PROFESSIONAL MEDICAL PRODUCTS

GIMA ABPM PULSE RATE MONITOR

User manual

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

Gima 35110

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Made in China

IPXX

0123

REF **ABPM50**

EU REP Prolinx GmbH
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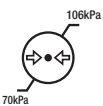

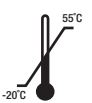

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MD

M35110-EN-Rev.7-08.26

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:

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.

CONTENTS

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 hurt or damnification due to improper use,please refer to "**Safety Precautions**" and use this product properly.

For an overall introduction to the Blood Pressure Monitor, please refer to **General Information**.

For basic operating instructions, please refer to **Button Function**.

For allocation of interface sockets, please refer to **Interfaces**.

1.1 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. Otherwise it may lead to acute hemorrhage, or measurement error as a result of squeezed arm.**
- **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 thrombasthemia 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.

⚠ **Warning** ⚠

Do not modify this equipment without authorization of the manufacturer.

⚠ **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 electrosurgical equipment, patient safety must be given the highest priority.

The parts of the device that are in contact with the patient (cuffs, air pipes, enclosue, 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.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

⚠ **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.

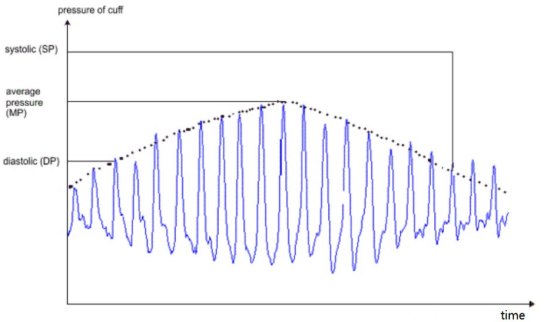
The Monitor shall comply with the standard IEC 80601-2-30:Particular requirements for basic safety and essential performance of

automated non-invasive sphygmomanometers.

This device is defibrillator protected,the time of defibrillation recovery is 5 seconds.Note that no precautions specific to the device is required during defibrillation, and defibrillation discharge has no effect on the monitor. The equipment uses the gray silicone airway, in case of the effect to the equipment when defibrillation device was used on the patient.

1.2 Basic principles:

During working,the air pump inflates the cuff to increase the pressure of the cuff and block the blood flow in the upper arm artery. When the cuff pressure is much higher than the systolic pressure(SP), the pulse wave disappears. As the cuff pressure drops, pulse waves begin to appear. When the cuff pressure drops from above to below the systolic pressure(SP), the pulse wave will suddenly increase. Maximum at average pressure(MP). Then it decays as the pressure of the cuff drops. Oscillographic blood pressure measurement is based on the relationship between pulse wave amplitude and cuff pressure to estimate blood pressure.



1.3 Intended purpose：

The device is used for ambulatory blood pressure monitor (ABPM) of patients in home and medical institutions .

Patient Population :

It is applicable for adult and pediatric individuals.

Intended users:

Medical staff or adult operators under medical staff guidance.

1.4 General instruction：

The device is applied to Blood Pressure(BP) measure and monitor for adult(including pregnant women) and

pediatric. It most stores 300 records of common user and 350 of ambulatory Blood Pressure data. Every record includes the detailed measure time, systolic blood pressure, diastolic blood pressure, mean blood pressure, pulse rate, error message and record number, etc.

The device is used in home and medical institutions for continuous NIBP monitoring of human body.The device in combination with the PC Software can achieve data review, measured results analysis, view of trend graph and other functions.Doctors can make analysis based on the data recordings.

This device has friendly operation interface, and adopts 2.4inch color LCD. It integrates data review function and display function which includes BIG FONT single record data review, data list, BP data trends chart, the current time,date,power and so on.

User can power on/off the monitor,start manual measure, set system parameters and so on with five keys in the front panel. (Please refer to "Button Functions" part for detail)

The left light is the running light, and the right light is the warning light.

The monitor does not have an alarm system, but it will prompt when the power is low, the measure is wrong, or the measure data exceeds the set limits. When the power is low or the measure is wrong, the prompt is audible and visual, the device will buzz intermittently and the warning light will flash to prompt the user to replace batteries or prompt the reason of the failed measurement; when the measure data exceeds the set limits, the prompt is audible, the font color of measure results will change to red. Users can open and close the prompt according to needs.

The cuff socket is located on the top of the device and the USB socket at the bottom of the device. The stored data can be transferred to computer with the USB interface, and then various operations can be performed by using the PC software. (Please refer to "Software Functions" part for detailed contents)

⚠ **Note** ⚠

In the common user mode, the monitor will periodically turn off backlight if there is no operation, and automatically shuts down if there is no operation for two minutes. When the backlight turn off in the ambulatory blood pressure mode, the running indicator intermittently flashes to prompt the device in running state.

The monitor can be used for ambulatory blood pressure monitoring (ABPM) in pregnant women. Its effectiveness for preeclampsia detection has not been established.

1.5 Button Functions

All the operations of the Blood Pressure Monitor could be completed with the buttons. The names of button are on them. They are:

- 

Press the button for a long time, then the system will start. Press it for a short time to return the boot-strap interface.

- 

The text in the middle bottom of the screen indicate the function of this key. Whatever menus the system is in, press the button and the system immediately executes a certain function.

- 

The text in the left bottom of the screen indicate the function of this key.

Such as: The button is the prompt switch in the boot-strap interface, up key in the "SYSTEM MENU", and left key in the "TREND" chart.

- 

The text in the right bottom of the screen indicate the function of this key.
Such as: the button is the data review key of current user in the boot-strap interface and down key in the "SYSTEM MENU" and right key in the "TREND" chart.

- 

Start/Stop button. If measuring, press this key to cancel the current measurement.

⚠ **Note** ⚠

- **After connecting the USB cable, all of the buttons are disabled. If the BP measurement is in progress, this measurement is will be automatically canceled.**
- **During measurement,**  **three buttons are all disabled.**

The rectangular mark in the screen moving with the operation of  ,  buttons is called “cursor”. Operation can be performed in any position at which the cursor can stay. When the item is not selected, the cursor is yellow; when selected, the cursor becomes red.

1.6 Interfaces

For the convenience of operation, different kinds of interfaces are in different parts of the device.
NIBP cuff socket is at the top of the device.

⚠ **Note** ⚠

The connection of the NIBP external air pipe is as shown:

① Cuff extension tube metal nozzle

② the socket for air pipe

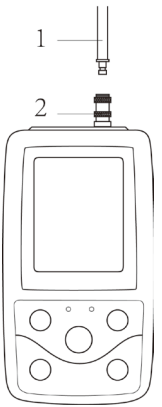


Figure 1.4.1 The Top External airway

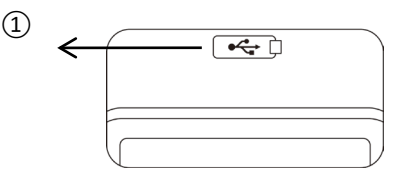


Figure 1.4.2 Bottom

At the bottom is the socket for USB:①The Socket for USB, connect the data line to upload data.

