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Chapter1 Introduction

- For an overall introduction to the monitor, please refer to **General Information**.
- For basic operating instructions, please refer to **Button Function**.
- For allocation of interface sockets, please refer to **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 function safely and normally before use.

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 monitor performance.

Warning

The disposal of scrap instrument and its accessories and packings(including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

Warning

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

Warning

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

Warning

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

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 CustomerService immediately.

In addition,the overall check of monitor,including the safety check such as the leakage current,should be performed only 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.

 **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	-20~60 (°C)

Humidity

Working	≤ 80 %
Transport and Storage	≤ 95 %

Altitude

Working	-500 to 4,600m(-1,600 to 15,000ft)
Transport and Storage	-500 to 13,100m(-1,600 to 43,000ft)

Power Supply

3 (V)DC
Pmax = 2.56VA

General instruction:

The monitor not only measure the ambulatory blood pressure,but also monitor the parameters of NIBP and SpO₂ .But it is applicable for adult only. It integrates parameter measuring modules function and display function in one device, featuring in compactness, lightweight.

The POWER switch is on the front panel. The RUN indicator and the ALARM indicator flash one time when the device is powered on. The ALARM indicator flashes when alarm occurs. The sockets of the sensors are at the top. USB is at the bottom of monitor.

This monitor is a user-friendly device with operations conducted by a few buttons on the front panel. Refer to Button Functions for details.

Measuring the ambulatory blood pressure function:

In this mode, the monitor can work 24 hours continuously. The monitor has the capability of recording up to 4800 measurements, the stored readings in the monitor are downloaded into the computer to proceed the function including Editing the data, Editing the trend graph, statistic, displaying the information, Editing the diagnostic information, setting the parameters and printing and so on. However, this monitor can not transmit data real-time in the process of measuring.

Monitoring function:

NIBP

— From left to right, there are Systolic pressure, Mean pressure and Diastolic pressure (unit: mmHg or kPa)

SpO₂

— SpO₂ (unit: %)

— Pulse Rate (unit: beats/minute) (When "BOTH" item is selected)

 **Note** 

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

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

Refer to Software Functions for details.

1.2 Button Functions

All the operations to the monitor are through the buttons at the bottom of the panel. The names of the buttons are above them. They are:

-  **POWER**

Press the button and the system will start.

 **Note** 

When the battery is low, the alarm occurs.

-  **MENU**

Whatever levels of menu the system is in, press the button and The system immediately executes a certain function.

-  **UP**

Press the button to select the menu item and modify the setup.

-  **DOWN**

Press the button to select the menu item and modify the setup. In the main interface press this button less

than 1 second to enter alarm pause status . Press "DOWN" for 1 second to enter the silence status and a  symbol appears at main screen. When the system is in silence status, any newly generated alarm will discharge the silence status and make the system give normal alarm status. .

 **Note** 

Pulse tone will be heard in Silence status, If new alarm occurs in Alarm Silence status, the system will

discharge Silence status automatically, or the silence status will be discharged automatically 1 minute later .

●  **NIBP**

Press to inflate the cuff to start a blood pressure measurement. When measuring, press to cancel the measurement and deflate the cuff.

Method to use the button to operate in the screen:

The rectangular mark in the screen that moves with the UP button or DOWN button is called “cursor”. Operation can be performed at any position at which the cursor can stay. When the item is not to select, the cursor is white; when press MENU to select the item , the cursor become red.

1.3 Interfaces

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

At the top is the Socket for SpO₂ Sensor and socket for NIBP cuff(Figure 1--1①)

①the Socket for NIBP cuff

②the Socket for SpO₂ Sensor



Figure 1.1 top

At the bottom is the socket for USB, as shown in Figure 1-2.

①the Socket for USB

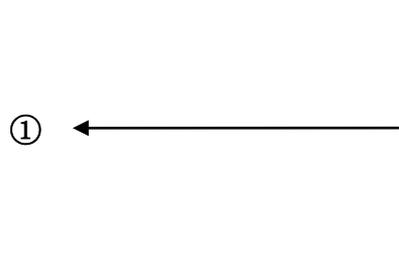


Figure 1-2 bottom

1.4 Accessories

- A a cuff for adult
- B a usb data line
- C a oximeter probe (Model: SpO₂-01-DR)
- D a disk (PC software)

E a pouch

F a user manual

 **Warning** 

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

Chapter 2 Getting Started

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

2.1 Open the Package and Check

Open the package and take out the monitor and accessories carefully. Keep the package 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 monitor will be supplied with two 'AA' alkaline batteries or high capacity. Before using the monitor you shall put the battery in the box of battery .

 **Note** 

When you don't use the monitor , you will take out the dry battery.

2.3 Power on the Monitor

Press **POWER** to power on the monitor. The indicator will flash, the system will enter monitoring screen of monitoring or ABPM, and you can perform normal monitoring now. Refer to System Menu for details.

 **Warning** 

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

 **Note** 

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

2.4 Connect Oximeter Probe

 **Note** 

For information on correct connection, refer to figure 2.4.1.



Figure 2.4.1

2.5 Connect NIBP Cuff

Connect NIBP extension conduit between the monitor and the patient.

⚠ Note ⚠

For information on correct connection, refer to figure 2.5.1.



Figure 2.5.1

Chapter3 Function Interface

- Main Interface
- System Menu

3.1 Main Interface

Press POWER to power on the monitor, The indicator will flash, the system will enter the main interface successfully.

ABPM : If there is no key-press operation within the time set in the BACKLIGHT TIME item, the monitor will enter standby mode. RUN indicator light flashes once every other 2 seconds, indicating the monitor is under working mode.

Monitoring Mode: BACKLIGHT TIME item setup is of no effect. The backlight is bright all the time.

The '04' will be displayed in the middle of the speaker and battery When the power is low.

The main interface is shown as the follow:

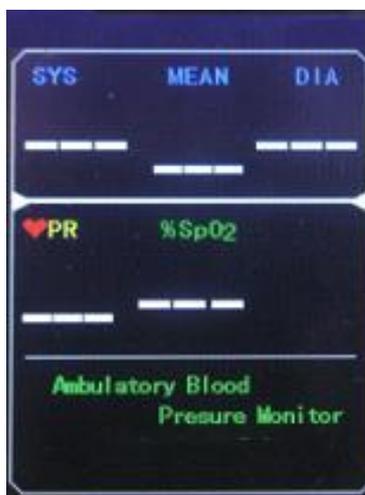


Figure 3.-1.1 ABPM main menu

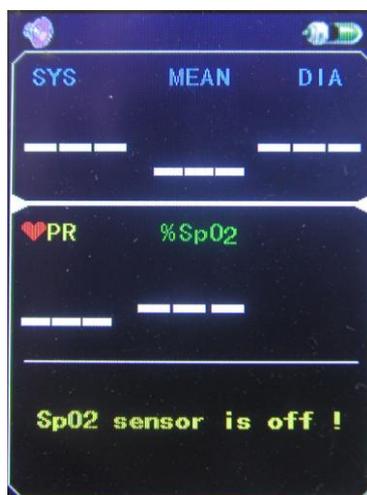


Figure 3.1.-2 MONITORING main menu

⚠ Note ⚠

When the register is full, ⚠ will be appeared at the top of screen. The note of the last value needs to be cleared.

3.2 System Menu

Press the MENU button on the panel to call up the [SYSTEM MENU]. You can perform option operations by using UP and DOWN buttons.



Figure 3.2 SYSTEM MENU

[PM BP SETUP], [PM SpO₂ SETUP] and [SpO₂ TABLE] are gray in the mode of ABPM. They can not be set up.

3.2.1 System Setup

Select the SYSTEM SETUP item in the [SYSTEM MENU]. The following menu will pop up.



Figure 3.2.1 SYSTEM SETUP

Users can set up the system time by selecting the [TIME] item.

If users select [YES] in the [DEFAULT] item, the Monitor will come back to factory default.

In the [LANGUAGE] item, users can select the words shown in Chinese or English in the screen.

If users select [ON] in the [ALARM] item, the loudspeaker turns on.  will be appeared in the main monitoring interface. On the other hand, when users select [OFF], the loudspeaker turns off,  will turns up.

In the [NEW PATIENT] item, if users select [OFF], the "Clear the last value?" dialog box will appear. Select [YES] again will delete the measure record of the last patient, then select [NO] back to the [SYSTEM SETUP MENU]. Else, selecting [NO] at first, the monitor will do nothing. Please pay attention to this function.

Users can select PM or ABPM in the [FUNCTION SELECT] item and correspond measures will be taken. In the [BACKLIGHT TIME] item, users can make it from 5 to 120 seconds with 5 seconds per step. Its funtion is to control the backlight time of the main interface in ABPM.

Under the ABPM, [DEFAULT], [ALARM] and [NEW PATIENT] can not be set up.

3.2.2 BP SETUP

Select [PM BP SETUP] in the ["SYSTEM MENU"]. The following menu will pop up.



Figure 3.2.2 BP SETUP

When users select [ON] in the [AUTO MEASURE] item, the Monitor will measure blood pressure according to the time selected in the [INTERVAL] item. When [OFF] is selected, manual measure is needed, simultaneously [INTERVAL] item turns gray and can not be set up.

The interval time (Unit: minute) setup in the [INTERVAL] item can be selected from the following options:
5, 10, 15, 20, 30, 45, 60, 90.

The alarm is on or off according to the high and low limits which have been set up. When the pressure higher than the high limit or lower than the low limit, the alarm will occur. [SYS ALM], [MEAN ALM] and [DIA ALM] can be processed separately.

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

- DIA ALM: 40~270 mmHg
- SYS ALM: 10~215 mmHg
- MEAN ALM: 20~235 mmHg

3.2.3 SpO₂ SETUP

Select [PM SpO₂ SETUP] in the "SYSTEM MENU". The following menu will pop up.



Figure 3.2.3 SpO₂ SETUP

For the [PULSE SOUND] item, you can choose its state. When it is "ON", pulse sound plays while the monitor measures the ambulatory blood pressure. When it is "OFF", pulse sound doesn't play while the monitor measures the ambulatory blood pressure.

For the [SpO₂ ALM HI/LO] item, you can set up [SpO₂ ALM HI] and [SpO₂ ALM LO]. Alarm occurs when SpO₂ value overflows.

For the [PR ALM HI/LO] item, you can set up [PR ALM HI] and [SpO₂ ALM LO]. Alarm occurs when PR value overflows.

SpO₂ and PR ALARM analysis alarm limits:

PARAMETERS	Max. HI	Min. LO	Step
SpO ₂	100	0	1
PR	254	0	1

3.2.
4

Patient Information

Pick the [ABPM INFO] item in the "SYSTEM MENU" to call up the following menu.

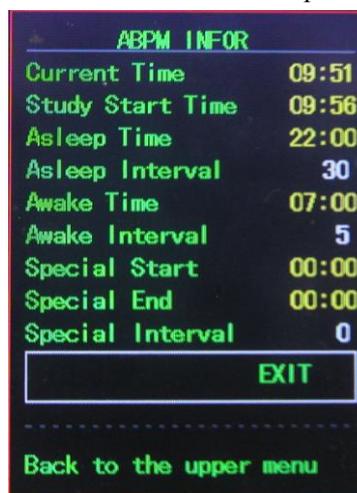


Figure 3.2.4 ABPM INFOR

The information in this interface can't be changed,until reinstall the parameter in software.

