



GIMA

PROFESSIONAL MEDICAL PRODUCTS

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GIMA ABPM PULSE RATE MONITOR

User Manual



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

REF 35110 / ABPM50



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Chapter 1

INTRODUCTION

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.



Warning

Possible explosion hazard if used in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.



Warning

You must verify if the device and accessories can work safely and normally before using.



Warning

Ensure that the environment in which the device is operated is not subject to any sources of strong electromagnetic interference, such as radio transmitters, mobile telephones, etc. Keep them far away high level electromagnetic radiation emitted from such devices may greatly affect the instrument performance.



Warning

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



Warning

Please choose the accessories which are approved or manufactured by the manufacturer, or else it may damage the device.



Warning

The monitor is only for use on one patient at a time.



Warning

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



Warning

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.

**Warning**

When used with Electro-surgery equipment, you must give top priority to the patient safety.

**Warning**

It is recommended that you check if there is any damage on the monitor 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. In addition, the overall check of monitor, including the safety check such as the leakage current, should be only performed by qualified personnel once every 12 months.

**Note**

Please choose the computer which should be ensured compliance with the requirements of IEC 60950, or else it may damage the device.

**Note**

The software was developed per IEC60601-1-4. The possibility of hazards arising from errors in the software program is minimized.

**Note**

The monitor shall comply with the standard EN1060 series:
Part 1: General requirements;
Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems (in course of preparation).

**Caution**

At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulation the disposal of such products. If you have questions concerning disposal of the product, please contact us or its representatives.

1.1 General Information

Environment:

Temperature Working	5~40 (°C)
Transport and Storage	-20~55 (°C)
Humidity Working	15%~80%
Transport and Storage	≤ 95 %
Altitude	80kPa~105kPa
Power Supply	3 (V) DC
	P ≤2.4VA

The device has life for 10000 times of BP measure(within 5 years).

Safety:



This device is defibrillator protected. 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.

General instruction

The device is applied to Blood Pressure(BP) measure and monitor for adult, pediatric, and neonatal. 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.

This device has friendly operation interface, and adopts 2.4inch color LCD. It integrates data review function and display function which includes large-print single record data review, data list, BP data trends chart, the current time,date,power,alarm 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).

There are sound and light alarm functions that the buzzer intermittently beeping and the red light flashing to prompt low power. When the measure result exceed the alarm limit, the color of the measure results style becomes red and aroses sound alarm. The user can turn on or off the alarm sound if necessary.

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

If there is no operation in the common user mode, the device will turn off backlight according to the “BACKLIGHT TIME” you set, and if no action for three minutes, the device will automatically turn off. When the backlight turn off in the Ambulatory Blood Pressure mode, the green indicator intermittently flashes to prompt the device in running state.

1.2 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. When turning on and off the monitor, the red light and the green both flash once to prompt that the on or off operation is successful. 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 alarm 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

During uploading data with the USB, all of the buttons are disabled. If measuring, the measurement is to be canceled..



Note

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.

1.3 Interfaces

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

**Note**

Cuff is connected to the monitor through the extended gas pipe.

1 Port of extended gas pipe

2 The socket for Gas pipe



Figure 1
The top external airway

At the bottom is the socket for USB

1 the Socket for USB, connect the data line to upload data



Figure 2
Bottom

1.4 Accessories

1 A cuff for adult

2 A USB data line

3 A disk (PC software)

4 BP extending tube

5 A pouch

**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.

Chapter 2

GETTING STARTED

- Open the package and check
- Dry battery installation
- Power on the instrument
- Connect patient sensors

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 Dry battery installation

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.



Note

When you don't use the equipment, you should take out the dry battery.

2.3 Accensione apparecchio

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



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.



Note

Check all the functions that possibly be used and make sure that the equipment is in good status.

2.4 Connect Sensor



Note

For information on correct connection of NIBP cuff, refer to Figure 3



Figure 3
Connection method

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

Chapter 3 FUNCTION INTERFACE

- Interfaccia principale
- Menu sistema

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 2 seconds to prompt the device in working state.

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

In the Main Interface:

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

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

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

The boot-strap interface is shown as the follow

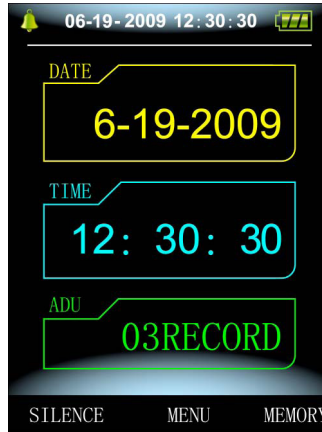


Figure 4
Common user boot-strap
interface 1



Note

All interfaces except the trend retain power icon, alarm switch, as well as a small font of the current time.



Note

After the register overflow, the first record will be overwritten, “Overflow” message is shown in the boot-strap interface. The interface is shown as the follow:



Figure 5
Common user boot-strap
interface 2

3.2 Measuring Interface

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



The measuring interface is shown as the follow:



Figure 6
Measuring interface



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)



Figure 7
Measure results interface 1

If there is an error during the measurement, an error message text will appear on the screen. If the ALARM 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.

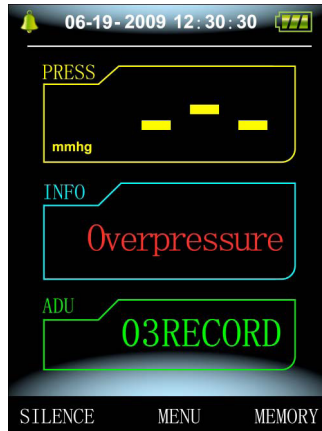


Figure 8
Measure result interface 2

3.4 System Menu

In the boot-strap 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   keys.



Figure 9
System menu

3.4.1 System setup

Enter "SYSTEM SETUP" item in the [SYSTEM MENU], the following menu will pop up:



Figure 10
System setup

“SYSTEM SETUP” menu includes:

“LANGUAGE” item has two choices: Chinese, English;

“UNIT” item has two choice: mmHg, kPa;

“USER PURVIEW” item cannot be operated: all;

“MEASURE MODE” item has three options: adult, pediatric, neonatal,

“BACKLIGHT TIME(s)”item has four choices: 15, 30, 60, 120.



Note

“Backlight Time” in the “System Settings” is used by the common user, backlight time in ambulatory blood pressure monitor (ABPM) is a fixed value of 5S.

Select “ABPM Setup” item in [System Setup] menu, the following menu will pop up:

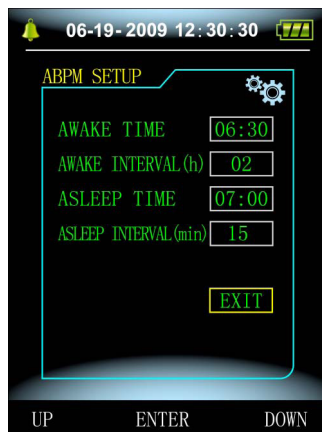


Figure 11
ABPM Setup

“AWAKE INTERVAL” (min/h) could be options: 15, 30, 60, 120;
 “ASLEEP INTERVAL” (min/h) could be options: 15, 30, 60, 120, 240;
 “AWAKE TIME” and “ASLEEP TIME” transformation unit are 30 minutes.

3.4.2 System Time

Select “System Time” item in [System Menu], the following menu will pop up:



Figure 12
System time

Select “Confirm” after time setup complete, time change is successful and exit system time setup and return the previous menu.
 Select “Exit” to cancel the setting and return to the previous menu.

3.4.3 Data Delete

Select “Yes” in “Data Delete” menu of [SYSTEM MENU], after you press certain key, the following menu will pop up:

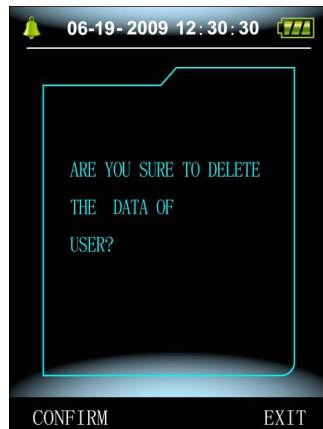


Figure 13
Data delete

If press “Confirm”, the common user data will be daleted, if press “Exit”, the operation will be cancelled.