1.7 Accessories

A Cuff (25～35 cm) for adult
Software
Cuff 1 (10～19 cm) for pediatric (Optional)
Cuff 2 (18～26 cm) for pediatric or adult(Optional)
Cuff 4 (33～47 cm) for adult(Optional)

⚠ **Note** ⚠

The monitor also can be equipped with pediatric, if necessary, please contact our company or its representatives.

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 of adult/ pediatric

Patient type	Model	Limb circumference	Width of the cuff	Manufacturer	Length of inflatable tube
Cuff 1(pediatric)	IGN0002	10～19 cm	8 cm	Contec Medical Systems	1.5 m or 3 m
Cuff 2(pediatric or adult)	IGN0003	18～26 cm	10.6 cm		
Cuff 3(adult)	IGN0040	25～35 cm	14 cm		

Cuff 4(adult)	IGN0050	33～47 cm	17 cm	Co., Ltd.	

⚠ **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.The service life of the cuff is about 2 years or 5000 times.(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 Getting Started

2.1 Open the Package and Check

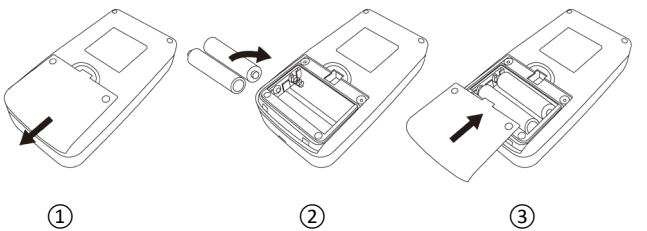
Open the package and take out the equipment and accessories carefully. Keep the package material for possible future transportation or storage. Check the components according to the packing list.

- Check for any mechanical damage.
- Check all the cables, modules and accessories.

If there is any problem, contact the distributor immediately.

2.2 Battery Assembly

The instrument will be supplied with two 'AA' alkaline batteries or high capacity. Before using the instrument, you shall put the battery in the battery box in the back of the Monitor .



① Demount the battery cover in the direction of the arrow.

② Install "AA" batteries according to ⊕⊖ 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 the Instrument

Hold the power button  , the indicator will flash once, which shows the boot-strap is successful, then release the button, and the system will enter the main interface.

Hold the power button  after power on, the indicator will flash once, which shows the shutdown is successful, and the device can be safely terminated.

⚠ **Warning** ⚠

If any sign of damage is detected, or the instrument 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 possibly be used and make sure that the device is in good status.

2.4 Connect Sensor

⚠ **Note** ⚠

For information on correct connection of NIBP cuff, refer to Figure 2.4.1

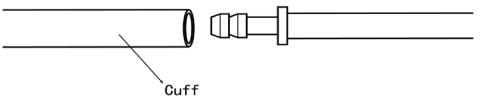


Figure 2.4.1 Connection Method

Connect the sensor between the Monitor and the measure part of the patient.

Chapter3 Function Interface

3.1 Main Interface

Press to power on the instrument. The indicator will circularly flash once, which show the boot-strap is success, then end pressing, the system will enter into the main interface.

In common user mode, if there is no key-press operation during the time which system sets, the device will turn off LCD and enter into standby mode, if there is no any operation in the standby mode, the device will automatically turn off; the "RUN" indicator flashes once every 3 seconds to prompt the device in working state.

When the power is low, the battery progress bar is empty, at the same time the prompt sound occurs, and the warning indicator flashes in fixed time.

In the Main Interface:

Prompt-switch status is displayed in the left top of the screen,  button can switch the prompt status shortly.

User bar displays the current patient type (adult, pediatric), and the amount of the common user's data record.

Current date and time is displayed in the middle top of the screen.

⚠ **Note** ⚠

- **All interfaces except the trend retain power icon, prompt switch, as well as a small font of the current time.**
- **The oldest record will be overwritten after the memory overflows. “Overflow" message is shown in the main interface.**

3.2 Measuring Interface

Measuring interface displays real-time cuff pressure and the current measurement information. In the meurement process, except the  and the  buttons, other buttons are disabled.

⚠ **Note** ⚠

In any interface except the measurement, press  **key to exit current interface and back to the boot-strap interface.**

3.3 Measure Result Interface

The measure result includes:

SYS: systolic blood pressure (mmHg/kPa)
DIA: diastolic blood pressure (mmHg/kPa)
PR: pulse rate (bpm)

If there is an error during the measurement, an error message text will appear on the screen. If the PROMPT SOUND is set to be on, the sound would occur. Press the SILENCE key to stop the sound and press it once more to continue.

3.4 System Menu

In the main interface, according to the text in the middle bottom of the screen, press  button, then enter the system menu and execute different option operations by using  and  buttons.

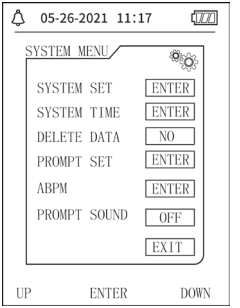


Figure 3.4.1 System Menu

3.4.1 System Setup

Enter "SYSTEM SET" item in the [SYSTEM MENU], the "SYSTEM SET" menu includes:

"LANGUAGE" item: switch the current system language;

"UNIT" item has two choice: mmHg, kPa;

"MEASURE MODE" item has three options: adult, pediatric;

"ABPM SET" item: set ABPM parameters:

"BACKLIGHT TIME(s)" item: 15, 30, 60, 120

⚠ **Note** ⚠

"BACKLIGHT TIME" in the "SYSTEM SET" is used by the common user, ambulatory blood pressure backlight time is a fixed value of 5s.

To perform ambulatory blood pressure monitoring, first select "ABPM SET" item in [SYSTEM SET] menu, the pop-up menu is shown in the Figure3.4.2:

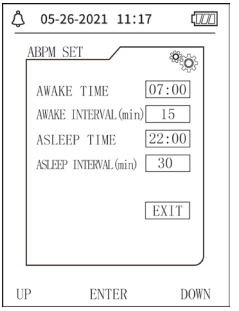


Figure 3.4.2 ABPM Setup

Options for "AWAKE INTERVAL(min)" and "ASLEEP INTERVAL(min)": 5,10,15, 20, 30, 40, 60, 90, 120, 180,

240;

The step of each adjustment for "AWAKE TIME" and "ASLEEP TIME" is 30 minutes. The adjustment range: 00:00~23:30.

⚠ **Note** ⚠

The set measurement interval in "AWAKE INTERVAL" and "ASLEEP INTERVAL" is time interval when automatically start the measurement under the mode of ambulatory blood pressure, not including manual starting. For example: set "AWAKE TIME" to 7:00, set "AWAKE INTERVAL" to 15min, then, the device will make the first blood pressure measurement at 7:15; if the user start a blood pressure measurement by pressing measuring button between 7:00-7:15, the device will also automatically start the measurement at 7:15, and not affected by manual measurement.