3.2.5 BP TABLE

Pick the [BP TABLE] item in the “SYSTEM MENU” to call up the following menu.

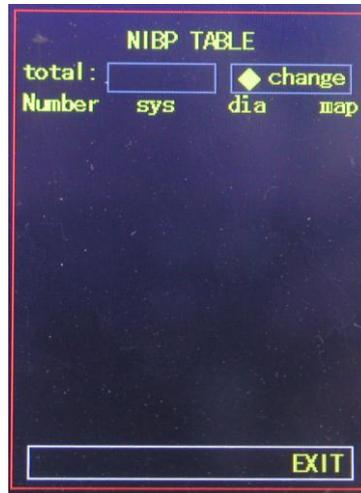


Figure 3.2.5.1 NIBP TABLE

[total]: the number is the total of all data have been measured from accessing this interface the first time.The sequence number of the current first line will be displayed when changing the data or turning over pages. Every page can contain 10 data at most.

Select the [change] item to enter the [Change The Number] menu:



Figure 3.2.5.2 CHANGE

When the number which you input is more than the total,it will prompt ">total". Blood preasuremeasure one time per 5 minutes,and the most number of times is 4896.

3.2.6 SpO₂ TABLE

Pick the [SpO₂ TABLE] item in the “SYSTEM MENU” to call up the following menu.

%SpO ₂ TABLE		
total :	30	change
Number	%SpO ₂	PR
30	98	81
29	98	81
28	98	81
27	98	80
26	98	81
25	98	81
24	98	81
23	98	81
22	98	81
21	98	85
		EXIT

Figure 3.2.6.1 SpO₂ TABLE

[total]: the number is the total of all data have been measured,while accessing this interface for the first time.The sequence number of the first line currently will be displayed,while changing the data or turning over page.Every page can contain 10 data at most.

Select the [change] item to enter the [Change The Number] menu:

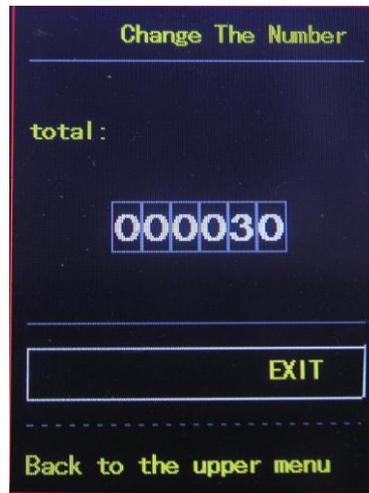


Figure 3.2.6.2 CHANGE

When the number which you input is more than the total,it will prompt ">total".The blood preasure is measured once per 1 s,and the most number of times is 183000.

3.2.7 DEMO function

Select the [DEMO] item to enter DEMO status.In the DEMO status, press the "MENU KEY",and system returns to the "MAIN MENU".

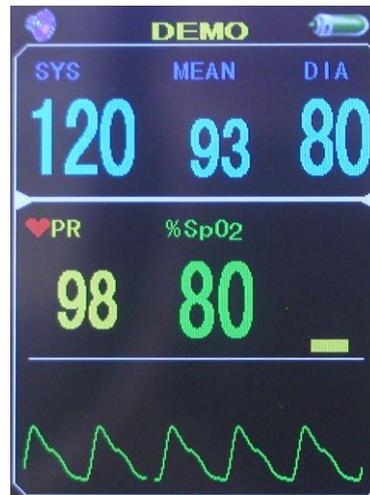


Figure 3.2.7 DEMO

⚠ Note ⚠

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

When it is ambulatory blood pressure state, [PM BP SETUP], [PM SpO₂ SETUP] and [SpO₂ TABLE] can't be changed in the "MAIN MENU".

Chapter 4 SpO₂ Monitoring

4.1 What is the SpO₂ Monitoring

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

How the SpO₂ / PLETH Parameter Works

- Arterial oxygen saturation is measured by a method called pulse oximeter. It is a continuous, non-invasive method based on the different absorption spectra of reduced hemoglobin and oxyhemoglobin. It measures how much light, sent from light sources on one side of the sensor, is transmitted through patient tissue (such as a finger or an ear), to a receiver on the other side.
The sensor measurement wavelengths are nominally 660nm for the Red LED and 940nm for Infrared LED. Maximum optical power output for LED is 4 mW.

- The amount of light transmitted depends on many factors, most of which are constant. However, one of these factors, the blood flow in the arteries, varies with time, because it is pulsating. By measuring the light absorption during a pulsation, it is possible to derive the oxygen saturation of the arterial blood. Detecting the pulsation gives a PLETH waveform and pulse rate signal.

- The SpO₂ value and the PLETH waveform can be displayed in the main screen.

 **Warning** 

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

 **Warning** 

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

 **Note** 

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

4.2 Precautions during SpO₂/Pulse Monitoring

 **Note** 

- Make sure the nail covers the light window;
- The wire should be on the backside of the hand.

 **Note** 

SpO₂ waveform is not proportional to the pulse volume.

⚠ Warning ⚠

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

⚠ Warning ⚠

Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin. Check per 2~3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.

4.3 Monitoring Procedure

SpO₂ plethysmogram measurement

1. Switch on the monitor.
2. Attach the sensor to the appropriate site of the patient finger.
3. Plug the connector of the sensor extension cable into the SpO₂ socket , please pay attention to the direction of the sensor.
4. Please pull out the sensor When measure is over.

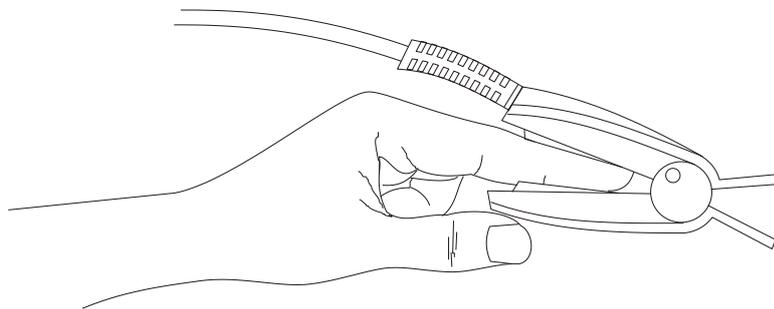


Figure 4.3 Mounting of the sensor

4.4 Maintenance and Cleaning

Care and Cleaning

⚠ Warning ⚠

Turn off the monitor before cleaning the monitor or the sensor

⚠ Warning ⚠

Do not subject the sensor to autoclaving.

Do not immerse the sensor into any liquid.

Do not use any sensor or cable that may be damaged or deteriorated.

Cleaning:

- Use a cotton ball or a soft mull moistened with hospital-grade ethanol to wipe the surface of the sensor, and then dry it with a cloth. This cleaning method can also be applied to the luminotron and receiving unit.
- The cable can be cleaned with 3% hydrogen dioxide, 70% isopropanol, or other active reagent. However, connector of the sensor shall not be subjected to such solution.

Chapter 5 NIBP Monitoring

5.1 Introduction

- The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method.
- There are two modes of measurement available: manual and automatic . Each mode displays the diastolic, systolic and mean blood pressure.
 - In the MANUAL mode, only one measurement is conducted for each time.
 - In the AUTO mode, the measurement is cycled; you can set the interval time to 5/10/15/20/30/45/60/90 minutes.

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

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.**

5.2 NIBP Monitoring

Warning

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 monitor 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 arm or leg following the instructions below (Figure 5.2).
 - 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.

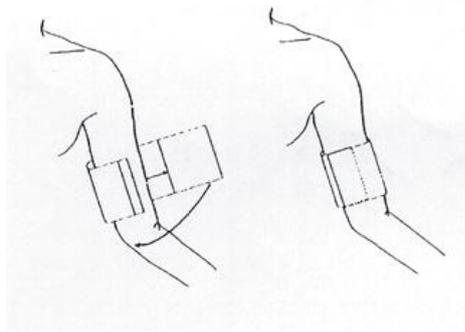


Figure 5-2 Applying Cuff

⚠ Note ⚠

Don't let the cuff contact with skin directly, but the thickness of clothes shouldn't be more than 3 cm.

⚠ Note ⚠

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
Adult	25 ~ 35 cm	14 cm	1.5 m or
Large Adult	33 ~ 47 cm	17 cm	3 m
Thigh	46 ~ 66 cm	21 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. Press the NIBP button on the front panel to start a measurement.

5.3 NIBP Message and Explanations

Message	Explanation	Cause
02	Self-test failure	Probe or A/D sampling error.
06	Loose cuff	Cuff is not connected correctly.
07	Air leakage	Air leakage in the valve or airway.
08	Atmospheric pressure error	Valve can not be open.
09	Signal is too weak	Object measuring the pulse is too weak or the cuff is

		loose.
10	It is over the range	Object measuring blood pressure is over the measurement range.
11	Excessive movement	When measuring, signal the presence of excessive movement or pseudo-differential interference.
12	Overpressure	Cuff pressure is over the scope ,ADU 290 mmHg
13	Saturated signal	Movement or other factors lead to too big signal amplitude.
14	Air leakage	There is air leakage in the airway
15	System failure	There is something wrong with NIBP module ,A/D sampling or soft of system after turning on the device.
19	It spends too much time	Measuring is over certain specified time .When pressure of adult cuff is 200mmHg,it may spend 120s.If not, it may spend 90s.

5.4 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 monitor.
- Do not wipe the inner part of the connector socket when cleaning the monitor.

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.

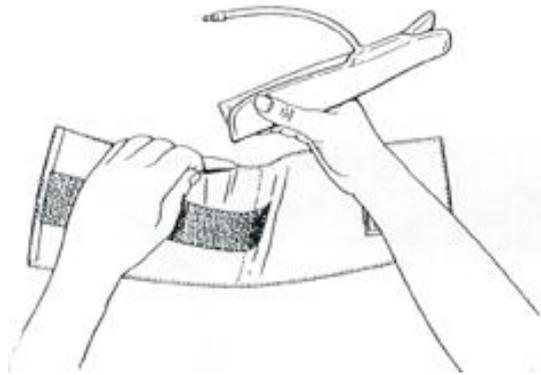


Figure 5.3 Replace Rubber Bag in Cuff

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.

5.5 Transportation and storage

A. The packed device can be transported by ordinary conveyance or according to transport contract. The device can not 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°C~60°C; Humidity: ≤95%

5.6 Key of Symbols

Signal	Description
	Warning – See User Manual
SYS	Systolic pressure
MEAN	MEAN pressure
DIA	Diastolic pressure

%SpO₂	The pulse oxygen saturation(%)
PR	Pulse rate (bpm)
	Close the sound
	Open the alarm sound indication
	Close the alarm sound indication
	Type BF
SN	Serial number
---	<ol style="list-style-type: none"> 1. the finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator
IPX1	Ingress of liquids rank

Chapter 6 Installation of the software

- Demand of editor
- Installation of software

6.1 Demand of editor

Processor: Pentium IV 1.8G or more

Operation System:XP

EMS memory: 256M and up

Hard Disk: 40G or more

Display: 17 inch or more

CD-ROM

Serial port

Resolution of printer: 600 DPI

6.2 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:

Open Windows Explorer.

Click on the root CD-ROM directory.