3.4.4 Alarm Setup

Select “ALARM SOUND” item in [SYSTEM MENU] to switch on or off the sound of alarm. [refer to Figure 9 system menu]. Select “ALARM SETUP” item in [SYSTEM MENU], the following menu will pop up:

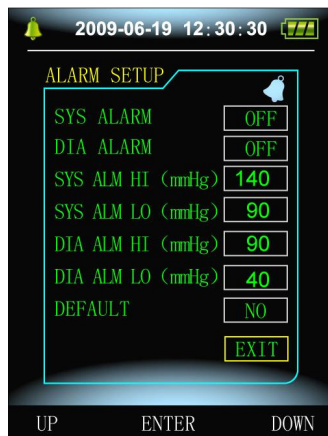


Figure 14
Alarm setup

“SYS ALARM” and “DIA ALARM” can control closing or unsealing of the SYS and DIA alarm separately.

The alarm 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 “ALARM SOUND” is on, “SYS ALARM” or “DIA ALARM” accordingly on, the alarm will occur.

The adjustable ranges of the high and low limits of the adult mode alarm are as follows:

SYS ALM: 40~270 mmHg

DIA ALM: 10~215 mmHg

The adjustable ranges of the high and low limits of the pediatric mode alarm are as follows:

SYS ALM: 40~200 mmHg

DIA ALM: 10~150 mmHg

The adjustable ranges of the high and low limits of the neonatal mode alarm are as follows:

SYS ALM: 40~135 mmHg

DIA ALM: 10~100 mmHg

“Default” includes the main content:

Measure mode: adult;

Alarm parameter:

Use mode	High pressure high limit	High pressure low limit	Low pressure high limit	Low pressure low limit
Adult	140	90	90	40
Pediatric	120	70	70	40
Neonatal	100	60	60	20

Alarm switch: close;

Measure unit: mmHg;

Ordinary user backlight time: 15s;

ABPM switch: close;

Asleep time: 22:00;

Asleep measurement interval: 30 minutes;

Awake measurement interval: 15 minutes;

Awake time: 7:00;

SYS Alarm switch: close;

DIA Alarm switch: close.

3.4.5 ABPM Menu

Select “ABPM” menu in [System Menu], the following menu will pop up.

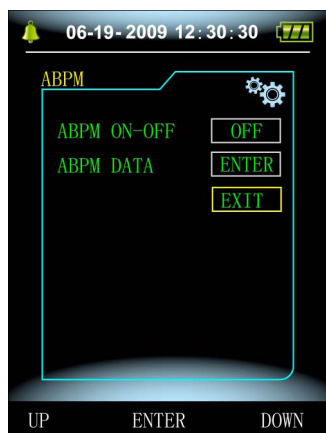


Figure 15
ABPM

In “ABPM” menu, “ABPM ON-OFF” select “ON”, then prompt message of ABPM of the current user, such as:

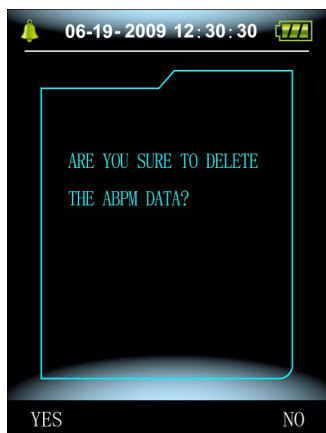


Figure 16
ABPM prompt menu

Press  button, clear the ambulatory blood pressure measure data, and enter ambulatory Blood Pressure Mode;

Press  button, save ambulatory Blood Pressure measure data, and enter ambulatory Blood Pressure Mode;

Press  button, give up the choice, and return the previous menu.

3.4.6 ABPM Data Review

3.4.6.1 ABPM “large-print” Data Review

Select “ABPM Data” item in “ABPM” menu, the following interface will pop up.

Every record is an interface, and display content 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.

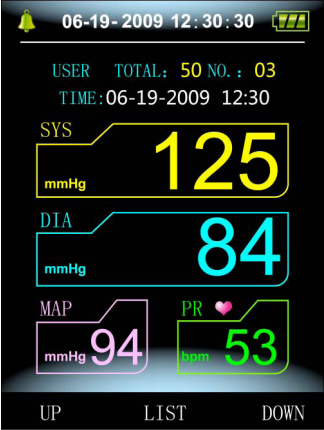


Figure 17
ABPM “large-print”

3.4.6.2 ABPM Data “Table”

Press  button to select “trend” in ABPM large-print data review menu, the following interface will pop up

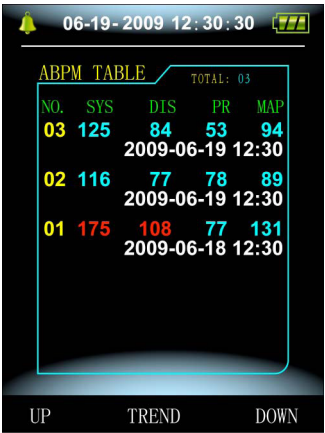


Figure 18
ABPM “Table”

A interface contain 5 records, every record includes time, high pressure, low pressure, mean pressure, Pulse Rate.

3.4.6.3 ABPM Trend

Press  button to select “trend”, in ABPM large-print data review menu, the following interface will pop up:

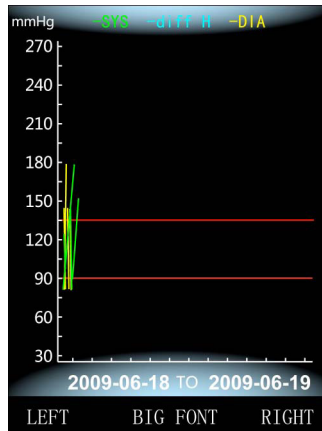


Figure 19
ABPM “trend”

Trend interface can trace 100 record trends, if measuring data are more than 100 items, press ,  buttons can 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 displayed dates that are at the bottom of trends shown the trend for the first point and last point of data recording time.

3.4.7 Ordinary User Data Review

3.4.7.1 Ordinary User “large-print” Data Review

Press  button to enter the ordinary user “large-print” data review in boot-strap interface, the following interface will pop up:

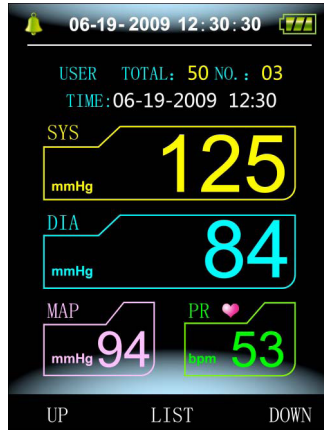


Figure 20
Ordinary user “large-print”

Display content is similar to ambulatory blood pressure large-print data review.

3.4.7.2 Ordinary User Data Table

Press  button to pop up the ordinary user data table in the ordinary user large-print data review, the interface is as shown:

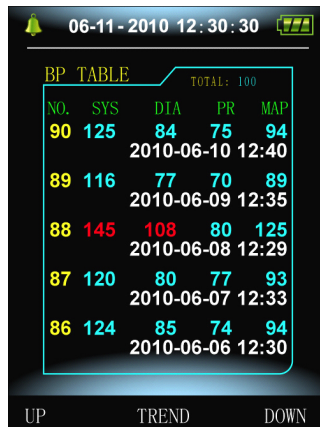


Figure 21
Ordinary user data table

Display content is similar to ambulatory blood pressure large-print data review.

3.4.7.3 Ordinary User Measure Data Trends

Press  button to pop up the ordinary user data table in the ordinary user data table, the interface is as shown:



Figure 22
Trends

Display content is similar to ambulatory blood pressure large-print data review.

3.5 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 23
ABPM working interface

If alarm sound occurs, press SILENCE key to stop it and press it again to continue.

Long press  button, the exit ABPM hint interface will pop up:

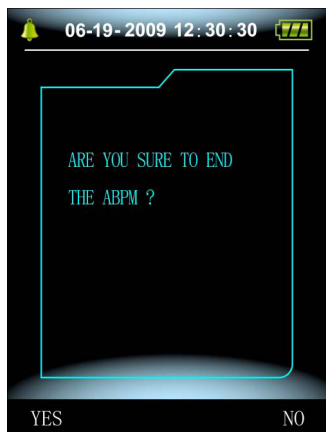


Figure 24
ABPM exiting prompt interface

Press  button to exit ABPM working environment, and enter the ordinary user working environment, and display the boot-strap interface;

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

Long press  button, turn off device hint interface will pop up :



Figure 25
Turn Off Device Prompt Interface

Press  button to turn off the device.