After each item of this interface is set, the ambulatory blood pressure menu also need to be correctly set to start the ABPM function. Refer to 3.4.5 ambulatory blood pressure menu for details.

3.4.2 System Time

Select "SYSTEM TIME" item in [SYSTEM MENU], the following menu will pop up:

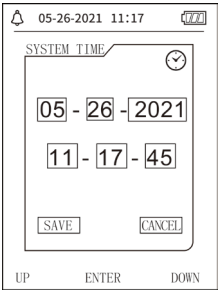


Figure 3.4.3 System Time

Select "SAVE" after completing time setup, time change is successful and exit system time setup and return the previous menu. Select "CANCEL" to cancel the setting and return to the previous menu.

3.4.3 Data Delete

Select "YES" in " DELETE DATA" menu of [SYSTEM MENU], after you press certain key, the following menu will pop up:

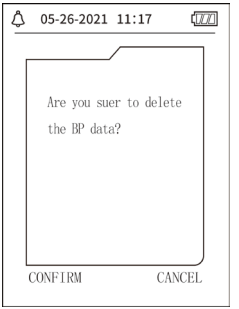


Figure 3.4.4 Data Delete

If press "CONFIRM", the common user data will be deleted, press "CANCEL", the operation will be canceled.

3.4.4 Prompt Setup

Select "PROMPT SET" item in [SYSTEM MENU] to enter its setup interface, then make corresponding settings according to the following procedure:

"SYS PROMPT" and "DIA PROMPT" can control closing or unsealing of the SYS and DIA prompt separately.

The prompt is on or off according to the high and low limits which have been set up. When the measure result is higher than the high limit or lower than the low limit, and meanwhile, the "PROMPT SOUND" is

on, "SYS PROMPT" or "DIA PROMPT" accordingly on, the prompt will occur.
The adjustable ranges of the high and low limits of the adult mode prompt are as follows:
SYS PROMPT: 30~270 mmHg
DIA PROMPT: 10~220 mmHg
The adjustable ranges of the high and low limits of the pediatric mode prompt are as follows:
SYS PROMPT: 30~235 mmHg
DIA PROMPT: 10~195 mmHg
"DEFAULT" includes the main content:
Measure mode: adult;
Parameter prompting limit:

User mode	Systolic pressure high limit	Systolic pressure low limit	Diastolic pressure high limit	Diastolic pressure low limit
Adult	140	90	90	40
Pediatric	120	70	70	40

PROMPT SOUND switch: OFF;

Measure unit: mmHg;

Ordinary user backlight time: 120s;

ABPM switch: END;

Asleep time: 22:00;

Asleep measurement interval: 30minutes;

Awake measurement interval: 15minutes;

Awake time: 7:00;

SYS PROMPT switch: OFF;

DIA PROMPT switch: OFF.

Note: The monitor does not have an alarm system.

3.4.5 ABPM Menu

1. ABPM mode

After the ambulatory blood pressure menu is operated correctly(refer to 3.4.1), select "ABPM" menu in [SYSTEM MENU] to enter its interface.

Switch the "ABPM ON-OFF" to "BEGIN", then a prompt message for ABPM of current user will pop up, such as:

Figure 3.4.5 ABPM Prompt Menu

Press button, clear the ambulatory blood pressure measure data, enter ambulatory blood pressure mode, and start the ambulatory blood pressure monitoring. Refer to Figure 3.4.6 for the ABPM interface.

Press button, save ambulatory blood pressure measure data, enter ambulatory blood pressure mode, and start the ambulatory blood pressure monitoring. Ambulatory blood pressure measurement record includes previous data. Refer to Figure 3.4.6 for the ABPM interface.

Press button, give up the choice, return the previous menu, and the ambulatory blood pressure monitoring is not turned on.

2．ABPM Working Interface

In ABPM working environment, backlight is only for 5 seconds, except the , press any key to wake the backlight, ABPM working interface is as shown:

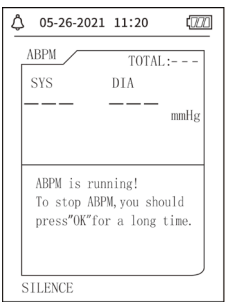


Figure 3.4.6 ABPM Working Interface

If PROMPT SOUND occurs, press SILENCE key to stop it and press it again to continue.

In ABPM working interface, long press  button, the exit ABPM hint interface will pop up. In this interface, press  button to exit ABPM working environment, and enter the ordinary user working environment, the boot-strap interface will be displayed. In the exit ABPM hint interface, press  button to exit the interface, and return the ABPM working interface.

In the ABPM working interface, to turn off the device, exit the ABPM mode first, then long press the power switch to turn it off.

3. ABPM Data Review

Select "ABPM DATA" item in "ABPM" menu to enter the data review interface.

"BIG FONT" display interface: Every record is an interface, and display contents include: the current user, total of the current user record data, serial number of the record, stored time of the record, high pressure, low pressure, mean pressure, Pulse Rate.

In the ABPM "BIG FONT" data review interface, press  button to select "LIST", the data table interface will pop up. Each interface contains 5 records, every record includes time, high pressure, low pressure, mean pressure, Pulse Rate.

In the ABPM "LIST" data review interface, press  button to select "TREND", the data trend interface will pop up. Trend interface can trace 100 trend records, if measuring data are more than 100 items, press  ,  buttons to glide trend curve for left and right, the scale of the vertical axis and the starting point, end point automatically adjust according to the width of the stored data. The

date displayed at the bottom of trends are the data recording time of the first point and last point respectively for current trend.

3.4.6 PROMPT SOUND

After selecting "ON", the loudspeaker turns on. The symbol  will display in the main interface.

After selecting "OFF", the loudspeaker turns off,  will appear. 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 sound setting can be changed if the password is correct.

3.5 Ordinary User Data Review

Ordinary User "BIG FONT" Data Review

Press  button to enter the ordinary user "BIG FONT" data review in boot-strap interface. Display content is similar to ambulatory blood pressure BIG FONT data review.

Ordinary User “LIST” Data Review

Press  button to pop up the ordinary user data “LIST” in the ordinary user BIG FONT data review interface. Display content is similar to ambulatory blood pressure data list.

Ordinary User “TREND” Data Review

Press  button to pop up the ordinary user data “TREND” in the ordinary user LIST data review interface. Display content is similar to ambulatory blood pressure trend.

the device. Press  button to exit the interface, and return the ABPM working interface.

Chapter 4 NIBP Measuring

4.1 General

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.

It is applicable for adult and pediatric usage.

⚠ **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 thrombasthemia 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.