Double click file PM50_Patient_Monitor_V1.1_Setup.exe.

Follow the instructions in the screen.

Chapter 7 Introduction to the software

7.1 User register

Each time you open the software will appear the following dialog box for the user's name. Type in user's name. To change user go to "File" then click on "Change User". This feature is available to allow each user to store his or her own configurations, such as thresholds.



Figure 7.1.1 User Register

Click "Delete" button will delete the current selected user info and configuration. Click "Delete all" Button will delete all users info and their configurations.

If you are a new user, click "Okay" Button will appear the following dialog box.

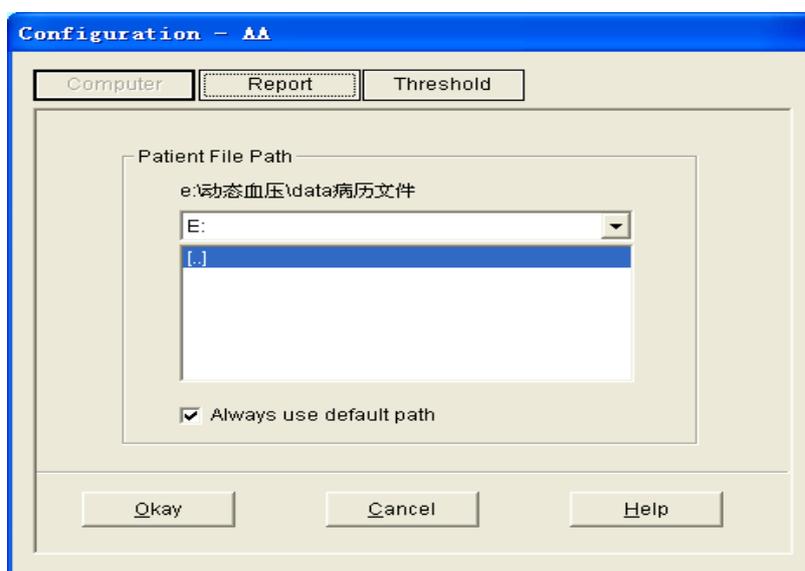


Figure 7.1.2 Set file path

"Patient File Path": Choose the downloading route of your case. As soon as the data are downloaded in computer, the case document will save this path.

If you check the "Always use default path" checkbox, then data searches will always begin at the default path. If the checkbox is not checked, then data searches will always begin at the last path used.

7.2 The main interface

When the settings of the user's configuration information are finished, the main interface is

entered, as the following pictured displayed:

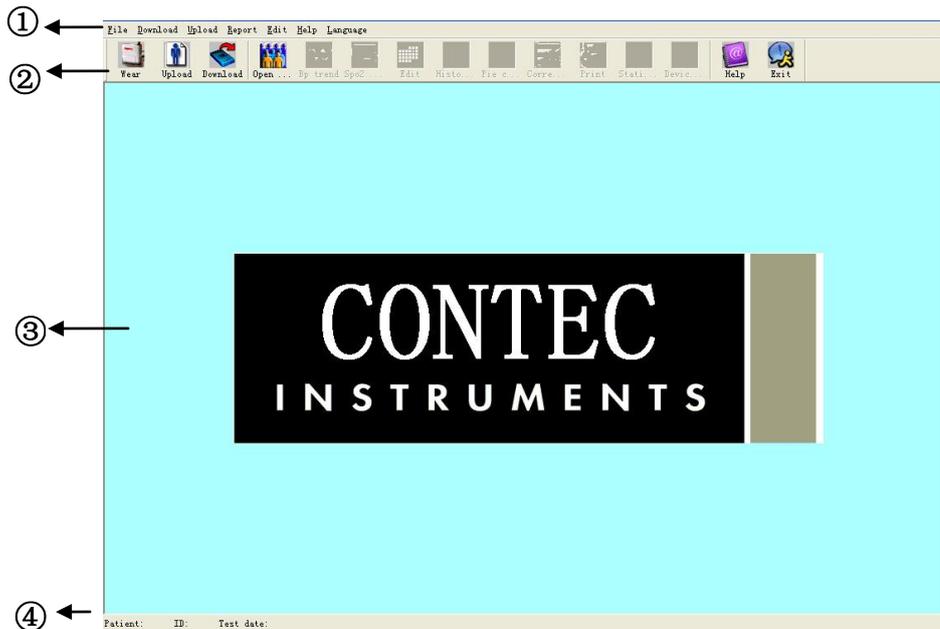


Figure 7.2 the main operating interface

1. Menu bar The main operating menu of this software
2. Toolbar Shortcut keys for functions of frequent use
3. Displaying areas of the trending pictures
After choosing the case which is edited, it is used for displaying date of the trending picture.
4. Status bar Display the name, ID, and the data collecting date of the patient.

7.3 Wear



Press the shortcut key , will pop up the following dialog box.

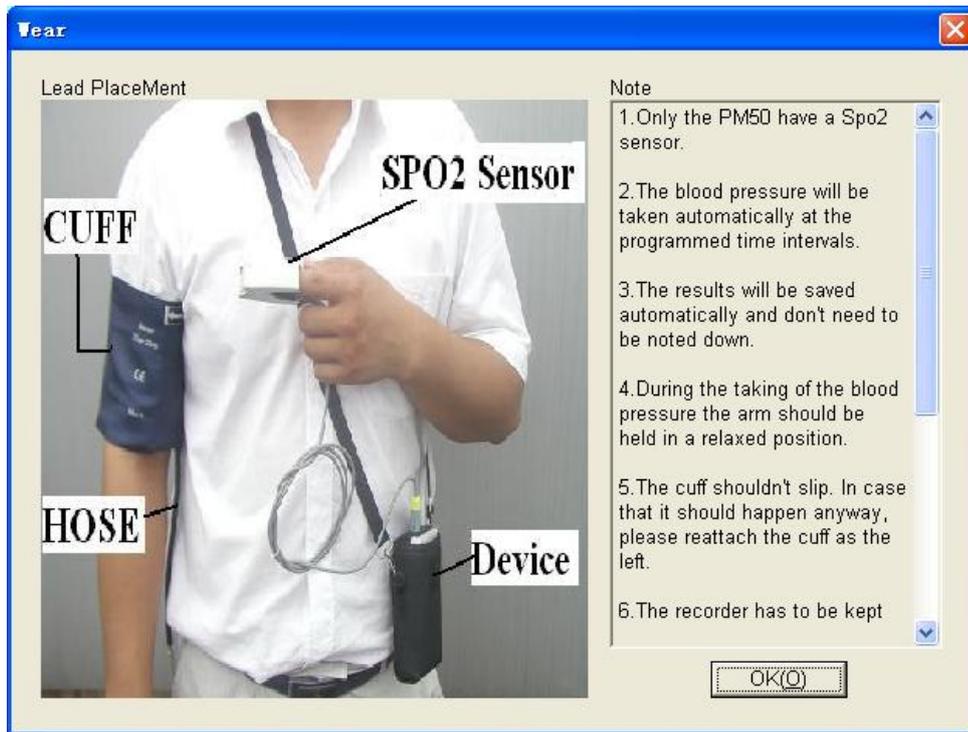


Figure 7.3 Wear

You can wear the device according to the picture above. Please read the "Note" Carefully before use.

7.4 Design the measurement plan

Note : Before you upload the test parameters to the device , make certain:

1. The device is connected to the computer via the serial port.
2. The device is turned on.

Steps:



Upload

1. Press the shortcut key **Upload** , or from the menu select "Upload" ,the following dialoga box will appear .



Figure 7.4.1 Select the status of the device

2. If the item you choosed is "ABPM" the following dialog box will appear.

Time Periods	Time	Interval
Awake	7:00	5 mins
Asleep	22:00	30 mins
Special Start	None	None
Special End	None	None

Figure 7.4.2 Upload test parameters

Patient Name, Patient ID : mark the patient.

Current Time: That is the time of beginning to collect the parameter.

Study Start Time: Collecting start time. It defaulted in the 5 minutes after setting the collecting parameter.

Start key : Whether supporting the manual collecting.

Time Periods:

Among that, Awake refers to the patient in the un-sleeping situation, and Asleep refers to the sleeping situation.

Special Start and **Special End** are optional items.

You can set the fixed time to collect the data. Interval setting refers to the intervals of the collecting time. To reduce the impact of the patient's sleep, settings of the general collecting intervals are longer.

Take the above picture as an example: the range of un-sleeping time is 7:00-22:00, the range of sleeping time is 22:00-7:00, the intervals of the un-sleeping time are 5 minutes, and the intervals of the sleeping time are 30 minutes.

The range of sleeping time, the range of un-sleeping time, the range special testing time are displayed by the picture forms in the right corner of the screen. Thus, it is convenient to design the parameter.

If the item you choosed is "Patient Monitor" the following dialog box will appear.

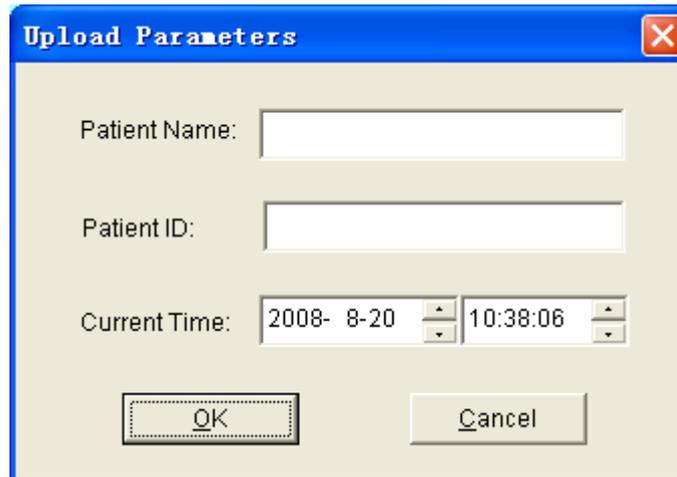


Figure 7.4.3 Upload test parameters

3. Select the "OK" button will appear the following dialog box show the progress as the data is transferred.



Figure 7.4.4 Uploading progress bar

7.5 Data download

Before you download the measurement data from device , make certain:

1. The device is connected to the computer via the serial port.
2. The device is turned on.
3. Disconnect the device from patient before you connecting it to any piece of hardware such as your personal computer (to avoid electric shock)

The downloaded patient data will be saved in your default computer path. If you want to change the storage path, from the menu select "Download" and the select "Set file path", and then the dialogue box(Figure 7.1.2) referred before will be showed up, operators can change the path.



Press the shortcut key **Download** , or from the menu select "Download" and then select "Do Download" will appear the following dialog box .Permitting you select what data you want to download(ABPM data or Patient Monitor data).

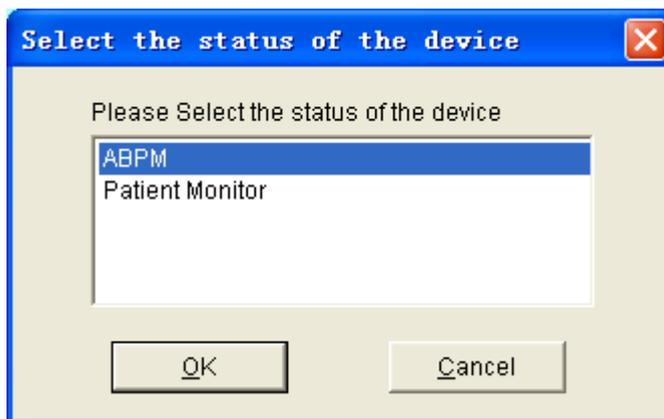


Figure 7.5.1 Select the status of the device

The following dialog box will appear to show the progress as the data is transferred.