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

Chapter 4

NIBP MEASURING

4.1 Introduction

- The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method.
- There are two modes of measurement available: manual, automatic.
- Every mode displays the systolic, mean, diastolic blood pressure and pulse rate.
- It is applicable for adult, pediatric, and neonatal usage.



Warning

1. 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.
2. 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.
3. Ensure that the correct mode setting is selected when performing measurements on children and newborn (Refer to measuring mode menu setting), and use children and newborn special cuff. It may be dangerous for using error patient mode, because the upper adult blood pressure level does not apply the children and newborn.

4.2 NIBP Measuring



Warning

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



Warning

Make sure that the air conduit connecting the blood pressure cuff and the equipment is neither blocked nor tangled.

1. Plug in the air hose and switch on the system.
2. Apply the blood pressure cuff to the patient's upper arm following the instructions below (Figure 26).
 - Ensure that the cuff is completely deflated.
 - Apply the appropriate size cuff to the patient, and make sure that the symbol "Φ" is over the appropriate artery. Ensure that the cuff is not

wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.

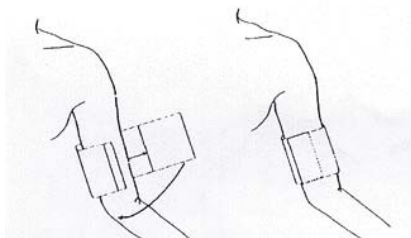


Figure 26
Use cuff



Nota

The width of the cuff should be either 40% of the limb circumference (50% for neonates) or 2/3 of the upper arm length. The inflatable part of the cuff should be long enough to encircle 50-80% of the limb. The wrong size of cuff can cause erroneous readings. If the cuff size is in question, then use a larger cuff.

Size of reusable cuff for neonate/children/adult

Patient type	Limb perimeter	Cuff width	Hose
Infant	10 ~ 19 cm	8 cm	1.5 m or 3 m
Child	18 ~ 26 cm	10.6 cm	
Adult1	25 ~ 35 cm	14 cm	
Adult2	33 ~ 47 cm	17 cm	
thigh	46 ~ 66 cm	21 cm	

Size of disposable cuff for neonate

Size No.	Limb perimeter	Cuff width	Hose
1	3.1 ~ 5.7 cm	2.5 cm	1.5 m or 3 m
2	4.3 ~ 8.0 cm	3.2 cm	
3	5.8 ~ 10.9 cm	4.3 cm	
4	7.1 ~ 13.1 cm	5.1 cm	

- Make sure that the cuff edge falls within the range of mark <->. If it does not, use a larger or smaller cuff that fits better.
- 3.** Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart. If this is not possible you should apply the following corrections to the measured values:

- If the cuff is placed higher than the heart level, add 0.75 mmHg (0.10 kPa) for each inch of difference.
 - If it is placed lower than the heart level, deduct 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 boot-strap interface information area).
 5. Press  button on the front panel, and start a measurement.

4.3 Operation Hints

1. To start auto measuring:

Access ABPM SETUP menu and pick the “Asleep Interval” item and “Awake Interval” item, in which the user may select the time interval value for auto measurement. After that, enter “ABPM” menu and select the entrance, enter into ABPM working environment, and the system is automatically inflated measurement in accordance with the setting 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 blood pressure 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

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and measuring time increases. The user should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

- **Patient Movement**

Measurements will be unreliable or cannot 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 cannot be made at a heart rate of less than 40 bpm and greater than 240 bpm.

- **Round Patient**

The thick fat layer of body will reduce the measurement accuracy, because the fat that come from the shock of arteries cannot access the cuffs due to the damping.

4.4 NIBP Error Message and Explanations

Explanation	Cause
Self-test failure	A/D sampling error
Loose cuff	Cuff is not connected correctly
Air leakage	Air leakage in the valve or airway
Atmospheric pressure error	Valve cannot be open.
Signal is too weak	Object measuring the pulse is too weak or the cuff is loose
It is over the range	Object measuring blood pressure is over the measurement range
Excessive movement	When measuring, signal the presence of excessive movement or pseudo-differential interference
Overpressure	Cuff pressure is over the scope, ADU 300 mmHg, Newborn: 150mmHg
Saturated signal	Movement or other factors lead to too big signal amplitude
Air leakage	There is air leakage in the airway
System failure	There is something wrong with NIBP module, A/D sampling or soft of system after turning on the device
It spends too much time	Adult: When cuff pressure is 2KPa (15mmHg,) it may spend 3 minute (180S) Newborn: When cuff pressure is 0.67KPa (5mmHg,) it may spend 90S

4.5 Maintenance and Cleaning



Warning

- Do not squeeze the rubber tube on the cuff.
- Do not allow liquid to enter the connector socket at the front of the equipment.
- Do not wipe the inner part of the connector socket when cleaning the equipment.

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 this method. The cuff should not be dry-cleaned.

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

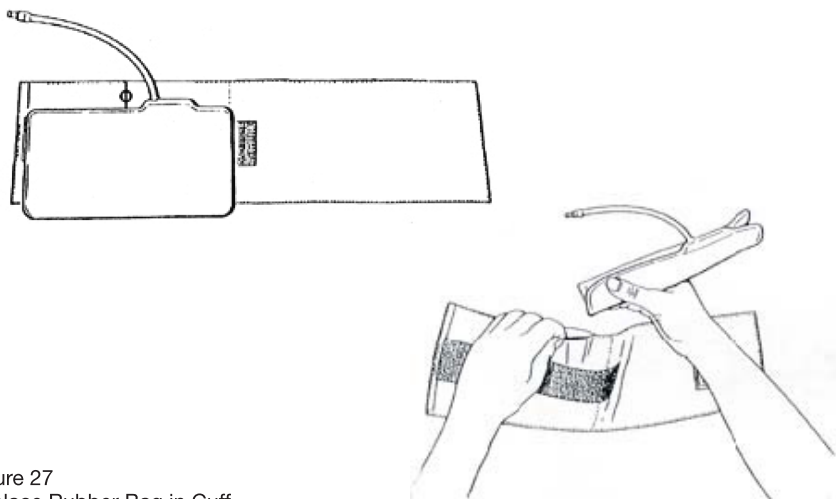


Figure 27
Replace Rubber Bag in Cuff

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.

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.

4.6 Transportation and Storage

- A.** The packed device can be transported by ordinary conveyance or according to transport contract. The device cannot be transported mixed with toxic, harmful, corrosive material.
- B.** The packed device should be stored in room with no corrosive gases and good ventilation. Temperature: $-20^{\circ}\text{C}\sim 55^{\circ}\text{C}$; Humidity: $\leq 95\%$.

4.7 Key And Symbols

Simbolo	Descrizione
	Warning – See User Manual
SYS	Systolic pressure
MAP	MAP pressure
DIA	Diastolic pressure
PR	Pulse rate (bpm)
ADU	Adult
PED	Pediatric
NEO	Neonatal
ABPM	Ambulatory Blood Pressure Monitor
INFO	Information
	Open the alarm sound indication
	Close the alarm sound indication
	WEEE (2002/96/EC)
	Type BF defibrillator proofed applied parts
SN	Serial number
IPX0	Ingress of liquids rank
 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community
	European Representative

Chapter 5

INSTALLATION OF THE SOFTWARE

5.1 Demand of editor

Processor: Pentium IV 1.8G or more

Operation System: Windows XP

EMS memory: 256M and more

Hard Disk: 40G or more

Display: 17 inch or more

CD-ROM

USB: 2 or more

Resolution of printer: 600 DPI

5.2 Installation of software

- 1 Place the CD-ROM in the CD-ROM compartment located on your computer.
- 2 If Auto Play for CDs is enabled, place CD in reader and follow instructions when they appear in the screen; otherwise follow install instructions below:
 - a. Open Windows Explorer.
 - b. Click on the root CD-ROM directory.
 - c. Double click file Setup.exe.
 - d. Follow the instructions in the screen.