4.1.1 Accurate Measurement Way

PATIENT position in NORMAL USE, including:

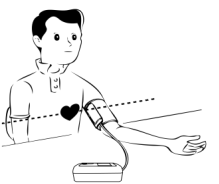
A recommendation that the PATIENT relax as mush as possible and not talk during the measurement PROCEDURE.

Comfortably seated.

Leg uncrossed.

Back and arm supported.

Middle of the CUFF at the level of the right atrium of the heart.



⚠ **Note** ⚠

- Do not speak or move during measuring.
- Do not user 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 Section 1.1 for the contraindications of NIBP measurement.
- When measuring on pediatric patients, be sure to select the correct measurement mode (refer to the measurement mode setting) and use specified cuff for pediatric . Using incorrect

measurement mode may cause danger to the patient, because the adult pressure level is relative high and is not suitable for pediatric patients.

■ The device has double overpressure protection for hardware and software. If over-inflating occurs, the device will reset and deflate immediately. If the device keeps over-inflating status, please disconnect the cuff from the device, and cut off the power or turn off the device.

■ The performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature,humidity and altitude.

■ Please use the device under proper temperature and humidity (refer to Specification), otherwise measured result may not accurate.

⚠ **Note** ⚠

Measure should be taken in a quiet place，and relax the body.

Remain still 4~5 minutes before measure.

Relax the body, do not let the muscle function.

Do not talk and move during the measure.

Wait 4~5 minutes when measuring in succession.

Do not use mobile equipment such as mobile telephone near the device.

4.2 Applying the Cuff and NIBP Measuring

⚠ **Warning** ⚠

Before starting a measurement, verify that you have selected a setting appropriate for your patient. (adult, pediatric). Do not apply the cuff to a limb that has an intravenous infusion or catheter. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

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

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 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 (Figure4.2.1).

- 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.

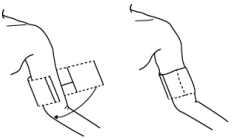


Figure 4.2.1 Cuff applying

3. Connect the cuff to the airway tube. The 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. Check whether the measure mode is appropriately selected. (the measure mode displays in the information area of the main interface).
5. Press button on the front panel to start inflating and measuring.

⚠ Note ⚠

The operator should stand adjacent to the patient and press button on the front panel to start

inflating and measuring.

4.3 Operation Hints

1. To start auto measuring:

In ABPM SETUP menu, select the "ASLEEP INTERVAL" item and "AWAKE INTERVAL" item, in which the user may select the time interval for auto measurement. After that, enter "ABPM" menu and select to enter the ABPM working environment, and the system will start inflating and measuring automatically according to the set time interval.

⚠ **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.

2. To stop auto measuring:

During auto measuring, press  button at any time to stop auto measurement.

3. To start a manual measuring:

- **Press**  **button to start a manual measuring in the ordinary user working environment.**
- **During the idle period of auto measuring process, press**  **button at any time to start a manual measurement. Then press**  **button to stop manual measurement and the system**

continues executing auto-measuring program.

⚠ **Note** ⚠

If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

⚠ **Warning** ⚠

If liquid is inadvertently splashed on the equipment or its accessories, or may enter the conduit or inside the monitor, contact local Customer Service Center.

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

Measurements will be unreliable or can not perform if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

Cardiac Arrhythmia's

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused

an irregular heartbeat. The measuring time thus will be prolonged.

Heart-lung Machine

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

Pressure Changes

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

Severe Shock

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

Heart Rate Extremes

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

Obesity patient

The thick fat layer of body will reduce the measurement accuracy, because the fat that come from the shock of arteries can not access the cuffs due to the 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);
Continuous measurement for a long time;

4.4 NIBP Error Messages and Solutions

Display message	Cause	Solution
Low power	Device battery is low.	Replace the battery. If the problem still exists, please contact us.
Loose cuff	Cuff is not connected correctly.	Reconnect the cuff. If the problem still exists, please contact us.
Air pressure error	Valve can not be open.	Restart the device. If the problem still exists, please contact us.
Weak signal	Object measuring the pulse is too weak or the cuff is loose.	Check the cuff connection, tighten the cuff if it is loose.
Over range	Object measuring blood pressure is over the measurement range.	Take another measurement. If the problem still exists, please contact us.
Excessive movement	Movement may result in too much interference in the signal during measuring process.	Be sure to keep still during measuring process.
Over pressure	Cuff pressure is over the scope, ADU 300 mmHg.	Check the cuff to make sure it is not blocked or squeezed.

Saturated signal	Movement or other factors may lead to too big signal amplitude.	Check the connection of air tube to make sure it is not squeezed. Patient should keep quiet and then take a new measurement.
Air leakage	Possible air leakage in the valve or airway	Check the air tube and the cuff.
System failure	Possible failure caused by pump, air valve or pressure sensor.	Please contact us.
Timeout	The time for a single measurement exceeds the maximum measurement time (adult: 180s).	Check the connection of air tube and tighten the cuff.

4.5 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. Before cleaning,the accessories and main unit must be separated.
Do not squeeze the rubber tube on the cuff.

Cleaning

Reusable accessories that come into contact with patients need to be cleaned after each use.

The following cleaning agents for cleaning reusable accessories have been validated:

isopropanol （70%）

To avoid long-term damage to accessories, it is strictly prohibited to use alcohol or alcohol containing washing solutions to wipe the outer surface of the accessories.

Cleaning steps:

Clean the places (such as gaps and grooves) that are not easy to wipe on the surface of the reusable accessories with a medical brush dipped in disinfectant (no liquid drips from the brush),brush for three minutes; then use a clean and soft cloth to absorb an appropriate amount of cleaning agent, screw it dry, and thoroughly wipe all external surfaces, pay attention to avoiding the interface, and wipe for two minutes. Repeat this step for three times, until there is no obvious residue.

1、Wipe the extra cleaner with a new cloth or a paper towel soaked in water until there is no obvious detergent residue.

2、Put the reusable accessories in a cool and well ventilated place to let it dry naturally and thoroughly.

Disinfection

To avoid long-term damage to the accessories, we recommend disinfecting the accessories only when deemed necessary by the regulations of your hospital.

The following disinfectants for disinfecting reusable accessories have been validated:

isopropanol （70%）

Disinfection steps:

Clean the places (such as gaps and grooves) that are not easy to wipe on the surface of the reusable accessories with a medical brush dipped in disinfectant (no liquid drips from the brush),brush for three minutes; then use a clean and soft cloth to absorb an appropriate amount of cleaning agent, screw it dry, and thoroughly wipe all external surfaces, pay attention to avoiding the interface, and wipe for two minutes. Repeat this step for three times, until there is no obvious residue.

Wipe the extra cleaner with a new cloth or a paper towel soaked in water until there is no obvious detergent residue.

Put the reusable accessories in a cool and well ventilated place to let it dry naturally and thoroughly.