Figure 7.5.2 Downloading progress bar

After completion, a dialog box will prompt for where the data file was saved.

7.6 Choose patient data to edit



Press shortcut key **O**pen . . . , or from the menu select "File" and select "Open data" the following dialog box will appear:

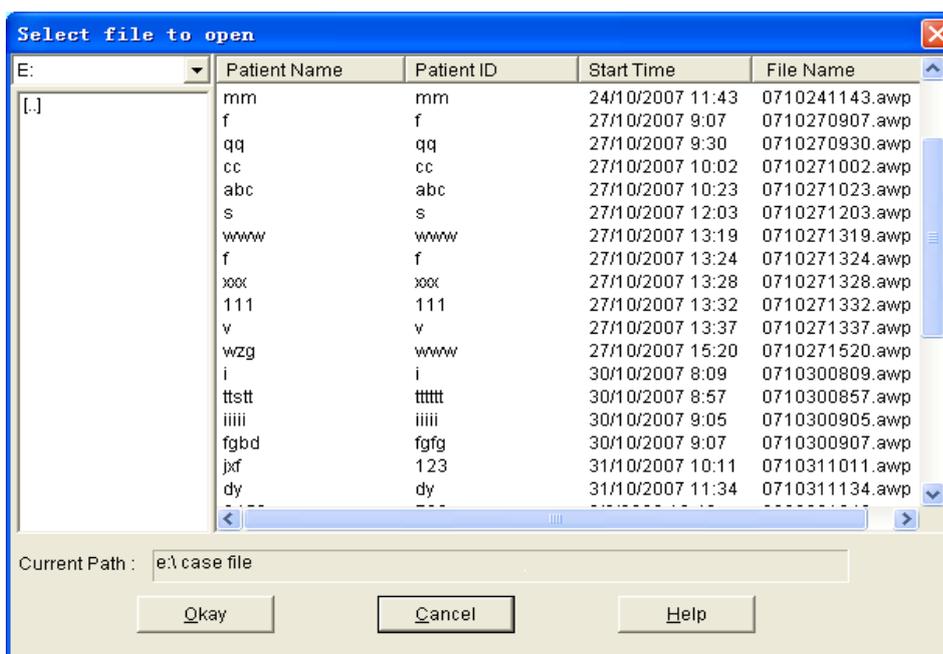


Figure 7.6 Patient file select

The above dialog box lists the data files found in your current directory. You may use the drive and directory boxes to select a different drive or directory to search for patient files. Select a data file by highlighting the patient's name, and then press the "Okay" button. You may now edit the data.

7.7 Delete data file

If you feel some patient data are not necessary, you can delete them. From menu select "File" and then select "Delete Data" to show patient data delete interface which is similar to patient data select interface, showed as below:

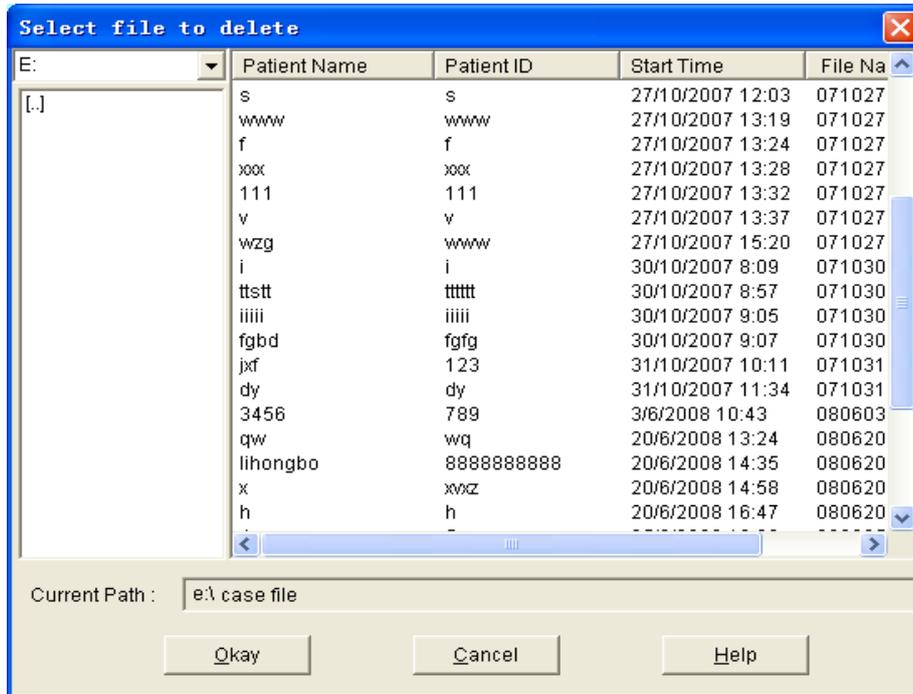


Figure7.7 Data file delete

You are able to delete one single file or some files at the same time, to delete some files at the same time; you could push "Ctrl", and click the file you want to delete at the same time. After selection, click "Okay" button, the "sure to delete" Dialog will appear. Click "YES" to complete the delete operation. If you want to cancel, please click "NO".

7.8 Data file backup

Sometimes, you may want to save one original copy before you edit a file, under this situation, you should do patient data backup.

From the menu select "File" and then select "Copy data", will appear the following dialog box, permitting you to select which data files to copy.

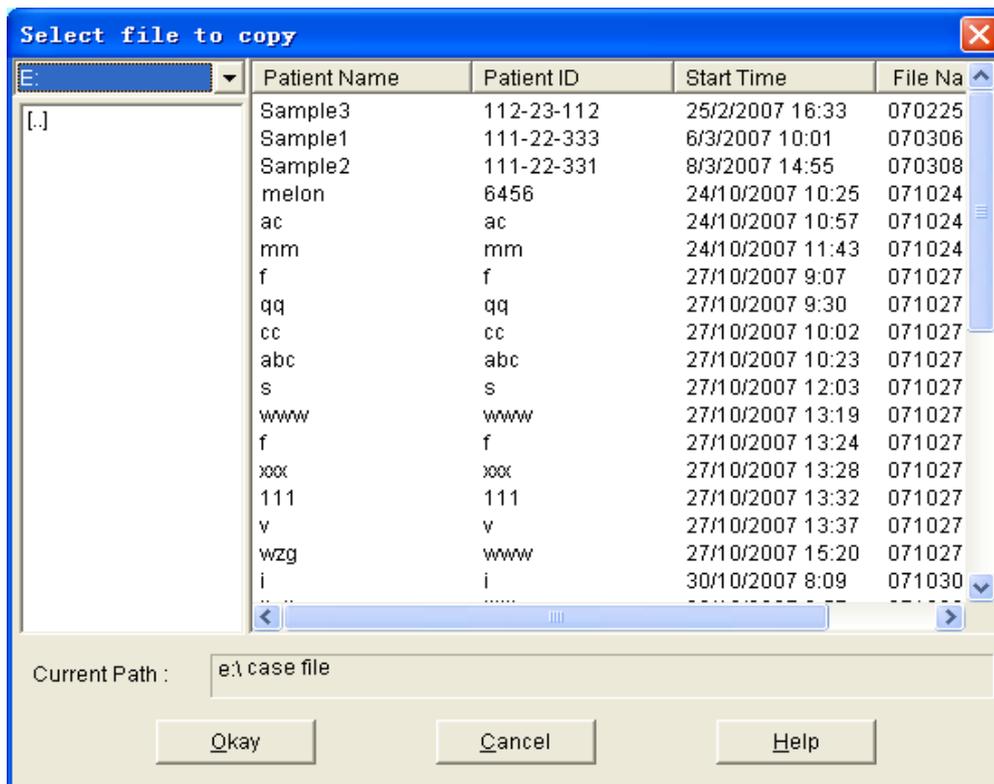


Figure7.8.1 Data file copy

Select or deselect items by clicking on the rows using the mouse. When all desired selections have been made , select "Okay".

The following dialog box will appear, permitting you to select the disk drive or directoy to copy to.

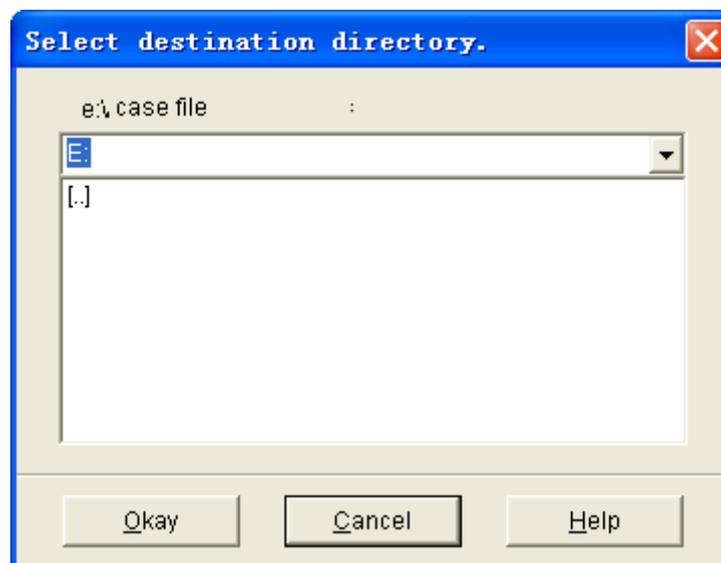


Figure 7.8.2 Backup path settings

Once you have selected the destination drive or directory , select "Okay". You may also select "Cancel" to end the dialog without copying patient data.

7.9 Edit Blood pressure data



Press the shortcut key **Edit**, or from the menu select "Edit" and then select "Bp Data" the following dialog box will pop up.

*=7/182(3.8%)	Number	Time	Date	BP(mmHg)	HR(BPM)	MAP(mmHg)	PP(mmHg)	TC	Comment
	1	16:38	25-2-2007	124/87	87	98	37		
	2	16:48	25-2-2007	120/84	81	96	36		
	3	16:58	25-2-2007	118/86	71	97	32		
	4	17:08	25-2-2007	117/84	75	96	33		
	5	17:18	25-2-2007	136/92	72	109	44		
*	6	17:28	25-2-2007	120/79	84	94	41		
	7	17:38	25-2-2007	124/81	95	94	43		
	8	17:48	25-2-2007	124/80	88	96	44		
	9	17:58	25-2-2007	128/71	81	100	57		
	10	18:08	25-2-2007	122/82	67	90	40		
	11	18:18	25-2-2007	119/75	68	87	44		
	12	18:28	25-2-2007	124/77	70	91	47		
	13	18:38	25-2-2007	121/83	68	95	38		
	14	18:48	25-2-2007	132/84	76	97	48		
	15	18:58	25-2-2007	124/83	81	95	41		
	16	19:08	25-2-2007	113/89	72	81	44		
	17	19:18	25-2-2007	115/72	72	84	43		
	18	19:28	25-2-2007	117/82	76	93	35		
	19	19:38	25-2-2007	131/94	96	106	37		
	20	19:48	25-2-2007	119/85	84	96	34		
	21	19:58	25-2-2007	120/84	76	96	36		
	22	20:05	25-2-2007	118/75	78	86	43		
		

Figure 7.9 Data edit page

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

*=6/60 (10.0%): 60 represents the total data sum, 6 represents the data amount deleted, 10.0% stands for data present deleted.