Chapter 6

INTRODUCTION TO THE SOFTWARE

6.1 Main interface

Double click software by left key of the mouse to enter the main operation interface as follows:

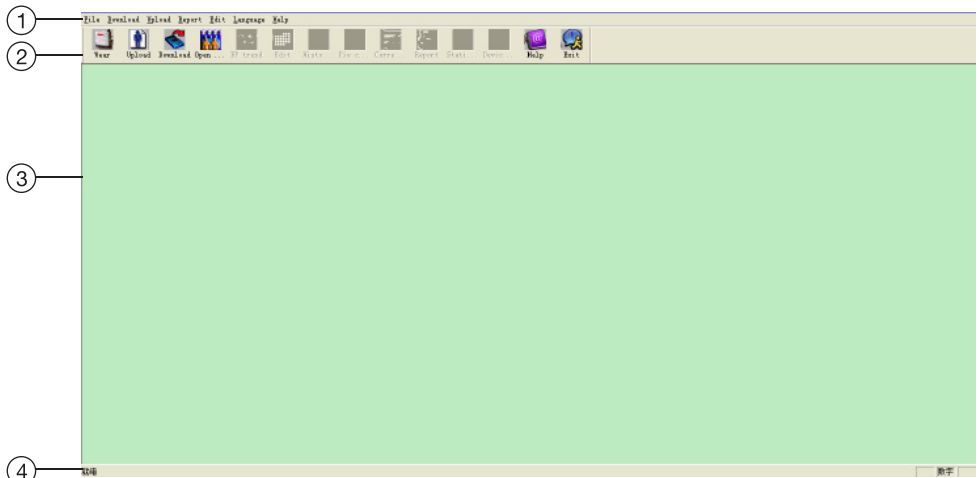


Figure 28
Main operating interface

- 1 **Menu bar:** main operation menu of the software
- 2 **Toolbar:** shortcut operation button of frequent function
- 3 **The middle area is trend graph display area:** After choosing the case that would be edited, display the data trend graph
- 4 **Status bar:** after choosing the case that would be edited, display patient name, ID and data collection date.

6.2 Wear

Click shortcut key  , and the “Lead PlaceMent” dialog box will appear..

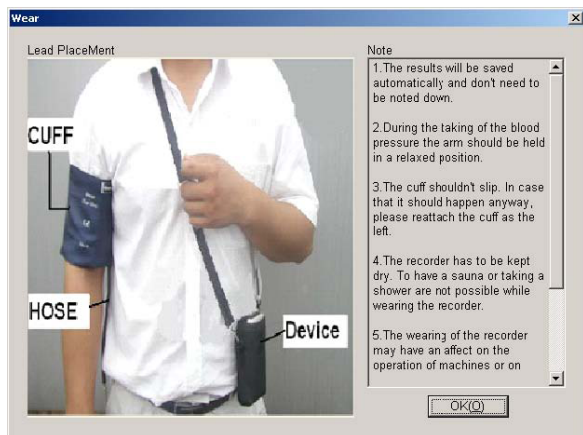


Figure 29
Wear

You can wear the device accroding to the picture above. Please read the “Matters need” before use.

6.3 Set File Path

Downloaded case data will be recorded in the case path.If you want to change the case path, you can click menu item “Set file path”. After the setting dialog box appears, you can change the case path. Display as follows:

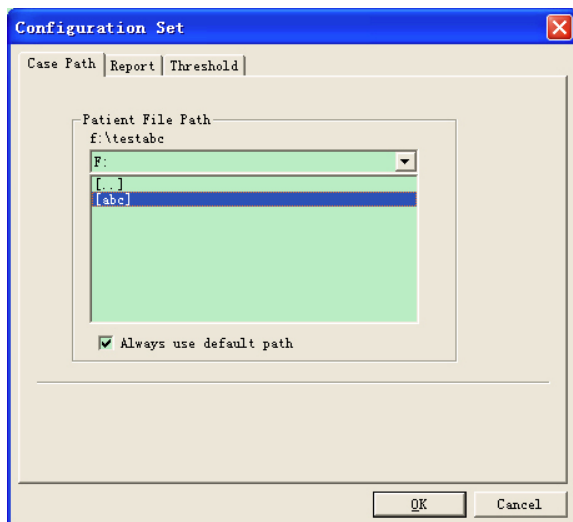
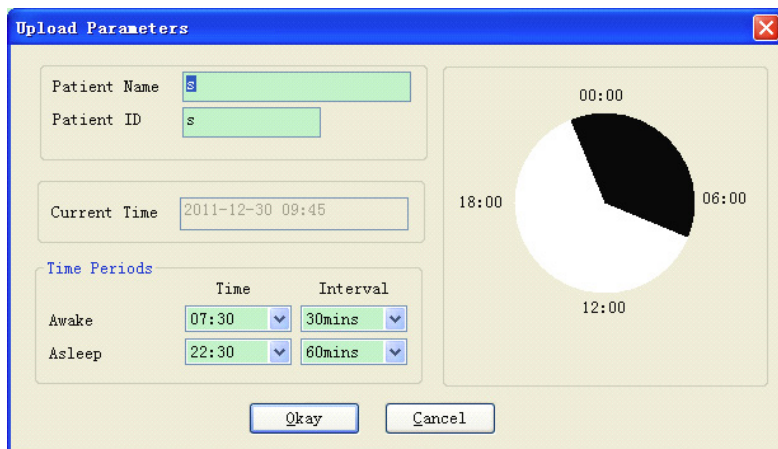


Figure 30
Set file path

Patient file path: choose patient file path. After downloading data from the monitor, the case file is saved in this path.
If you choose “ Always use default path “ item, the default case file path is program installation file path.

6.4 Set Collection Project

Click shortcut key  , or click menu bar **Upload** item, and the “ Upload parameters “ dialog box will appear:



	Time	Interval
Awake	07:30	30mins
Asleep	22:30	60mins

Figure 31
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-tomorrow 7:30. 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.

The user could select connection way: USB or WIRELESS(the device without WIRELESS connection way).When uploading, the choice dialog box will appear to prompt patient to select connection way.If you pitch on “do not show this next time”, this dialog box will not appear when uploading or downloading, and upload according to the connection way the use has chosen.



Figure 32
Set Connection Way

If the user uses WIRELESS to upload, the dialog box as follows will appear. Click “Scan” to begin to search.Select device, then click “connect” to download.

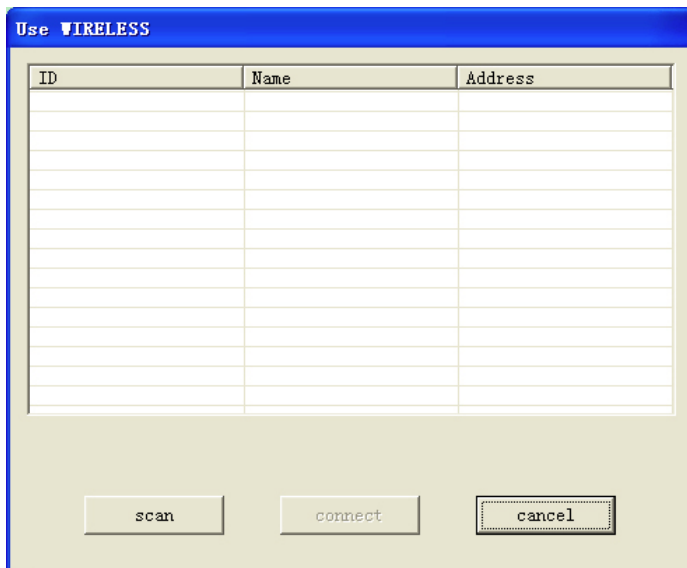


Figure 33
Scan Vicinal WIRELESS
Equipment

Uploading schedule is as follows:



Figure 34
Uploading Schedule

6.5 Download Data

Before downloading data, please insure:

1. The monitor is connected with computer accurately.
2. The monitor is on.
3. Ensure that the monitor isn't connect with patient when the monitor is connected with computer.



Click shortcut key **download** or menu item “Download”, then select connection way. After right connecting, begin to download data.

The schedule display is as follows:

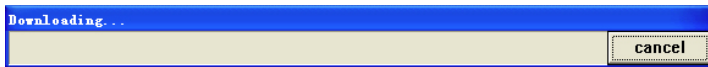


Figure 35
Downloading Schedule

After finishing downloading, prompt dialog box will appear, and the case data will be saved in the case file path.