The cuff can also be machine-washed or hand-washed. Before washing, remove the latex rubber bag. Allow the cuff to dry thoroughly after washing, then reinsert the rubber bag.

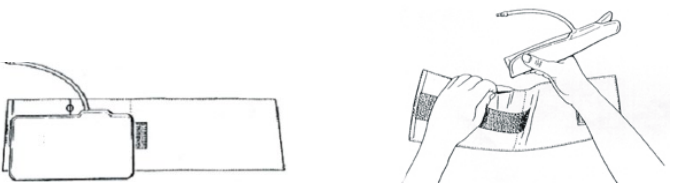


Figure 4.5.1 Replace Rubber Bag in Cuff

To replace 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 complete 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.

⚠ **Note** ⚠

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.

Storage:

⚠**Advice**⚠

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

4.6 Transportation and Storage

- The packaged device can be transport by general vehicle or according to the order contract. Do not transport the device mixed with toxic, harmful or corrosive materials.
- The device after packaged should be stored in a well ventilated room without any corrosive gas, temperature range: -20℃~+55℃, relative humidity no more than 95%.

4.7 Key and Symbols

Your device may not contain all the following symbols.

Signal	Description	Signal	Description
	Caution		Refer to instruction manual/ booklet.
SYS	Systolic pressure	DIA	Diastolic pressure
MAP	Mean blood pressure	PR	Pulse rate (bpm)
SN	Serial number	EMC	Electromagnetic compatibility
IPXX	The degree of protection against ingress of water	P/N	Material code of manufacturer
ADU	Adult	INFO	Information

PED	Pediatric		Type BF defibrillator proofed applied parts
ABPM	Ambulatory Blood Pressure Monitor		Silence
	Free of natural rubber latex		Open the prompt sound indication
	Close the prompt sound indication		Fragile, handle with care
	Batch code		Storage atmospheric pressure limitation
	This way up		Storage humidity limitation
	Keep dry		Date of manufacture
	Storage temperature limitation		Pulse rate (bpm)
	Manufacturer		1.No Pulse rate 2.An indicator of signal inadequacy

	Batteries Power	CE 0123	This item is compliant with Regulation(EU)2017/745 of the European Parliament and of the Council of 5 April 2017.
	1.No NIBP data to review 2.An indicator of signal inadequacy	EU REP	European Representative
	WEEE disposal	MD	Medical device
	Recyclable		Imported By
UDI	Unique Device Identifier	REF	Product code

Chapter5 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

Chapter6 Software Functions

6.1 Access

When the software runs for the first time, a “Welcome” window pops ups to notify the user that the software is running. If Secure Login is not enabled, click the “Continue” button to access the Main interface. If Secure Login is enabled, clicking the “Continue” button will enter the User Management interface (refer to Section 6.22 User Management for details). Click the “Quit” button to close the software.

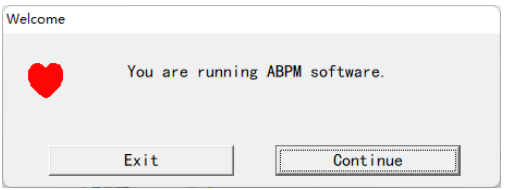


Figure 6.1 Welcome Interface

6.2 Main Interface

The Main interface of the software is displayed as follows:

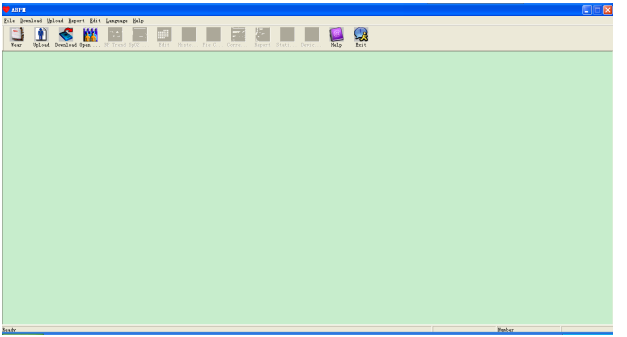


Figure 6.2 Main Interface

6.3 Wear

After clicking the shortcut key 

, the following figure appears. Before using the device, please read "Matters need" carefully, and wear the device according the following figure.

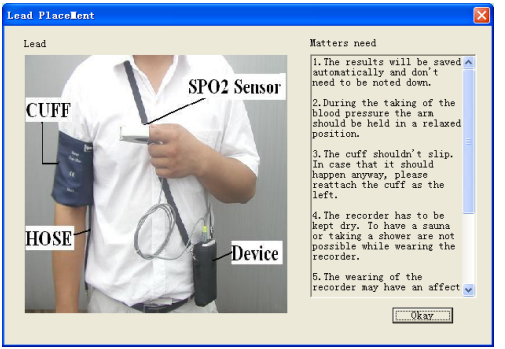
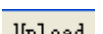


Figure 6.3 Wear

6.4 Setting for Collection Plan

Click shortcut key 

, or click menu bar 

item, and the " Upload parameters " dialog box will appear:

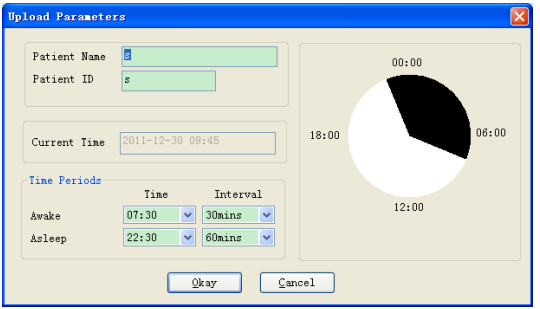


Figure 6.4 Set Collection Parameter

As above figure, the doctor could set parameter according to the patient status and diagnosis requirement, then the monitor could finish the collection according to the setting.Parameter explanation is as follows:

Patient Name: the patient's name

Patient ID: the patient's ID number.It is used for marking patient, and it is exclusive in order to avoid homonymy patient arisen state

Current Time: Current system display time

Time Periods:
Awake Time: the patient is awake state
Asleep Time: the patient is asleep state
Interval: collection Interval.In order to reduce the effect to the patient sleep, the asleep collection interval should be longer.
For example as above figure:the awake time area is 7:30-22:30, and the asleep time area is 22:30-tomorrow7:30. The awake collection interval is 30 minutes, and the asleep collection interval is 60 minute.
The asleep time area and awake time area will be display at the right side.
When the parameter setting is finished, click " Okay " to upload the project to the monitor.

6.5 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 6.1.2) 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.

6.6 Open Data File

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

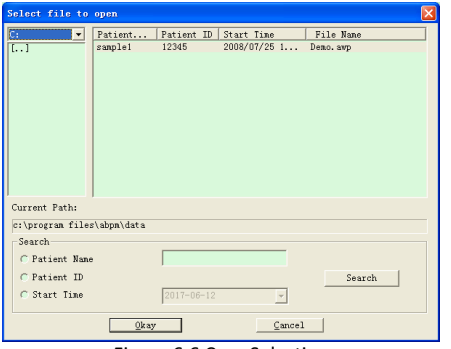


Figure 6.6 Case Selection

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.

