 Pie Chart

The pie chart interface is divided into four regions, from left to right, the first region is value display

area which displays the Maximum, Minimum and Average values among the measurement values, the second region is pie chart display area, the third is the setting area for pie chart color and values, and the last is the time display area, it has three options: "All", "Day" and "Night", which can respectively display the analysis values in each period.

8.17 Correlation Line



Press the shortcut key **Corre...**, the following interface will appear:

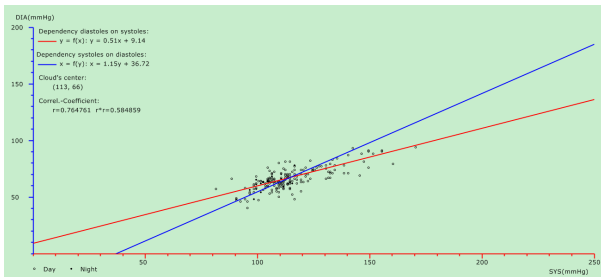


Figure 8.17 Correlation Line

The horizontal axis is the systolic pressure axis, the vertical axis is the diastolic pressure axis. Red represents the dependence for diastolic pressure to systolic pressure; blue represents the dependence for systolic pressure to diastolic pressure. The hollow circle is the BP value measured in the day, and the solid circle is the BP value measured at night.

8.18 Print Report

After editing the BP data and diagnosis information, click "Report", the software will create a series of diagnosis reports, you can select all pages or some of them for printing. Select "Configure Report" in "Report", then the following figure will appear.

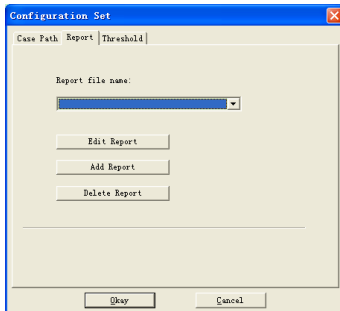


Figure 8.18.1 Configure Report

You can select a report configured for printing, or click "Edit Report" to edit the selected report.

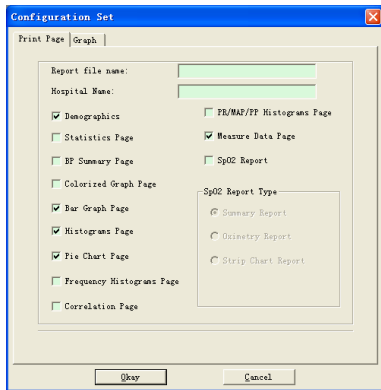



Figure 8.18.2 Edit Report


The SpO₂ analysis report can only be printed when the case file contains the SpO₂ and "SpO₂ report" is selected.

Click "Add Report" to add a new report. If you don't need the current report, you can also click

"Delete Report" to delete it.



Click the shortcut key  or select "Report" from menu to preview the report, then select "Print" to print the report.





















8.19 Help








Click the shortcut key  to its sub-menu, which gives a brief description for each program function. In addition, you will find "Help" button in each operation interface, click it to check the description for this function, which is convenient for you to quick know the use of software.

Chapter 9 Key of Symbols

Your device may not contain all the following symbols.

Signal	Description	Signal	Description
	Caution: read instructions (warnings) carefully		Follow instructions for use
SYS	Systolic pressure	DIA	Diastolic pressure
MAP	Mean blood pressure	PR	Pulse rate (bpm)
SpO ₂	Functional arterial oxygen saturation	EMC	Electromagnetic compatibility
IPXX	Enclosure protection grade	P/N	Material code of manufacturer
ADU	Adult	NEO	Neonatal
ABPM	Ambulatory blood pressure monitoring mode	PM	Patient monitoring mode
PED	Pediatric	INFO	Information

	Serial number		Recyclable
	Close the sound		Class II applied
	Close the prompt sound indication		Open the prompt sound indication
	Lot number		Use by date
	This way up		Fragile, handle with care
	Keep in a cool, dry place		Atmospheric pressure limit
	Temperature limit		Humidity limit
	Manufacturer		Date of manufacture
	Batteries Power		Pulse rate (bpm)
	<ol style="list-style-type: none"> 1. the finger clip falls off (no finger inserted) 2. Probe error 3. Signal inadequacy indicator 		<ol style="list-style-type: none"> 1.No Pulse rate 2.An indicator of signal inadequacy

	WEEE disposal		Medical Device compliant with Directive 93/42/EEC
	Authorized representative in the European community		Type BF applied part
	Not made with natural rubber latex		Imported By
	Product code		