Number: stands for data collection serial number.

Time: stands for collection time.

Date: stands for collection date.

BP: number before "/" stands for high blood pressure, number back "/" stands for low blood pressure.

HR: Heart rate.

MAP: Mean pressure.

PP: Pressure difference between high and low blood pressure.

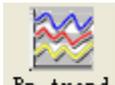
TC: error code(refer to chapter 9)

Comment: comment.

7.10 Trend Edit

BP Trend Edit

When you selected the data file, the BP trend will be shown in the screen automatically. In other



interfaces you can press shortcut key **Bp trend** 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.

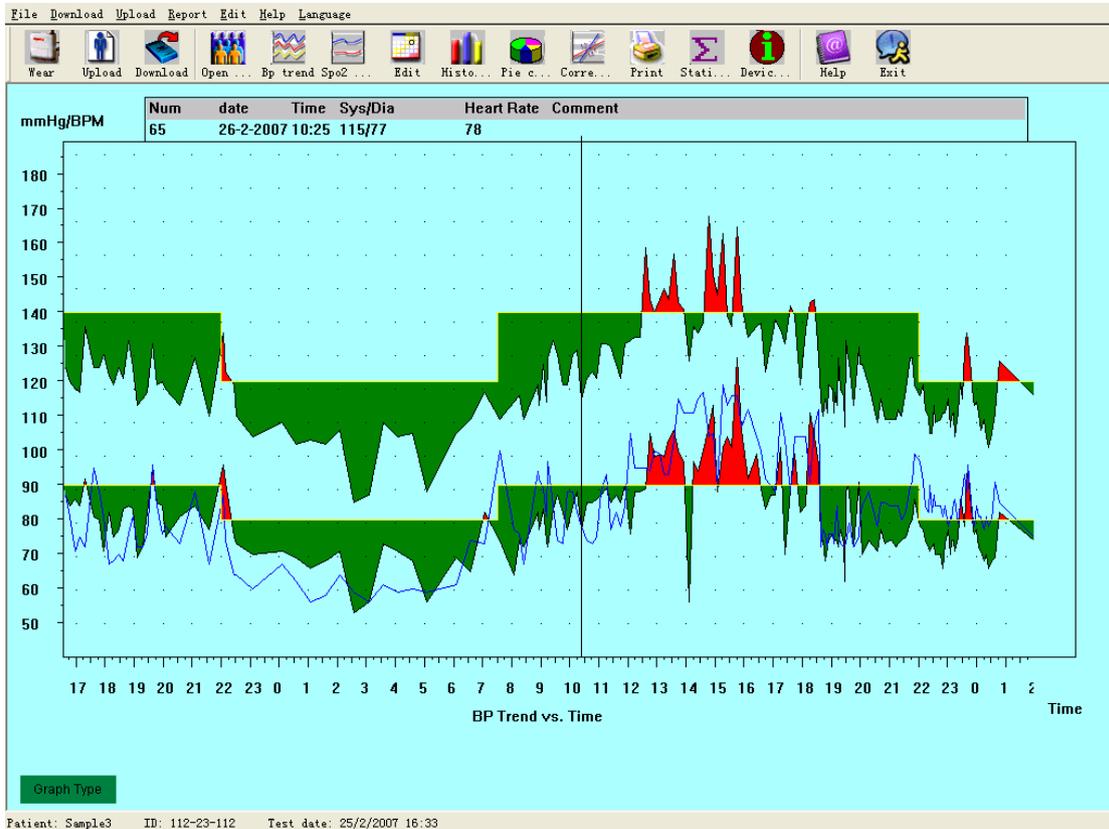


Figure 7.10.1 Color filler type BP trend

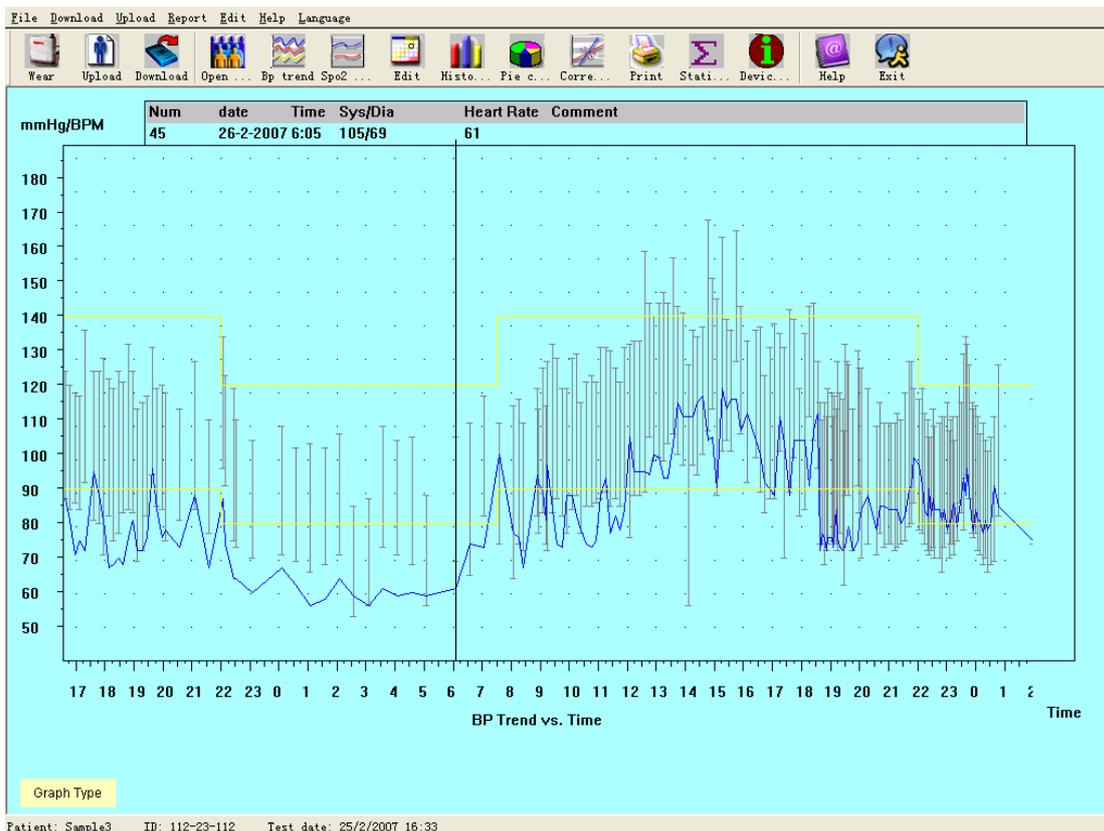


Figure 7.10.2 Dotted line type BP trend

When you move the mouse on the trend area, on the top of the trend area the detail data information about the mouse points will show, including the data serial number, collection time and collection date, high/low blood pressure value, heart rate, comment, etc. Press mouse' left button 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 the mouse' left button down, dragging the mouse to the right stretch the BP Trend. Of course you can also dragging the mouse to the left shrink the BP Trend. When you stretching the BP Trend, if the trend length beyond the trend show area will appear a horizontal scroll bar, you can see any part of the trend by changing the scroll bar's pos.

Move the mouse to the y-axis area, press the mouse' left button down, dragging the mouse to the top stretch the BP Trend. Of course you can also dragging the mouse to the bottom shrink the BP Trend.

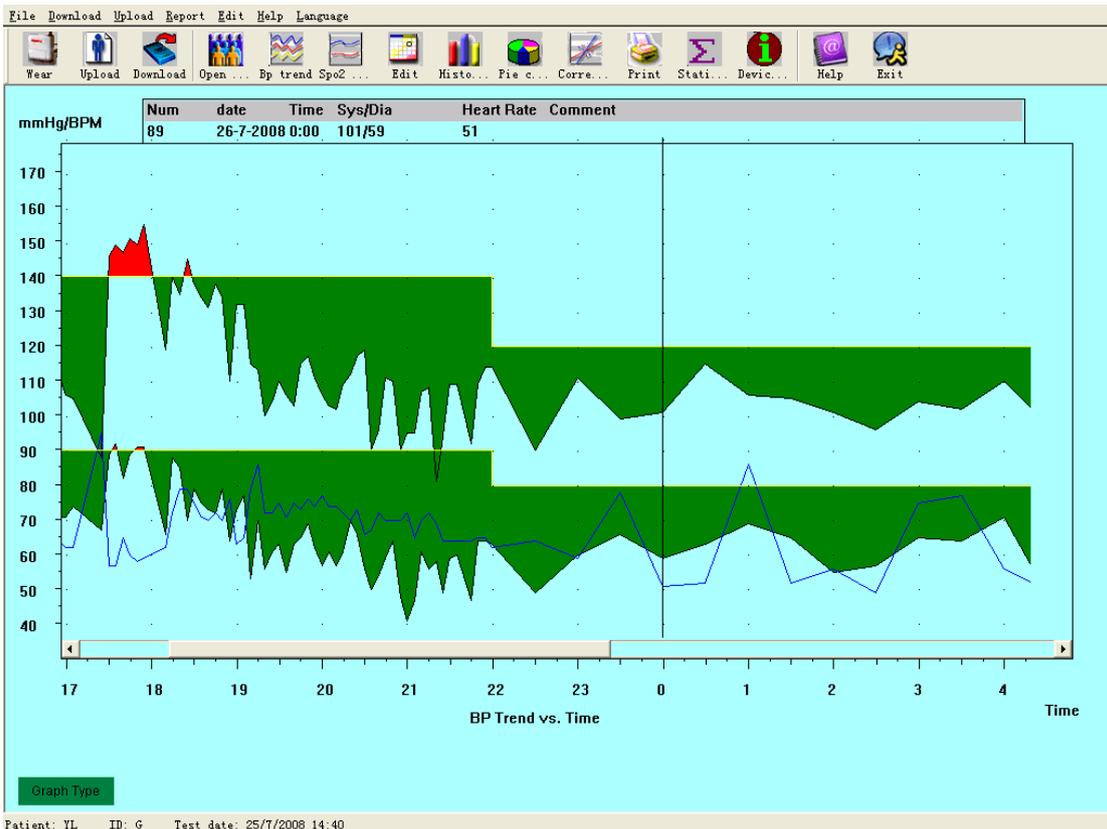


Figure7.10.3 Stretch BP Trend(time axis)