6.6 Select the Case to be Edited

Before editing case, first choose the case to be edited. Click shortcut key or menu item “open data” to enter “Select file to open” interface. Display as follows:

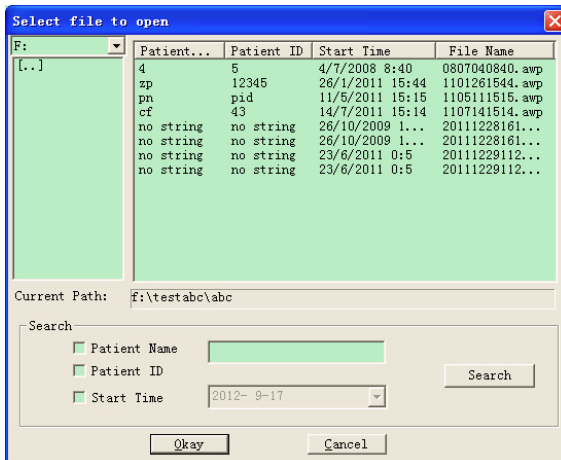


Figure 36
Select Case

In this interface, you can choose the file to save case. If the file has case, the file information will be displayed with list form, including these information: Patient Name, Patient ID, Start Time and File Name. Select the case file to be edited, and click “ Okay “ or double click to open the case file and edit it.

6.7 Delete Case

If you are sure that some cases don’t be needed, you can delete then. Click menu item “Delete data”, and deleting case interface will appear which is similar to the “Select file to open” interface. Display as follows:

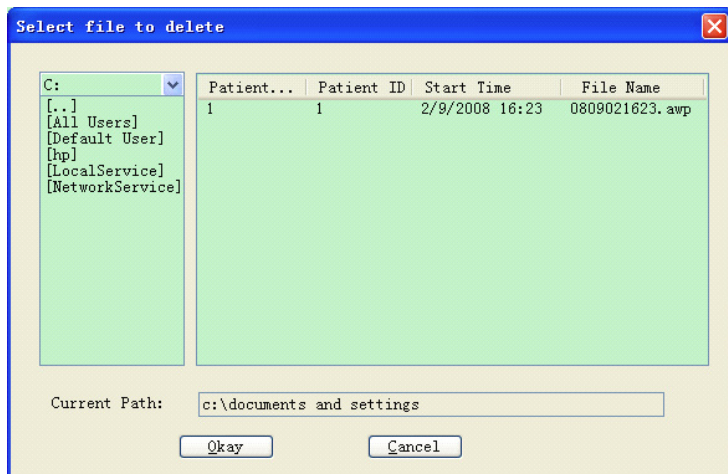


Figure 37
Select File to Delete

You can delete individual file, also can delete multifile. If you want to delete multifile, press “Ctrl” key, at the same time click the file to be delete. After selecting, click “Okay”, and prompt dialog box will appear. Click “Yes” to finish deleting operation, and click “ No” to cancel deleting operation.

6.8 Copy Case

Sometimes before you edit case, you may want to save a copy of originality data. Here you need to copy the case. Our software supplies this function. Choose menu item “Copy data”, and the interface will appear as follows:

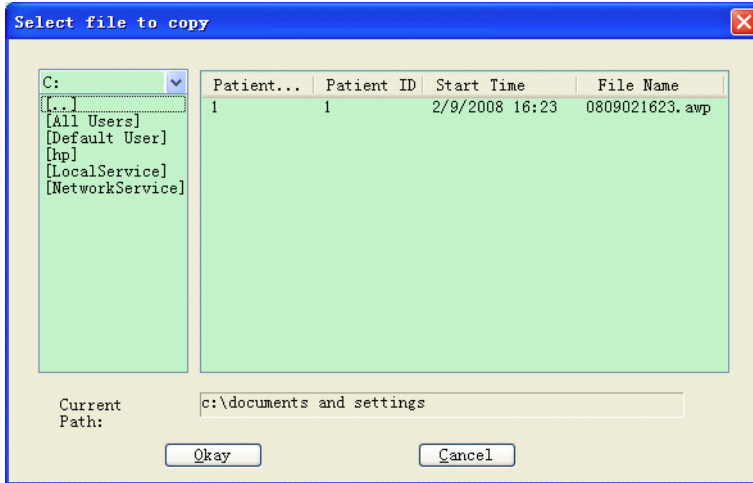


Figure 38
Select File to Copy

The copying case method is similar to the deleting file method. You can select multifile at the same time. After selecting the file, click “Okay”, and “Select destination directory” will appear. You can set destination director path. After setting path, click “Okay” to finish operation. Display as follows:

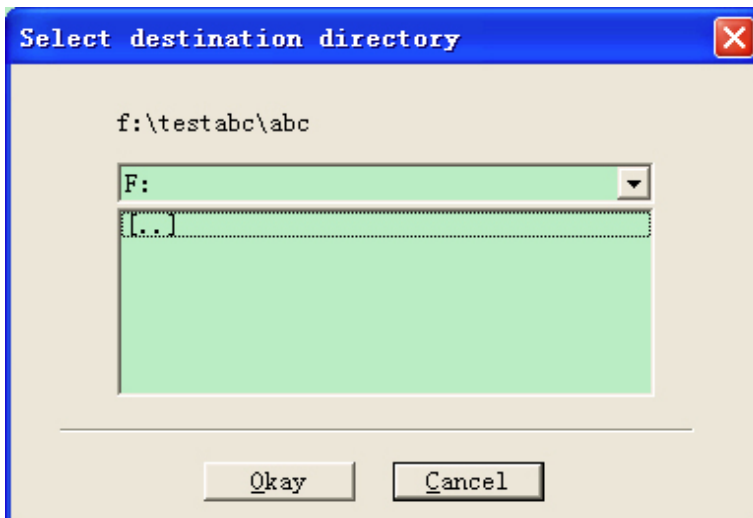
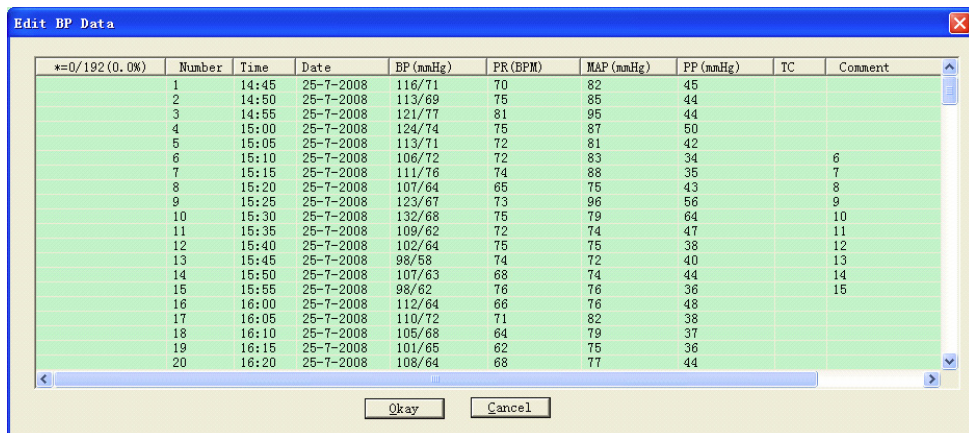


Figure 39
Set Destination
Director Path

6.9 Edit BP Data

You can edit every piece of data. Click shortcut key  or select menu item “Edit” to display “BP Data” interface as follows:



*=0/192(0.0%)	Number	Time	Date	BP (mmHg)	PR (BPM)	MAP (mmHg)	PP (mmHg)	TC	Comment
	1	14:45	25-7-2008	116/71	70	82	45		
	2	14:50	25-7-2008	113/69	75	85	44		
	3	14:55	25-7-2008	121/77	81	95	44		
	4	15:00	25-7-2008	124/74	75	87	50		
	5	15:05	25-7-2008	113/71	72	81	42		
	6	15:10	25-7-2008	106/72	72	83	34		6
	7	15:15	25-7-2008	111/76	74	88	35		7
	8	15:20	25-7-2008	107/64	65	75	43		8
	9	15:25	25-7-2008	123/67	73	96	56		9
	10	15:30	25-7-2008	132/68	75	79	64		10
	11	15:35	25-7-2008	109/62	72	74	47		11
	12	15:40	25-7-2008	102/64	75	75	38		12
	13	15:45	25-7-2008	98/58	74	72	40		13
	14	15:50	25-7-2008	107/63	68	74	44		14
	15	15:55	25-7-2008	98/62	76	76	36		15
	16	16:00	25-7-2008	112/64	66	76	48		
	17	16:05	25-7-2008	110/72	71	82	38		
	18	16:10	25-7-2008	105/68	64	79	37		
	19	16:15	25-7-2008	101/65	62	75	36		
	20	16:20	25-7-2008	108/64	68	77	44		

Figure 40
Editing BP Date Interface

In the interface, you can see the particular information of every data.

*=0/192(0.0%):192 is total number of data, 0 is the number of deleted data, 0.0% is the percent of deleted data.