6.7 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.

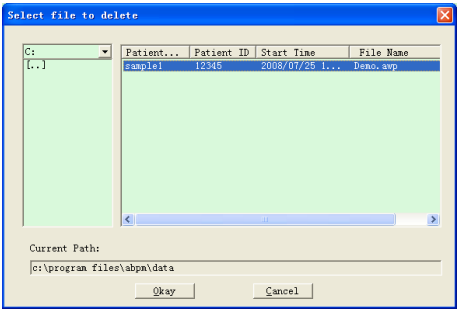


Figure 6.7 Data File Delete

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.

6.8 Data File Backup

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

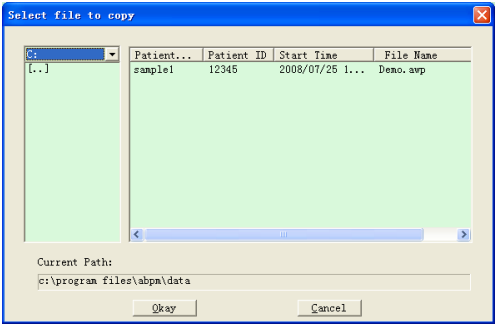


Figure 6.8.1 Data File Copy

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:

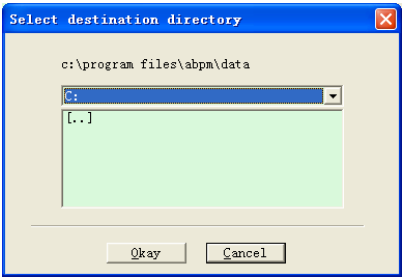


Figure 6.8.2 Backup Path Settings

6.9 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:

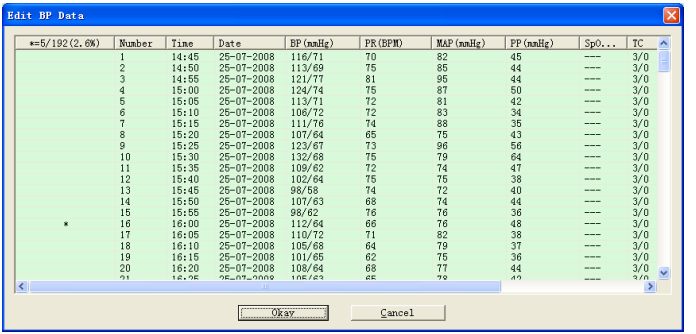


Figure 6.9 Data Edit Interface

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.

SpO_2(%): oxygen saturation, unit is %.

TC: error code /measurement mode(refer to chapter 4)

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.

6.10 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.

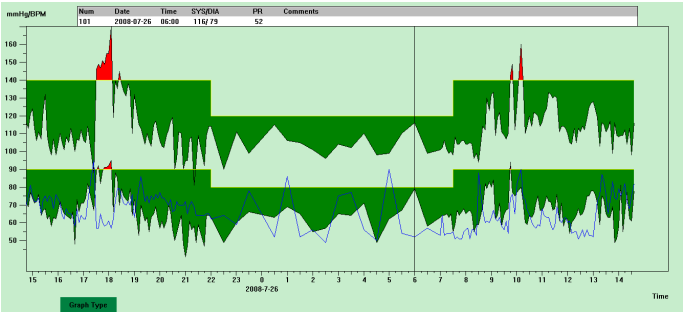


Figure 6.10.1 Color Filling Trend Ggraph

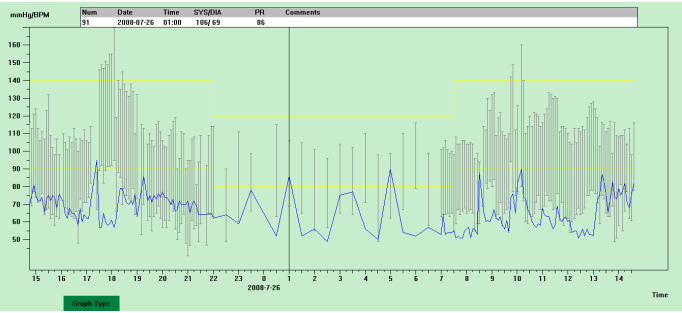


Figure 6.10.2 Dotted Line Trend Graph

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 tread 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.

6.11 Display of Statistics Information

Press the shortcut key 

or select "Report" from menu to enter its sub-menu shown as below.

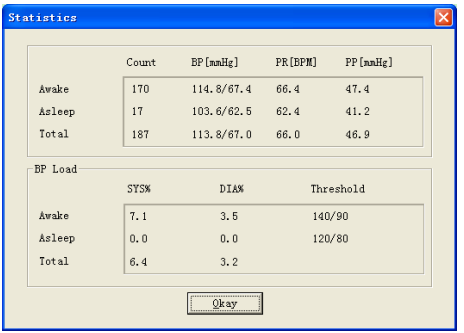


Figure 6.11 BP Statistics Information

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.

6.12 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.

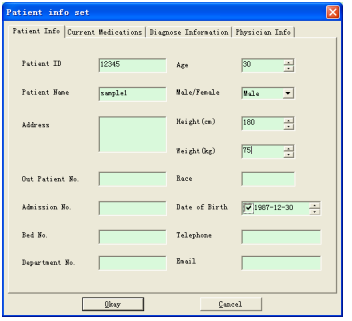


Figure 6.12 Edit Patient's Information

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.

6.13 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.

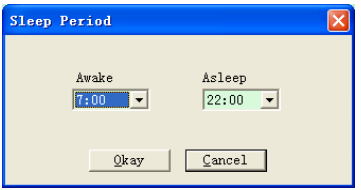


Figure 6.13 Sleep Time Setting

6.14 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.

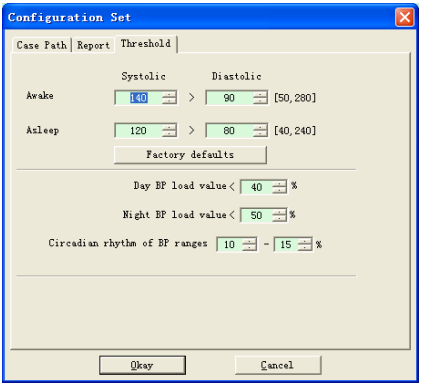


Figure 6.14 BP Threshold Setting

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.

6.15 Management Settings

The software provides the flexibility to enable or disable the Secure Login. Users can enable or disable this option to active the Secure Login function or not according to their demands.

◆ Start Welcome Interface: Check this option to display the Welcome interface after launching the software. For detailed information, refer to Section 6.1 Welcome to the Software.