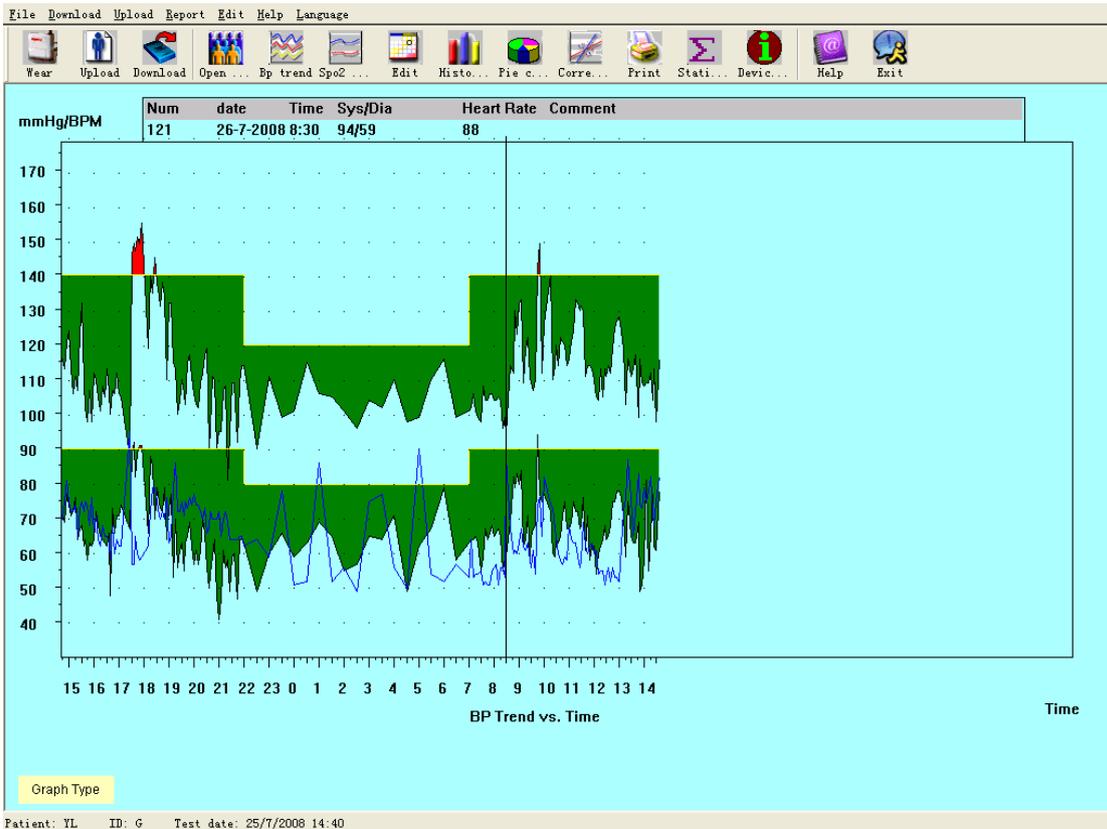


Figure7.10.4 Shrink BP Trend(time axis)

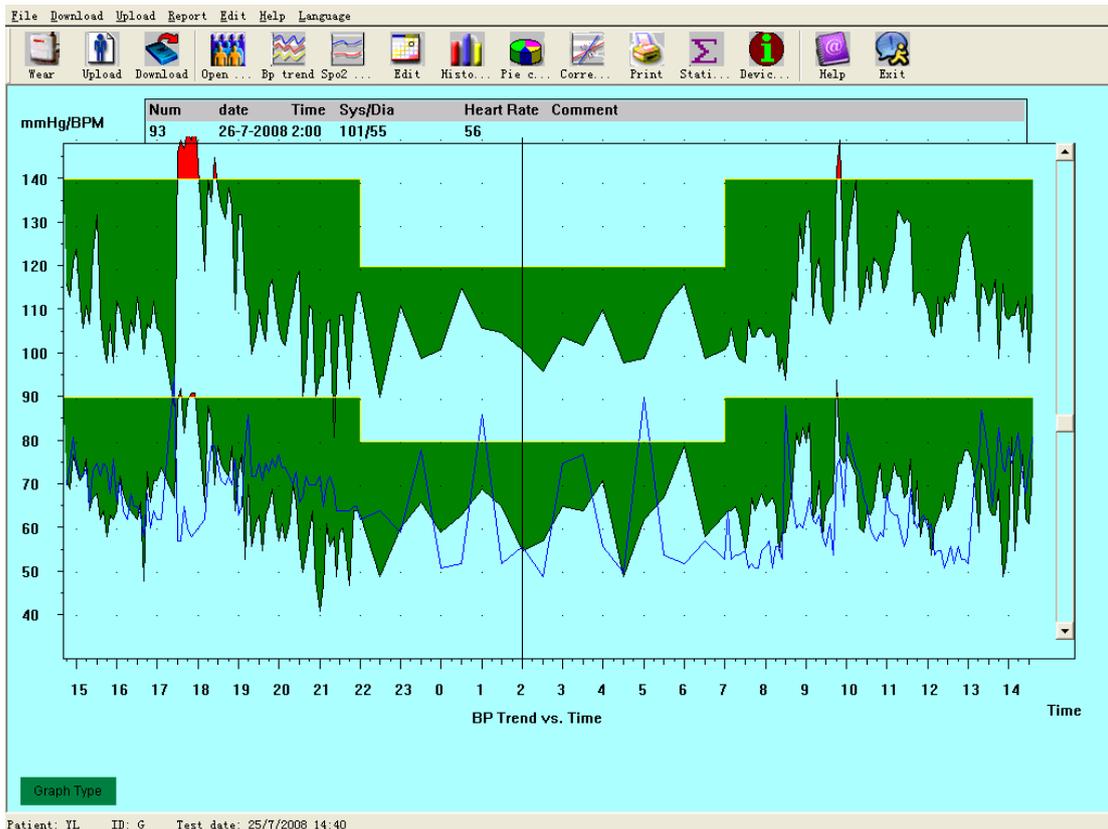


Figure7.10.5 Stretch BP Trend(y-axis)

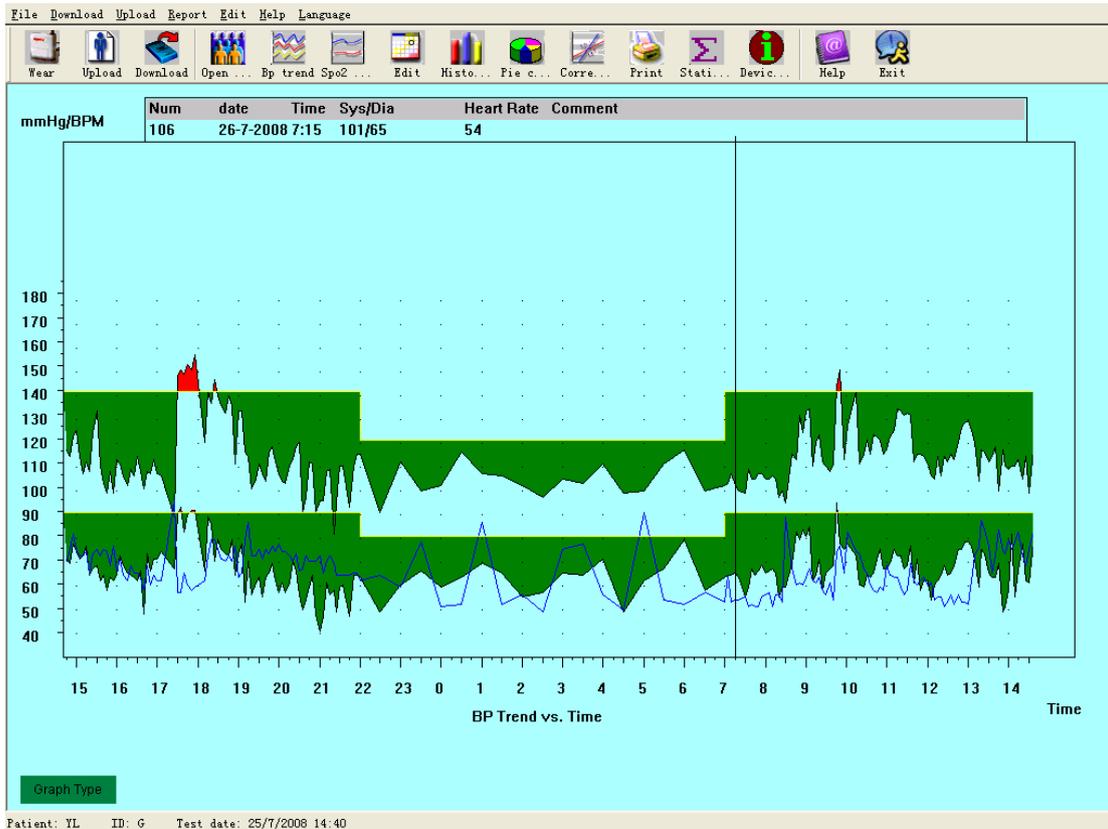


Figure7.10.6 Shrink BP Trend(y-axis)

SpO₂ Trend Edit

press the short cut key, will appear the SpO₂ trend interface.

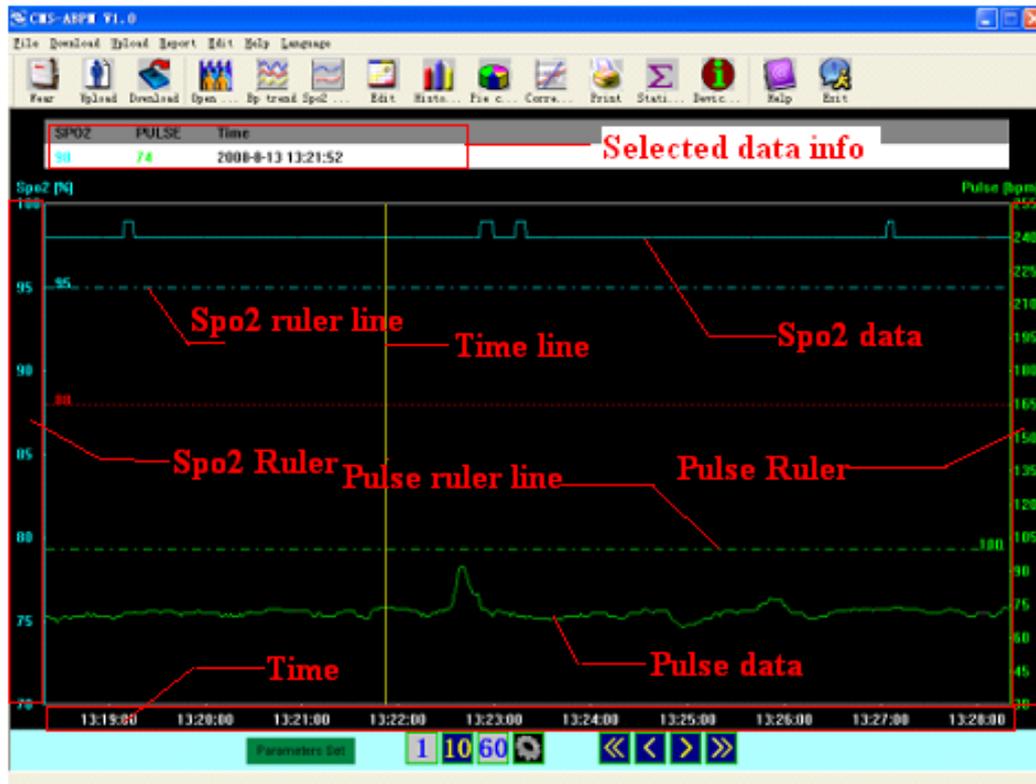


Figure 7.10.7 SpO₂ Trend

The following picture show different parts of the data area.

Move the mouse in the data area, you will see a yellow line, and on top of the data area is the "Selected data info", where you will see the exact SpO₂ and pulse value according to the time. Along with the mouse move, the value will change accordingly.