Number: data collection serial number

Time: collection time

Date: collection data

BP(mmHg): the number in front of “/” is high pressure value, and the number in back of “/” is low pressure value. The unit is mmHg.

PR(BPM): pulse rate value. The unit is BPM.

MAP(mmHg): Mean pressure. The unit is BPM

PP(mmHg): Pressure difference between high and low blood pressure.

The unit is BPM

TC: error code (refer to chapter 7)

Comment: comment for the data.

You can also edit the data. The sign “*” stands for the deleted data (the trend graph doesn’t display this data, and statistic data doesn’t include this data).

You can delete or add “*” sign by click left key of mouse in “*” area.

In comment area, double click any item to edit data and add comment.

The comment will be displayed

in the trend graph and saved in current case file.

6.10 Edit Trend Graph

After selecting case file, the BP trend graph will be shown in the screen

automatically. In other interfaces you can click shortcut key  to enter the BP trend interface. The “BP Trend” has two graph types: color filler type, dotted line type. You can switch from one graph type to another by push the “Graph Type” button.

As color filler type trend graph shown, the blue line is PR change curve, and the green area is the data area below threshold, and the red area is the data area above threshold.

The display effect of color filler type trend graph is as follows:

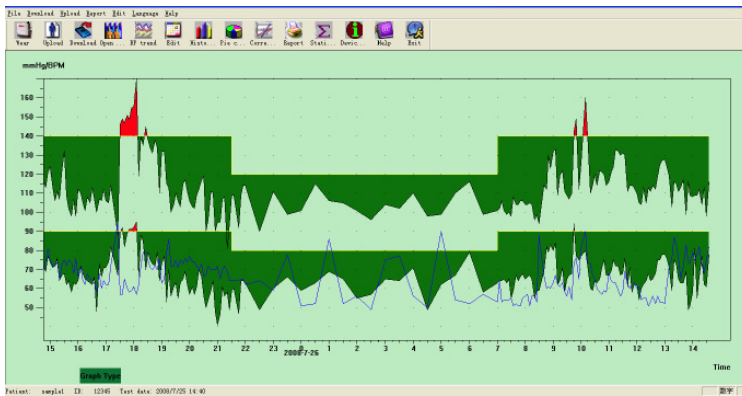


Figure 41
Color Filler Type
BP Trend Graph

As dotted line type trend graph shown, the blue line is PR change curve, and the yellow line is the high-low pressure threshold line, and the gray uprightness line is high-low pressure linked line of BP data for one time. The dotted line type trend graph is as follows:

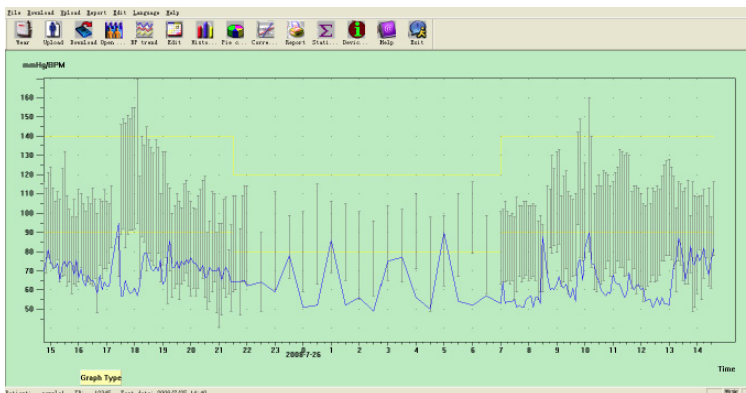


Figure 42
Dotted Line Type
BP Trend Graph

You can switch from one graph type to another by the “Graph Type” button. When you move the mouse on the trend graph area, on the top of the screen the detail data information about the mouse points will be shown, including the data serial number, collection time and collection date, high/low blood pressure value, pulse rate, comment, etc. Click left button of the mouse to delete or add the data point to be shown.

If the distance between the two data points is too short to move the mouse to one of the points, move the mouse to the time axis area, press left button of the mouse down, dragging the mouse rightwards to stretch the BP trend graph. Of course you can also drag the mouse leftwards to shrink the trend graph. When you stretch the trend graph, if the trend graph length is beyond the trend graph, the display area will appear a horizontal scroll bar, you can see any part of the trend graph by changing position of the scroll bar. Move the mouse to the y-axis area, press left button of the mouse down, dragging the mouse upwards to stretch the trend graph. Of course you can also drag the mouse downwards to shrink the trend graph.

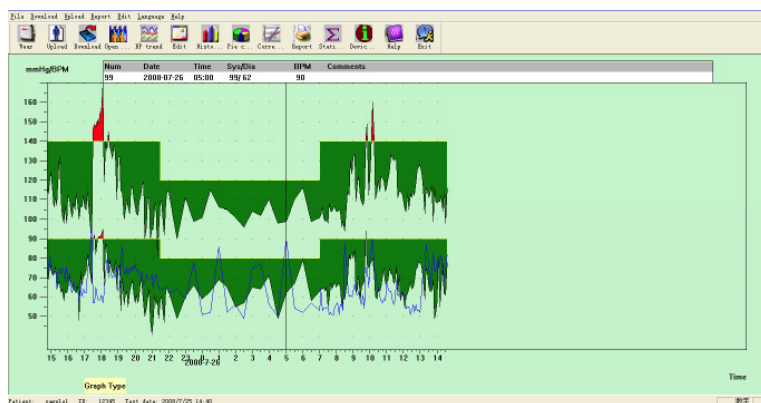


Figure 43
Shrink Trend
Graph(Time Axis)



Figure 44
Stretch Trend Graph
(Time Axis)

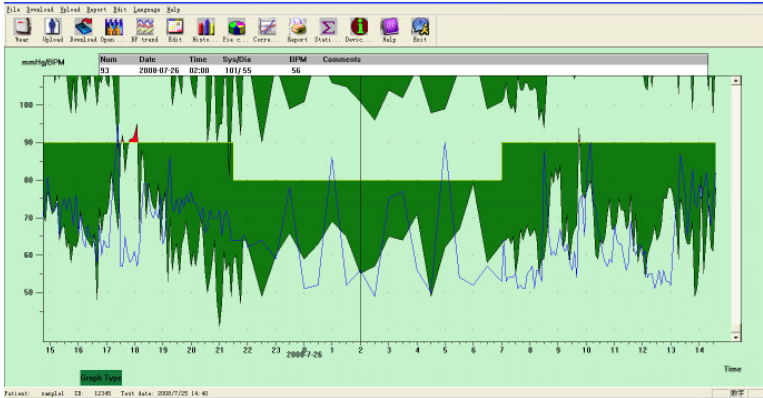


Figure 45
Stretch Trend
Graph (Y-Axis)

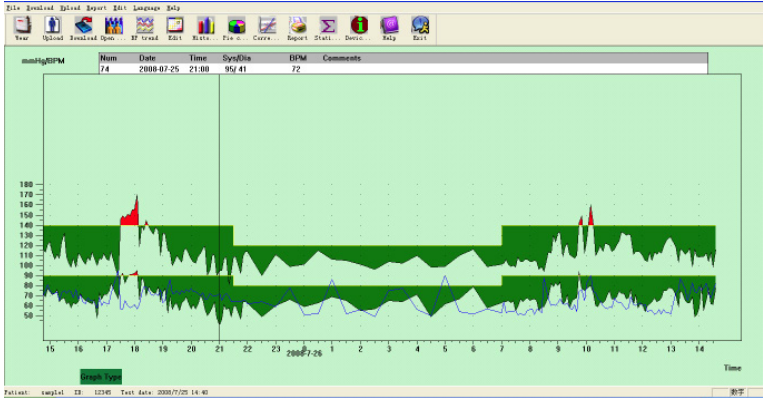


Figure 6.10.6
Shrink Trend
Graph (Y-Axis)

6.11 Edit of Diagnose Information.

Diagnose information includes following items: Patient information, Current Medications, Diagnose Information and Physician information. Select “Patient information”, and display as follows:

Patient info set

☐ Patient Info
 ☐ Current Medications
 ☐ Diagnose Information
 ☐ Physician Info

Patient ID	12345	Age	24
Patient Name	sample1	Sex	Woman
Address		Height (cm)	160
		Weight (kg)	45
Outpatient No.		Race	
Admission No.		Birthday	1987- 9-28
Bed No.		Telephone	1234567890
Department No.		Email	

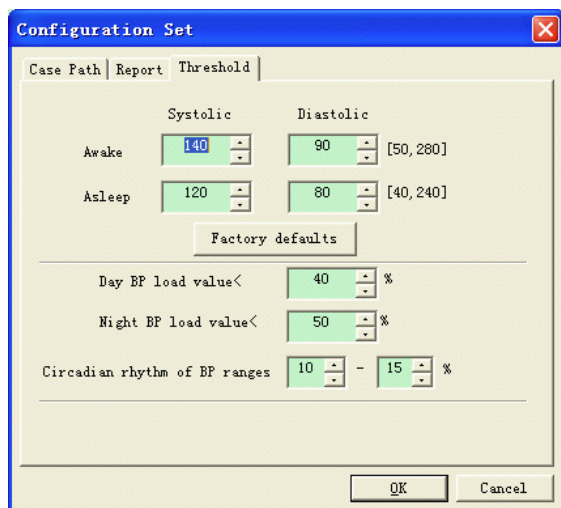
Figure 46
Edit Patient's Information

Click “OK”, and the patient information content will be saved in the case file in order to expediently display next time. At the same time all the information will be displayed in the report.