◆ Start Secure Login: check this option to access the user management and user login interfaces.For detailed information, refer to Section 6.20 User Management.

Note: In the software interface, click “System” > “Management Settings” to access the administrator verification interface. Enter the correct administrator password and click “OK” to access the management settings interface, where you can complete the above operations.

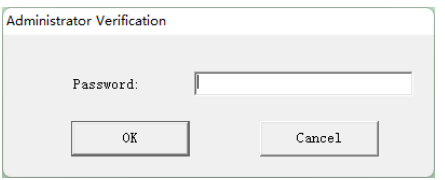


Figure 6.15.1 management settings

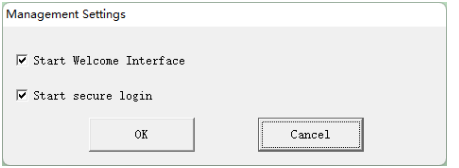


Figure 6.15.2 administrator verification

6.16 Histogram

Press the shortcut key 

, the following interface will appear.

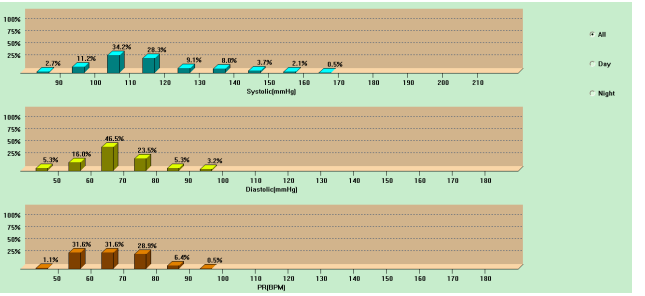


Figure 6.16 Histogram

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

6.17 Pie Chart

Press the shortcut key 

, the following interface will appear:

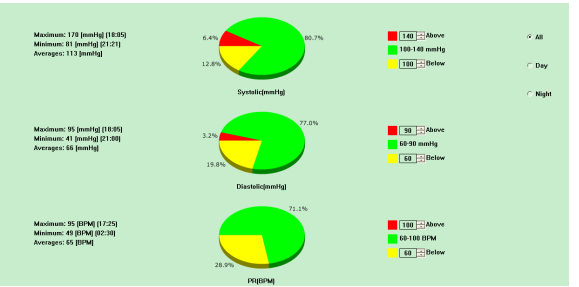


Figure 6.17 Pie Chart

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.

6.18 Correlation Line

Press the shortcut key 

, the following interface will appear:

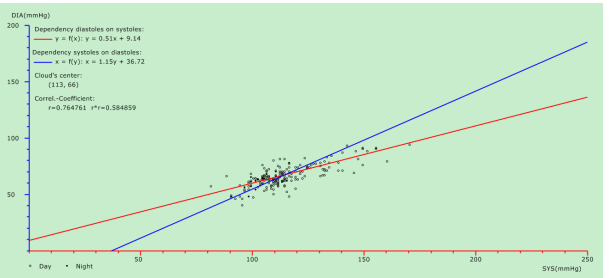


Figure 6.18 Correlation Line

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.

6.19 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.

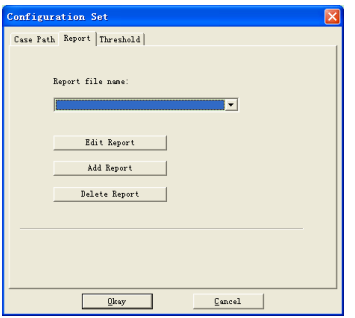


Figure 6.19.1 Configure Report

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

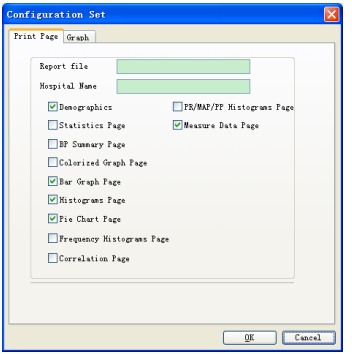


Figure 6.19.2 Edit Report

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.

6.20 User Management

This chapter applies when Secure Login is enabled (refer to Section 6.15 Management Settings for how to enable this function).

6.20.1 Administrator

When the software is launched for the first time (or if no users exist), the default "Administrator" interface will appear, as shown below. From here, you can log in to the administrator account or change the administrator password.

Figure 6.20.1 Administrator

Administrator login：

Enter the administrator password, then click “Login”.

The default password for the administrator account is “Abpm70605006c”.

Error prompt：

No.	Prompt	Error description
1	Password cannot be empty!	No password is entered.
2	Password error, please try again!	The entered password is incorrect.

Modify administrator password：

Click "Modify", enter a new password in the "New password:" and "Confirm password:" fields, and the "Login" button will change to "OK".

Enter the old password in the “Password” field and a new password in the “New Password” and “Confirm Password” fields, then click “OK” to update the password and log in to the administrator account.

Note: The password must be 8-16 characters long and include both letters and numbers.

Error prompt：

No.	Prompt	Error description
1	Password cannot be empty!	No old password is entered.
2	Password error, please try again!	The entered old password is incorrect.
3	The new password cannot be empty!	No new password is entered.

4	The new password is incorrect, please re-enter!	The new password format is incorrect.
5	Please enter the confirmation password!	No Confirm password is entered.
6	The confirmation password is incorrect, please re-enter!	The Confirm password format is incorrect or does not match the New password.

6.20.2 User Management

After successfully logging into the administrator account, the "User Management" interface will appear, as shown below. This interface is used to add or delete users.

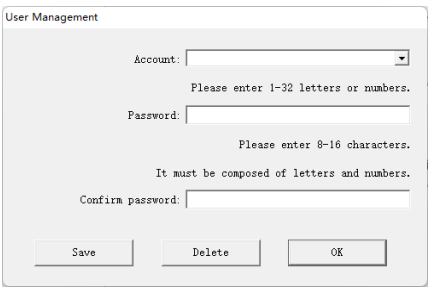


Figure 6.20.2 User Management

Add a new user：

Enter the account information and click “Save”. The message “Save successfully!” indicates that the new user has been added.

Account: 1-32 characters long, containing letters or numbers.

Password and Confirm password: 8-16 characters long, which must include both letters and numbers.

Error prompt：

No.	Prompt	Error description
1	Account cannot be empty!	No account is entered.
2	The account name is incorrect, please re-enter!	The account format is incorrect.
3	The new password cannot be empty!	No new password is entered.
4	The new password is incorrect, please re-enter!	The new password format is incorrect.
5	Please enter the confirmation password!	No Confirm password is entered.
6	The confirmation password is incorrect, please re-enter!	The Confirm password format is incorrect or does not match the New password.

Modify user password：

If the entered user account already exists, and the "Password" and "Confirm password" fields are filled correctly, click “Save” to update the password.

Delete user

Select the account to be deleted from the dropdown list, then click “Delete”. The message “Delete successfully!” indicates that the user information has been deleted.