The SpO₂ and pulse ruler lines show the exact value of the horizontal lines. You can reset these lines by keeping the mouse right button clicked on the "SpO₂ ruler" area or "Pulse ruler" area, and move the mouse.



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

"1": 1 minute. "10": 10 minute. "60": one hour. : manual set, click this button will pop up a dialog box, and you can set the length you want.



This 4 buttons are used to move the data offset, that is what time is at the left of the window.

"<<" and ">>" buttons move the offset back or forth by page length. If you select "1" as the page length, ">>" will move data time forward by 1 hour.

"<" and ">" buttons move the offset back or forth by step length. Step length is smaller than page size,

1 page often contains several steps, the steps are marked in the time area, and the time mark is marked each step length.

Click the "Parameters set" button will appear the following dialog box.

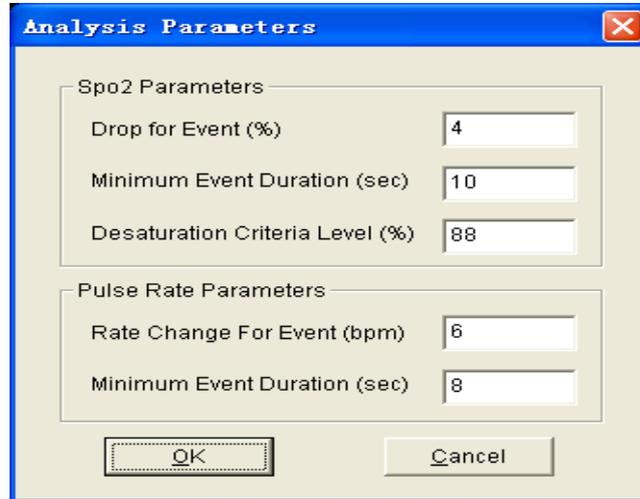


Figure 7.10.8 Analysis parameters settings

The setup in the dialog box above indicates:

SpO₂(desaturation)event: the SpO₂ value reduces at least 4% while the time keeps at least 10 seconds.

Pulse Rate event: the pulse rate fluctuates at least 6bpm while the time keeps at least 8 seconds.

7.11 Display the statistics information



Press the shortcut key **Stati...**, or from the menu select "Report" and the select "View Statistics" will pop-up the following dialog box.

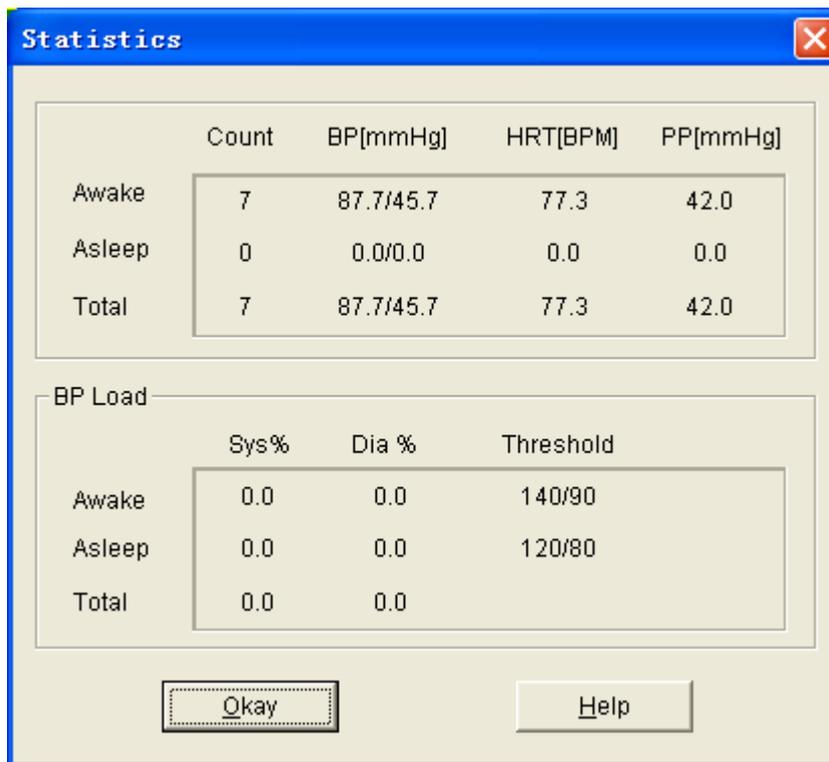


Figure 7.11 BP statistics information

7.12 Edit of diagnose information.

Diagnose information including following items: Patient information, Interpretation, Current Medication and Physician information.

From the menu select "Edit" and then select "Patient Data" will pop up the following dialog box.

The 'Patient Data' dialog box contains the following fields and options:

- Header: melon 111-222-33 25/7/2008 14:40
- Tabs: Interpretation, Physician Info
- Sub-tabs: Patient Info, Current Medications
- Patient ID: 111-222-33
- Patient Name: melon
- Address: Qinghuangdao
- Telephone: 13723388689
- Race: [Empty]
- Sex: [Empty]
- Birthday: [Empty]
- Height: [Empty]
- Weight: [Empty]
- Buttons: Okay, Cancel, Help

Figure7.12.1 Edit patient's information

click "Current Medications" switch to Current Medications interface, then you can modify the medications for the patient.

click "Interpretation" switch to Interpretation interface.

click "Physician Info" switch to the page of doctor's advice.

7.13 Sleep period change

Sleep period includes: Awake time and asleep time. Because when collecting patient parameter, patient not always fall asleep and awake according to collection data protocol strictly, you may need change your sleep period . After setup of sleep period, the software will calculate the data automatically, update the BP Trend and recalculate the statistic data.

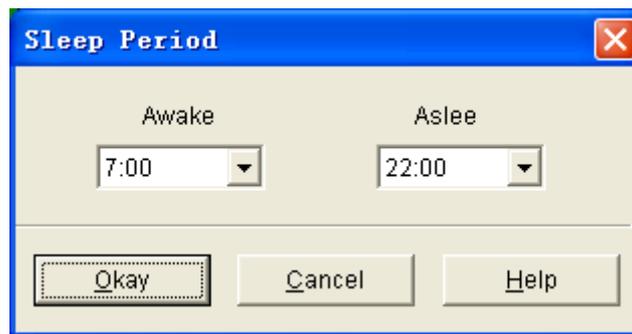


Figure 7.13 Sleep period dialog box

7.14 BP Thresholds

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

From the view select "Edit" and then select "Thresholds" will appear the following dialog box.

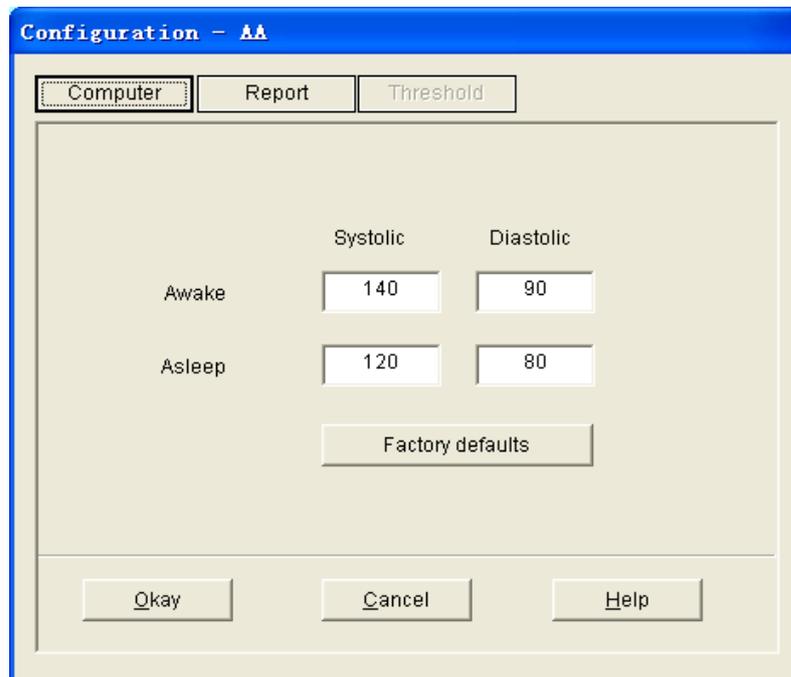


Figure 7.14 thesholds dialog box

The default, recommended thresholds for calculating Blood Pressure Load are 140/90 for awake

periods and 120/80 for sleep periods. These are the defaults used when you select the Factory Defaults button.

7.15 Histogram



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

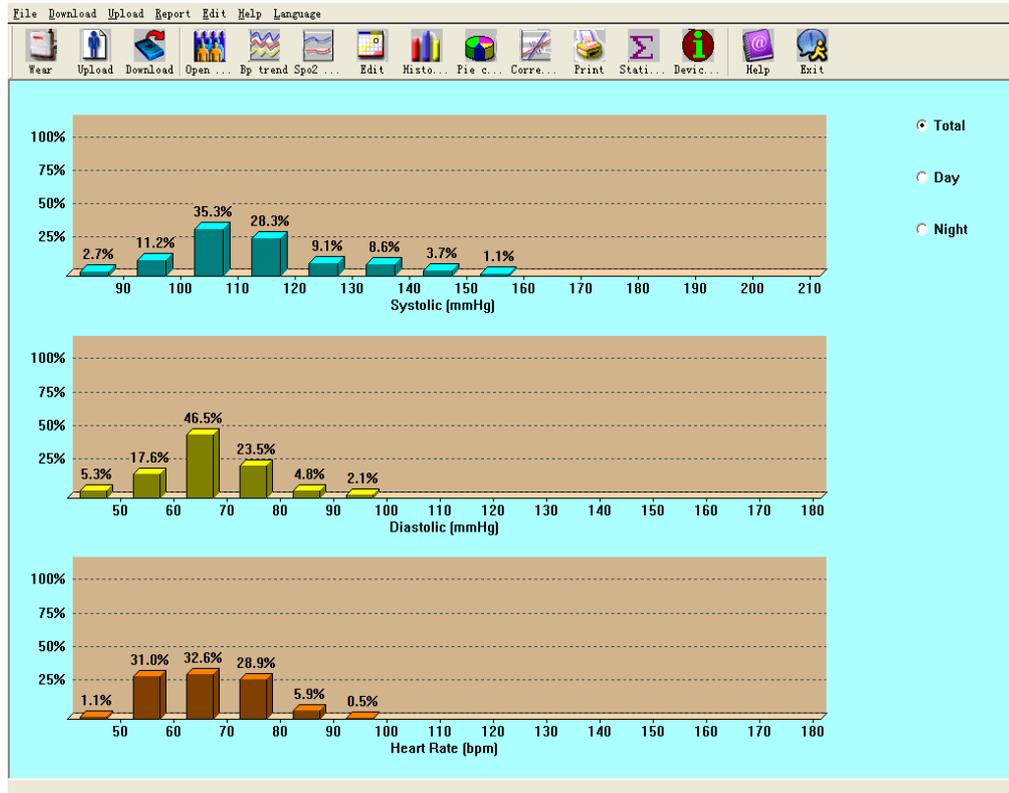


Figure 7.15 Histogram

All: Show all BP data statistics.

Day: Show only daytime statistics.

Night: Show only nighttime statistics.