6.12 Set BP Thresholds

After BP Thresholds being set up, the trend graph will renew automatically, statistic data will be recalculated.

From the view select “Edit” and select “Thresholds”, then the following dialog box will appear.



The dialog box titled "Configuration Set" has three tabs: "Case Path", "Report", and "Threshold". The "Threshold" tab is active. It contains two columns: "Systolic" and "Diastolic". Under "Systolic", there are two rows: "Awake" with a value of 140 and "Asleep" with a value of 120. Under "Diastolic", there are two rows: "Awake" with a value of 90 and "Asleep" with a value of 80. To the right of each row is a range in brackets: [50, 280] for Awake Diastolic and [40, 240] for Asleep Diastolic. Below these is a "Factory defaults" button. Further down, there are three rows for load values: "Day BP load value" set to 40%, "Night BP load value" set to 50%, and "Circadian rhythm of BP ranges" set to 10% - 15%. At the bottom are "OK" and "Cancel" buttons.

	Systolic	Diastolic	Range
Awake	140	90	[50, 280]
Asleep	120	80	[40, 240]

Factory defaults

Day BP load value < 40 %

Night BP load value < 50 %

Circadian rhythm of BP ranges 10 - 15 %

OK Cancel

Figure 47
Set BP Thresholds

The default recommended thresholds for calculating Blood Pressure Load are 140/90 for awake periods (07:00-22:00) and 120/80 for asleep periods (22:00-07:00). These are the defaults used when you select the Factory Defaults button.

“Day BP load value” and “Night BP load value” is important guide line which is used for knowing ponderance about heart blood vessel effect. BP load heightening is important danger factor of end-point event about heart, brain and kidney.

“Circadian rhythm of BP ranges” is a ration guide line which judge circadian rhythm state, and is important factor that the doctor knows syndrome about heart, brain and kidney circadian rhythm state for the patient whose BP circadian rhythm has disappeared. Generally speaking, “≥10%” means that the circadian rhythm is normal, and “<10%” means that the circadian rhythm is weakened or disappeared.

Setting normal value range helps to distinctly comparing of analysis data. The analytical data displays in the report.

6.13 Histogram



Click shortcut key **Histo...**, and the following interface will appear.

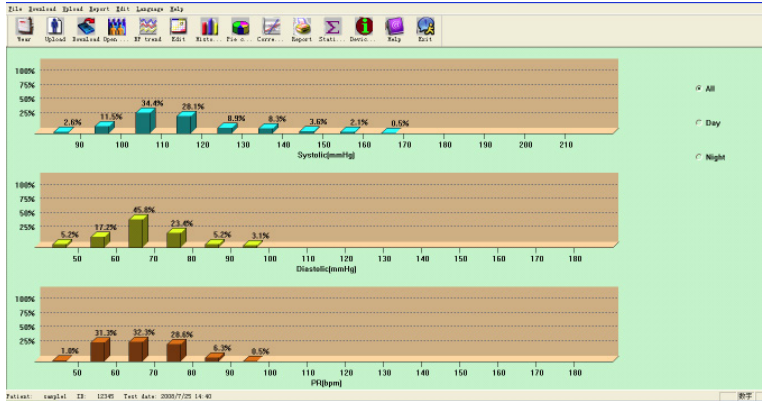


Figure 48
Histogram

All: Show all BP data statistics.
Day: Show only daytime statistics.
Night: Show only nighttime statistics.

6.14 Pie Chart



Click shortcut key **Pie C...**, and the following interface will appear.

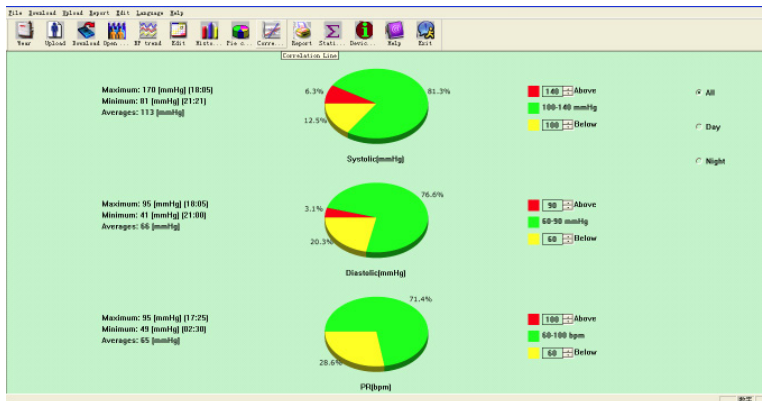


Figure 49
Pie Chart

The interface is divided into four areas. The most left area is maximum, minimum, and average value. The second area is pie chart. The third area

is the setting area for pie colour and corresponding value, and the BP value and be set by manual method and real-time displays. The forth area has three options including: All, Day and Night.

All: Show all BP data statistics.

Day: Show only daytime statistics.

Night: Show only nighttime statistics.

6.15 Set Print Report

After editing previous BP data, diagnosis information and so on, the software will create a series of analysis reports. You can select all pages or some of them for printing.

From the view select “Edit” and select “Configure Report”, then the following dialog box will appear.

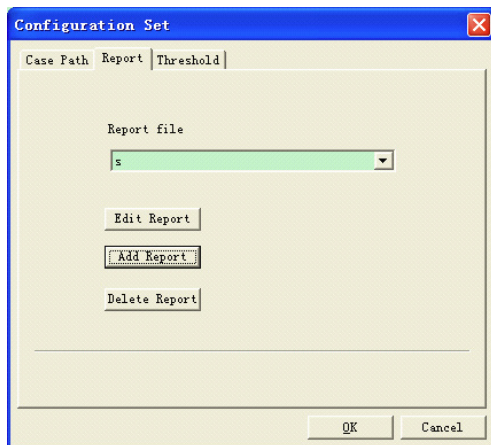


Figure 50
Report Configuration

You can click “Add Report” to add a new report. If you don’t need some report, you can click “Delete Report” to delete it. You can select an already exist report cyclostyle for printing. You may also click “Edit Report” to edit the selected report. You must select one report page at least.

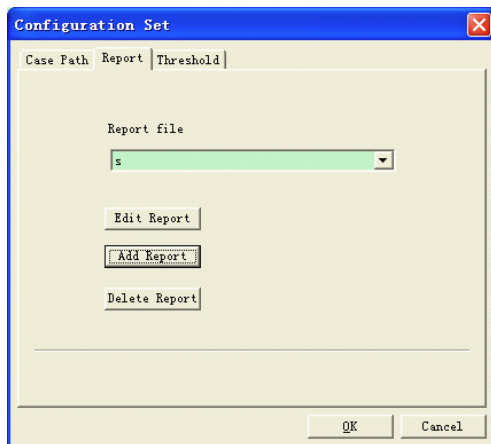


Figure 51
Edit Report

Demographics: include patient information, current medications, examining result summary and physician diagnosis information.

Statistics Page: particular data statistic information.

BP Summary Page: include BP benchmark value, BP load value, average value and diagnosis value.

Colorized Graph Page: display the colorized graph of BP data.

Bar Graph Page: display the bar graph of BP data

Histograms Page: display the histograms graph of BP data (Selected data in the histograms interface: All, Day, Night)

Pie Chart Page: display the pie chart of BP data (Selected data in the pie chart interface: All, Day, Night)

Frequency Histograms Page: display the histograms graph of high/low BP data for day and night.