Return to “User Login”

After completing the user management, click “OK” to return to the “User Login” interface.

6.20.3 User Login：

After adding new accounts, the “User Login” interface will appear, as shown below.

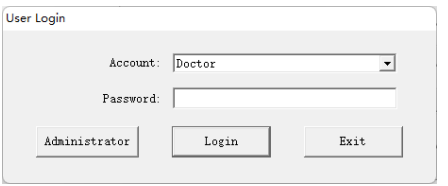


Figure 6.20.3 User Login

Select a login account, and enter the password, then click “Login”.

Click “Administrator” to access the “Administrator” interface.For detailed information, refer to Section 6.20 User Management.

Click “Exit” to close the software.

6.20.4 Security suggestions：

To protect the security of health data of patients, the following suggestions are provided:

1. Automatic screen lock: Configure the screen saver to display the Login interface when recovered; shorten the interval for automatic logoff when the system is idle, and advise users to log out or shut down the computer when leaving.

2. Users may use their Windows usernames and passwords or the Secure Login (see Section 6.20 User Management for details) provided by this software for login. When using the username and password, pay attention to the following two points:

(1) Configure complex passwords and change them regularly; it is recommended to enable the Windows password policy;

(2) Disable administrator and guest accounts; each user must have a unique identity;

3. Install security and antivirus software, and enable the firewall and automatic updates. Run antivirus software regularly;

4. Ensure the physical security of all device components (excluding removable media) storing personal information, i.e., they cannot be removed without tools;

5. This software contains health data and medical records that require protection and confidentiality. Do not copy that information to the removable storage media. If copying is necessary, always maintain the physical security of the media;

6. Before using USB storage devices, antivirus measures should be taken, such as performing virus scans on the USB device;

7. Disable the default Windows services including Remote Desktop, Telnet, and File Sharing;

8. Secure environment:

This product is intended to be operated within an environment that incorporates the following expected privacy and security protection measures:

(1) The computer on which this software is installed must be physically protected to prevent access by unauthorized users;

(2) External media containing patient data, reports, and logs must be protected. When no longer using it, data stored should be securely deleted and/or the media should be safely removed.

The monitor of the computer on which this software is installed should be positioned to ensure that only authorized users can view the screen content.

6.21 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.

Specification

Name	Ambulatory Blood Pressure Monitor	
The degree of protection against ingress of water	IP22	
Display	2.4'' color LCD Display	
Operating mode	Continuous operating	
NIBP Specifications		
Measurement Method	Oscillometric method	
Working modes	Automatic	
Cuff pressure range	0~300 mmHg(0~40.0 kPa)	
Blood pressure measurement Range	adult	SYS：30～270 mmHg(4.0~36.0 kPa) DIA：10～220 mmHg(1.3~29.3 kPa)
	pediatric	SYS：30～235 mmHg(5.3~ 31.3kPa) DIA：10～195 mmHg(1.3~ 26.0kPa)
Pulse measurement range	40~240/min	
Inflation	adult	160mmHg(21.33 kPa)
	pediatric	120mmHg(16kPa)
Prompt Range	adult mode	SYS PROMPT: 30~270 mmHg(4.0~36.0 kPa) DIA PROMPT: 10~220 mmHg(1.3~29.3 kPa)

	pediatric mode	SYS PROMPT: 30~235 mmHg(5.3~31.3 kPa) DIA PROMPT: 10~195 mmHg(1.3~26.0 kPa)
Overpressure protect	adult mode	297±3 mmHg（39.6±0.4 kPa）
	pediatric mode	260±3 mmHg（34.66 ± 0.4kPa）
Resolution		
Pressure	1 mmHg（0.133 kPa）	
Pulse Rate	1 /min	
Measurement Accuracy		
Cuff Pressure Accuracy	Static pressure: ±3 mmHg(±0.4 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	
Operating temperature/ humidity	+5 ºC~40 ºC 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 ºC~+55 ºC; Relative humidity: ≤95 %; No corrosive gas and drafty.	

Atmospheric pressure	700 hPa~1060 hPa
Power Supply	DC 3 V
Battery service life	When the temperature is 23 ºC, limb circumference is 270 mm, the measured blood pressure is normal, 2 "AA" alkaline batteries can be used about 150 times.
Rated Power	≤ 3.0 VA
Dimensions	128(L)*69(W)*36 mm(H)
Unit Weight	240 gram(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

The ambulatory blood pressure monitor is a portable device indicated for use in non-invasively measuring,pulse rate,non-invasive measurement of blood pressure of adult patients in hospital , medical facilities, and sub-acute environments.

Warning:

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 this equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Note:

This equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.

- The basic performance: NIBP measurement range:0~300mmHg(0~40.0 kPa).Error:Maximum mean error: ±5 mmHg,Maximum Standard deviation: 8 mmHg.PR measured range: 40 bpm ~ 240 bpm .

When the device is disturbed, the data measured may fluctuate, please measure repeatedly or in another environment to ensure its accuracy.

Other devices may affect this device even though they meet the requirements of CISPR.

Product configuration：

Serial number	name	Cable length
1	USB cable	1m

Table 1

Guidance and Declaration - Electromagnetic Emissions	
Emissions test	**Compliance**
Radiated RF EMISSIONS CISPR 11	Group 1
Radiated RF EMISSIONS CISPR 11	Class B
Harmonic distortion IEC 61000-3-2	Not applicable
Voltage fluctuations and flicker IEC 61000-3-3	Not applicable

Table 2

Guidance and Declaration - Electromagnetic Immunity		
Immunity Test	**IEC 60601 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable
Voltage dips and Voltage interruptions IEC 61000-4-11	0 % UT; 0,5 .cycle. At0°,45°,90°,135°, 180°,225°,270°and315°. 0 % UT; 1 cycle and 70 % UT ; 25/30 cycles; Single phase: at 0°. 0 % UT; 250/300 cycle	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0,15MHz to 80 MHz 80%AM at 1kHz	3 V 0,15MHz - 80 MHz 6 V in ISM and amateur radio bands between 0,15MHz to 80 MHz 80%AM at 1kHz

Radiated RF IEC61000-4-3	10V/m 80 MHz-2,7GHz 80%AM at 1kHz	10V/m 80 MHz-2,7GHz 80%AM at 1kHz
NOTE UT is the a.c.mains voltage prior to application of the test level		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity						
	Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**IEC60601-1-2 Test level (V/m)**	**Compliance level (V/m)**
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	385	380-390	TETRA 400	Pulse modulation b) 18 Hz	27	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	28	28
	710	704-787	LTE Band 13,17	Pulse modulation b) 217 Hz	9	9
	745					
	780					
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,	Pulse modulation b) 18 Hz	28	28
	870					
	930					

			LTE Band 5			
	1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	28	28
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	28	28
	5240 5500 5785	5100–5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	9	9

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