7.16 Pie chart



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

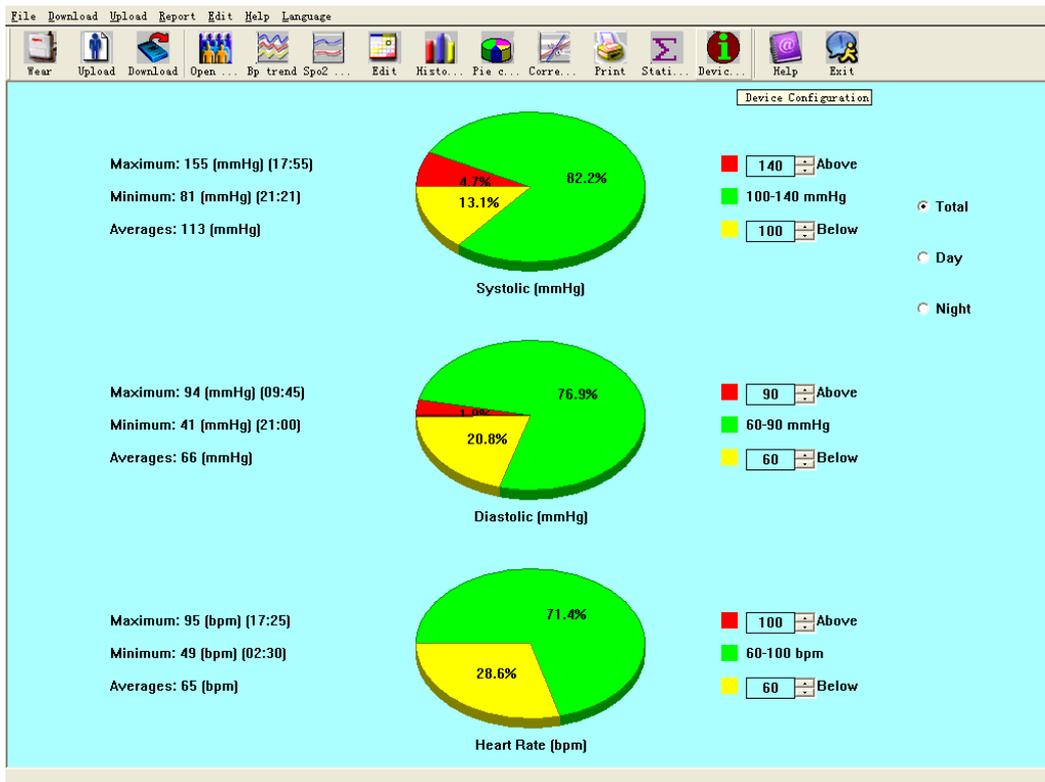


Figure 7.16 Pie chart

You can adjust to show the percentage of above normal value, normal value and below normal value. On the left, some statistics can be displayed, such as BP value, HR maximum, minimum, and average value, etc.

All: Show all BP data statistics.

Day: Show only daytime statistics.

Night: Show only nighttime statistics.

7.17 Correlation line



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

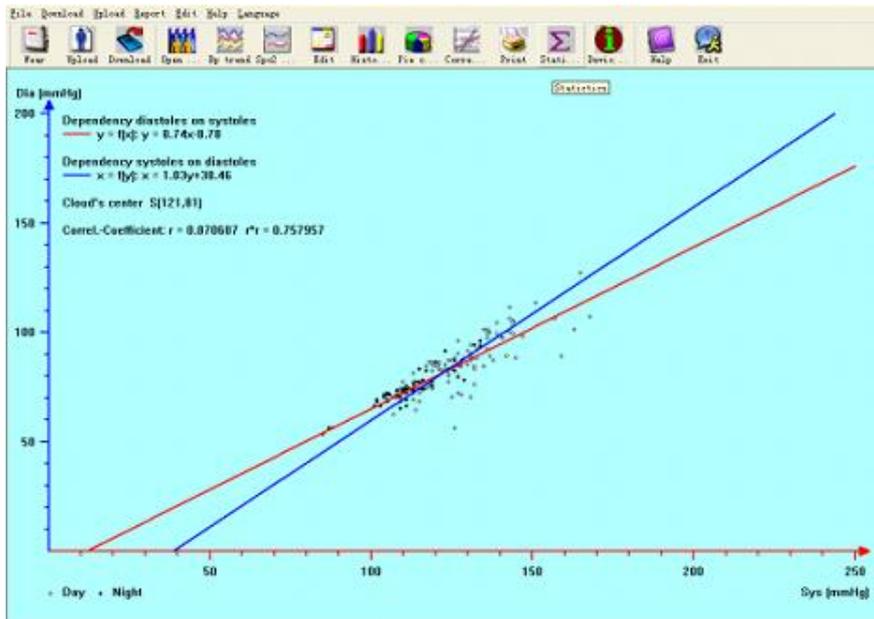


Figure 7.17 Correlation line

Red line represents systolic; blue line represents diastolic. White small circle represents day time BP value; black small circle represents night time BP value.

Histogram, Pie chart and Correlation line are usefull for your observation about the data.

7.18 Print report

After previous data edit, diagnose information edit, trend edit, and so on, the software will create a series of diagnose reports, you can select these pages or some of them for printing. The information of your selection can be saved as default print page for next time.

From menu select "Report" and then select "Configure Report" Will appear the following dialog box:

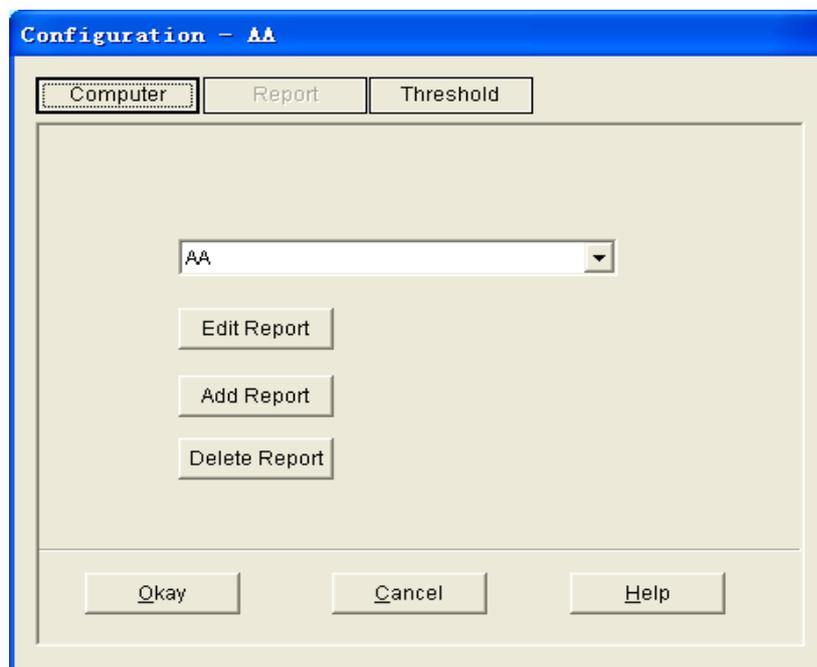


Figure 7.18.1 Configure Report

You can select an already exist report for print, you may also click "Edit Report" edit the selected report.

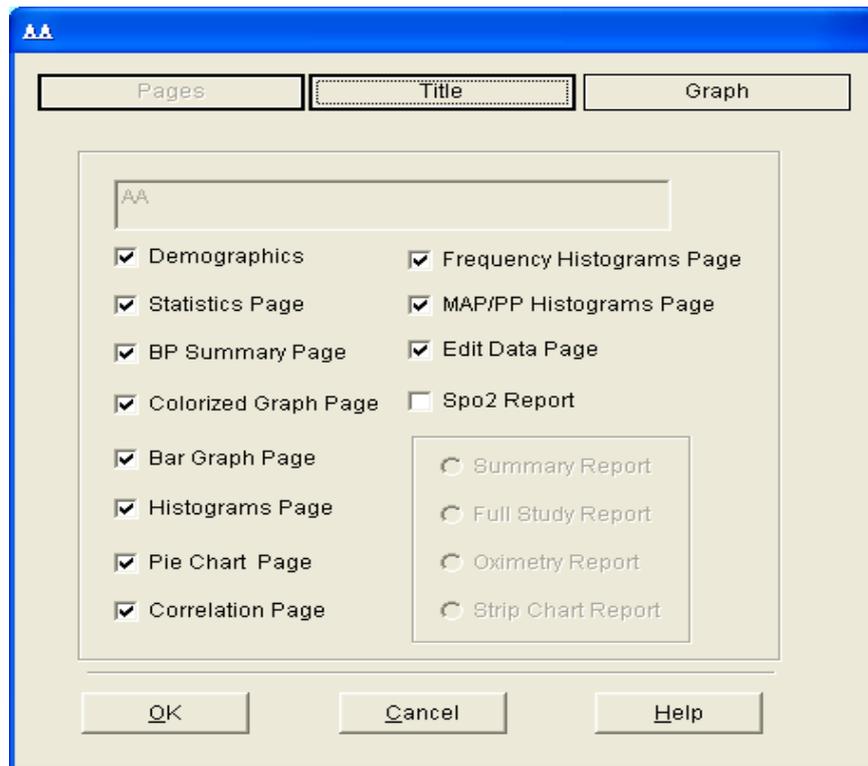


Figure 7.18.2 Edit Report

You can select all pages or some of them for printing. Only when the data file include SpO₂ data and you checked the "SpO₂ Report" could print SpO₂ report.

Click "Title" button, you may enter the title to print at the top of the printed report.

Of course you can also click "Add Report" add a new report. If you don't need the current report, you can also click "Delete Report" to delete it.

The default paper size is: A4, from the menu select "Report" and then select "Select printer", you can select a printer. From the menu select "Report" and then select "Print preview", you can preview the page you selected.

When you sure you want to print the report, press shortcut key  打印, or from menu select "Report" and then select "Print".

7.19 Help

Press shortcut key  **Help** will pop up help document. Meanwhile, you will find  in operation interface; click this button can also active the help document.

Chapter 8 Troubleshooting guide

Code	Descripti 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 time-out	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.
102	Self-check failed	Return for servicing.
110	Out of range	Retry again, if problem persists return for servicing.
115	System error	Return for servicing.

Appendix

Guidance and manufacture's declaration-electromagnetic emission for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The <i>PM50 Patient Monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of the <i>PM50 Patient Monitor</i> should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>PM50 Patient Monitor</i> 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 <i>PM50 Patient Monitor</i> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

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

Guidance and manufacture's declaration – electromagnetic immunity			
The <i>PM50 Patient Monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of <i>PM50 Patient Monitor</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. the manufacturer may recommend the ESD precautionary procedures to user.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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

Guidance and manufacture's declaration – electromagnetic immunity			
The <i>PM50 Patient Monitor</i> is intended for use in the electromagnetic environment specified below. The customer or the user of <i>PM50 Patient Monitor</i> should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 V_{rms} 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V_{rms}</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>PM50 Patient Monitor</i>, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
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 <i>PM50 Patient Monitor</i> is used exceeds the applicable RF compliance level above, the <i>PM50 Patient Monitor</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the <i>PM50 Patient Monitor</i> .			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

**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 <i>PM50 Patient Monitor</i>			
The <i>PM50 Patient Monitor</i> is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the <i>PM50 Patient Monitor</i> can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the <i>PM50 Patient Monitor</i> 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)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.67	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.			