Correlation Page: display correlation of SYS and DIA

PR/MAP/PP Histograms Page: display histograms graph of PR/MAP/PP data.

Measure Data Page: display all BP, PP, PR, comment and so on.

6.16 Print Report Preview



When you are sure that you want to print the report, click shortcut key or from menu select “Report”, then print preview page will appear.

Click  button or from menu select “Print” to print.

In print preview interface, click   button, or press “Ctrl” button glide mouse idler wheel for zoom.

In Demographics page, double click the black frame of “Current Medications” and “Comments&Diagnoses” information to edit content, and the edited content could be saved in the case file.

Examining result includes maximum, minimum, average value, BP threshold, BP load value and natural load value range (the range can be set in the benchmark value setting dialog box), circadian rhythm of BP ranges (the range can be set in the benchmark value setting dialog box), BP CV and so on.

BP CV commonly adopt BP SD (standard deviation)/average value to gain. The BP CV for All, Day and Night expresses BP fluctuant degree.

Patient Information			
Patient ID:	12345	Age:	24
Patient Name:	sample1	Sex:	
Address:		Height:	160
		Weight:	45
Outpatient No.		Nationality:	
Admission No.		Birthday:	1987/9/28
Bed No.		Telephone:	1234567890
Department No.		Email:	

Current Medications

Examine Result

All BP Averages:	113.7/66.9mmHg	BP threshold	140/90mmHg
Day BP Averages:	114.9/67.5mmHg	BP threshold	120/90mmHg
Night BP Averages:	104.5/61.6mmHg		
Day BP Load Value:Normal<40%		Night BP Load Value:Normal<50%	
SYS(>140mmHg) 7.1%		SYS(>120mmHg) 0.0%	
DIA(>90mmHg) 3.5%		DIA(>80mmHg) 0.0%	
Maximum SYS 170mmHg	on 2008/7/25 18:05	Minimum SYA 81mmHg	on 2008/7/25 21:21
Maximum DIA 95mmHg	on 2008/7/25 18:00	Minimum DIA 41mmHg	on 2008/7/25 21:00
Circadian rhythm of BP :SYS Night Des. 9.0%		DIA Night Des. 8.7%	Normal:10%-15%
BP CV: All: SYS 12.8%	DIA 14.5%		
Day: SYS 13.0%	DIA 14.5%		
Night: SYS 7.0%	DIA 11.8%		

Figure 52
Demographics Page Preview

In measure Data Page, if the time is night, the background is gray, and if the Sys or Dia is beyond threshold, the background is red.

Measured Data									
Num	Date	Time	Sys	Map	Dia	PP	PR	State	Comment
89	2008/7/26	(00:00)	101	71	59	42	51	3	
90	2008/7/26	(00:30)	115	77	63	52	52	3	
91	2008/7/26	(01:00)	106	79	69	37	86	3	
92	2008/7/26	(01:30)	105	78	65	40	52	3	
93	2008/7/26	(02:00)	101	68	55	46	56	3	
94	2008/7/26	(02:30)	96	69	57	39	49	3	
95	2008/7/26	(03:00)	104	78	65	39	75	3	
96	2008/7/26	(03:30)	102	76	64	38	77	3	
97	2008/7/26	(04:00)	110	82	71	39	56	3	
98	2008/7/26	(04:30)	98	61	49	49	50	3	
99	2008/7/26	(05:00)	99	74	62	37	90	3	
100	2008/7/26	(05:30)	110	78	67	43	54	3	
101	2008/7/26	(06:00)	116	92	79	37	52	3	
102	2008/7/26	(06:30)	99	70	58	41	57	3	
103	2008/7/26	(07:00)	101	75	63	38	53	3	
104	2008/7/26	(07:05)	102	73	64	38	64	3	

Figure 53
Measure Data Page Preview

<u>Measured Data</u>									
Num	Date	Time	Sys	Map	Dia	PP	PR	State	Comment
133	2008/7/26	(09:35)	107	80	67	40	61	3	
134	2008/7/26	(09:40)	110	80	68	42	54	3	
135	2008/7/26	(09:45)	142	106	94	48	74	3	
136	2008/7/26	(09:50)	149	120	77	72	76	3	
137	2008/7/26	(09:56)	112	90	75	37	65	3	
138	2008/7/26	(10:01)	126	93	77	49	82	3	
139	2008/7/26	(10:10)	160	100	80	80	90	3	
140	2008/7/26	(10:15)	140	95	72	68	74	3	
141	2008/7/26	(10:20)	110	76	60	50	73	3	
142	2008/7/26	(10:25)	114	77	59	55	67	3	
143	2008/7/26	(10:30)	120	75	64	56	65	3	
144	2008/7/26	(10:35)	114	78	63	51	60	3	

Figure 54
Measure Data Page Preview

6.17 Help



Click shortcut key to pop-up help file. It is the brief explanation for program function.

6.18 Exit



Click shortcut key to save configuration information and exit application.

Chapter 7

TROUBLESHOOTING GUIDE

Cod	Description on in Report Editor	Solution
1	No signal	Check position of cuff, tighten cuff
2	Overreach movement	Remain still during BP reading
4	Measurement timeout	Check air hose connections and make certain cuff is tight
85	Airway obstructed	Check air hose connections and make certain air tubing is not crimped
86	Measurement cancelled	Push START/STOP button to start reading
87	Cuff leak	Check air hose and cuff
88	Safety pause	Retry reading, push START/STOP button. If problem persists return monitor for servicing
89	Cuff overpressure	Check for blocked or kinked air hose
90	Battery low	Replace batteries. If problem persists return for servicing
105	Self-check failed	Return for servicing
110	Out of range	Retry again, if problem persists return for servicing
115	System error	Return for servicing

SPECIFICATION

Name	Ambulatory Blood Pressure Monitor		
Display	2.4" color LCD Display		
NIBP Specifications			
Measurement Method	Oscillometric method		
Working modes	Automatic		
Measurement Range	Pressure	adult pediatric neonatal	0~290mmHg(0~38.6kPa) 0~235mmHg(0~31.3kPa) 0~140mmHg(0~18.6kPa)
	Pulse: 40~240/min		
Inflation	adult	160mmHg	
	pediatric	120mmHg	
	neonatal	70mmHg	
Alarm Range	adult mode	SYS ALM: 40~270 mmHg DIA ALM: 10~215 mmHg	
	pediatric mode	SYS ALM: 40~200 mmHg DIA ALM: 10~150 mmHg	
	neonatal mode	SYS ALM: 40~135 mmHg DIA ALM: 10~100 mmHg	
Overpressure protect	adult mode	295±5mmHg	
	pediatric mode	240±5mmHg	
	neonatal mode	145±5mmHg	
Resolution			
Pressure	1mmHg		
Pulse Rate	±2 bpm or ±2% (select larger)		
Measurement Accuracy			
Cuff Pressure Accuracy	±3mmHg		
Error	The BP Value of the device is equivalence with the measurement value of Stethoscopy. The error meets all the conditions in the ANSI/AAMI SP-10:2002+A1:2003 +A2:2006.		
Operating Temperature/ Humidity	+5°C~+40°C	15%RH~80%RH	
Transport and Storage Temperature/Humidity	-20°C~+55°C	≤95%RH	
Atmospheric pressure	80kPa~105kPa		
Battery	2 “AA” alkaline batteries		
Accessories	Standard Configure: Adult Cuff: limb circumference 25-35cm (middle of upper arm) Software CD, User Manual, USB data line, BP extending tube, A pouch. Separate Sale: Pediatric Cuff: limb circumference 10-19cm (middle of upperarm) Neonatal Cuff: limb circumference 6-11cm (middle of upper arm)		

APPENDIX

Guidance and manufacturer's declaration – electromagnetic emissions for all EQUIPMENT and SYSTEMS

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	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The device is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such an environment.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.		
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



Disposal: *The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment. For further information on recycling points contact the local authorities, the local recycling center or the shop where the product was purchased. If the equipment is not disposed of correctly, fines or penalties may be applied in accordance with the national legislation and regulations.*

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product. This product meets high qualitative standards both as regards the material and the production. The warranty is valid for 12 months from the date of supply of GIMA. During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons. Labor costs and personnel traveling expenses and packaging not included. All components subject to wear are not included in the warranty. The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic device or software due to outside agents such as: voltage changes, electro-magnetic fields, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed. The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.