Chapter10 Specification

Name	Patient Monitor
The degree of protection against ingress of water	IPX1
Display mode	2.4" color LCD Display
Operating mode	Continuous operating
NIBP specification	
Measurement method	Oscillography method
Working mode	Automatic
Blood pressure	
Measurement range	Pressure:0~297 mmHg(0~39.6 kPa)
Cuff Pressure Accuracy	Static pressure: ± 3 mmHg(± 0.4 kPa)
Overpressure protection	Adult: 297 ± 3 mmHg (39.6 ± 0.4 kPa)
Pre-inflation value	Adult: 160 mmHg (21.33 kPa)
Resolution	1 mmHg (0.133 kPa)

Error	The BP value measured by the device is equivalent with the measurement value of Stethoscopy, perform clinical verification in accordance with the requirements in ISO 81060-2: 2013, whose error meets the followings: Maximum mean error: ± 5 mmHg Maximum Standard deviation: 8 mmHg
SpO₂	
Measurement range	0 %~100 %
Resolution	1%
Error	Measured value in range of 70%~100%, absolute error is $\pm 2\%$, below 70% unspecified.
Measurement Performance in Weak Filling Condition:	SpO ₂ and pulse rate can be shown correctly when pulse-filling ratio is 0.4 %, SpO ₂ error is $\pm 4\%$; the Pulse rate error is ± 2 bpm or ± 2 %, whichever is greater.
Pulse rate	
Measurement range	30 bpm~250 bpm
Resolution	1 bpm
Accuracy	± 2 bpm or 2% (whichever is greater)
Operating temperature/humidity	+5°C~40 °C 15%RH~85% RH(Non-condensing)

Transport	Transport by general vehicle or according to the order contract, avoid pounded, shake and splash by rain and snow in transportation.
Storage	Temperature: -20°C~+60°C; Relative humidity: ≤95%; No corrosive gas and drafty.
Atmospheric pressure	Working: 700hPa~1060hPa Transport and Storage: 500hPa~1060hPa
Power Supply	DC 3 V
Battery service life	When the temperature is 23°C, limb circumference is 270mm, the measured blood pressure is normal, 2 "AA" alkaline batteries can be used about 150 times.
Rated Power	≤ 3.0VA
Dimensions	128(L)*69(W)*36mm(H)
Unit Weight	240gram(without batteries)
Safety classification	Internally powered equipment Type BF defibrillation-proof applied par
Service life	The service life of the device is five years or 10000 times of BP measurement.
Date of manufacturer	See the label

Appendix

Table 1:

Guidance and manufacturer's declaration – electromagnetic emission	
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the device should assure that it is used in such and environment.	
Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable

Table 2:

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity test	IEC60601 test level	Compliance level
Electrostatic discharge (ESD) IEC61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Radiated RF IEC61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Conducted disturbances induced by RF fields IEC61000-4-6	3 V 0,15 MHz -80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz -80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Table 3:

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for EN-CLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380–390	TETRA 400	Pulse modulation 18 Hz	27	27
	450	430–470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28	28
	710	704– 787	LTE Band 13, 17	Pulse modulation 217 Hz	9	9
	745					
	780					
	810	800– 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28	28
	870					
	930					

	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28	28
	1845					
	1970					
	2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
	5500					
	5785					

Table 4:

Guidance and manufacturer's declaration - electromagnetic Immunity				
	Test Frequency	Modulation	IEC 60601-1-2 Test Level (A/m)	Compliance level (A/m)
Radiated RF IEC61000-4-39 (Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields)	134,2 kHz	Pulse modulation 2.1 kHz	65	65
	13,56 MHz	Pulse modulation 50 kHz	7,5	7,5



- Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and

the other equipment should be observed to verify that they are operating normally.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.”
- 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 PM50, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The cable types listed below must be used to ensure compliance with interference radiation and immunity standards:

Number	Name	Maximum lengths of cable (m)	Shielded cable
1	USB data line	1.00	Y
2	SpO ₂ probe	1.80	Y



Warning



Essential performance:

1. Under environmental conditions, the maximum error for the measurement of the cuff pressure shall be less than or equal to ± 3 mmHg (± 0.4 kPa) .
2. The reproducibility of the blood pressure determination of the automated sphygmomanometer shall be less than or equal to 3.0 mmHg (0.4 kPa).
3. The SpO₂ accuracy of pulse oximeter equipment is 2% over the range of 70% to 100% SaO₂.
4. Pulse rate accuracy: ± 2 bpm or 2% (whichever is greater)



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