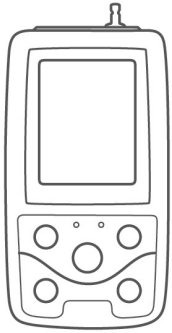
Patient Monitor

PM50

CE 0123



User Manual

Contec Medical Systems Co.,Ltd.

Contents

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 packing (including battery, plastic bags, foams and paper boxes) should follow the local laws and regulations.

⚠ **Warning** ⚠

Please choose the accessories and oxygen probe which are 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 use on one patient in same times.

⚠ Warning ⚠

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

⚠ Warning ⚠

A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

⚠ 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.

⚠ Warning ⚠

Please choose the computer which should be ensured compliance with the requirements of IEC60950, or else it may damage the device.

⚠ Warning ⚠

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

⚠ Warning ⚠

The Patient 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).

⚠ Warning ⚠

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.

⚠ Note ⚠

In the United States and the European Union, the monitor is only applicable for adult, the cuff and oxygen probe for pediatrics and neonate can not be used.

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 ≤ 3 VA

Safety

This device is defibrillator protected. Note that no precautions specific to the device are 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 monitors not only measure the ambulatory blood pressure, but also monitor the parameters

of NIBP, Pulse Rate and SpO_2. it is applicable for adult, pediatric, and neonatal. 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 have the capable of recording up to 4800 measurements, BP data trends chart. 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 cannot transmit data real-time in the process of measuring.

Monitoring function:

NIBP

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

SpO_2

— SpO_2(unit: %)

— Pulse Rate(unit: beats/minute)

the stored values of SpO_2 in the monitor can be downloaded into the computer too.

Alarm processing:

The user may turn on the alarm monitor by hand. When alarm is on, SpO_2 alarm is as follows: oxygen saturation and pulse rate displayed circularly for 5 times in 1scecond and tested the measured value whether it was exceeded or not at the same time; the blood pressure alarm is as follows: after the finish of the test, it will measure the high pressure, low pressure and the mean pressure every 4 second, until the end of the next test. The voices of the pressure and SpO_2 are same the only difference between them is the interval. Audible alarm is accompanied by visual alarm and the symbol of the alarm condition in the main interface was red.

Alarm priority: technical alarm such as low power, probe off > physiological alarm such as over the prescribed limit of the pressure and SpO_2.

⚠ **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 Main Parameters

A. Measurement of SpO_2

Measuring range: 0%~100%

Accuracy: when the SpO_2 measuring range is 70%~100%, the permission of absolute error is ±2%; below70% unspecified

B. Measurement of a pulse rate

Measuring range: 30bpm~250bpm
Accuracy: ±2bpm

C. Measurement of blood pressure

Measuring range:

ADULT:	SYS: 40-270 mmHg
	MAP: 20-235 mmHg
	DIA: 10-215 mmHg
PEDIATRIC:	SYS: 40-200 mmHg
	MAP: 20-165 mmHg
	DIA: 10-150 mmHg
NEONATAL:	SYS: 40-135 mmHg
	MAP: 20-110 mmHg
	DIA: 10-100 mmHg

Maximum mean error of measurement: ±5 mmHg.
Maximum experimental standard deviation: 8 mmHg.

D. Resolution

SpO_2: 1%, Pulse rate: 1bpm, blood pressure: 1mmHg

E. Measurement Performance in Weak Filling Condition

SpO_2 and pulse rate can be shown correctly when pulse filling ratio id 0.4%. SpO_2 error is ±4%, pulse rate error is ±2bpm.

1.3 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:

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 the button for 3 second, the instrument turns off. If power is low than 2.2V, the instrument can not turn on.

⚠ **Note** ⚠

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

MENU

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

UP

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

Press the button to select the menu item and modify the setup. In main interface, press UP key to enter silence state, again press UP key to cancel silence state.


DOWN

The text in the right bottom of the screen indicate the function of this key.
Press the button to select the menu item and modify the setup. In main interface, press DOWN key to enter alarm pause state, again press this key to cancel alarm silence state.


NIBP

Press to inflate the cuff to start a blood pressure measurement, and display the main interface. When measuring, press this button to cancel the measurement, deflate the cuff and "CANCEL" will appear in the main interface.
Note: When the frame of battery power sign is red in the main interface, pressing measure button is disabled.Here, self-motion measure can't be carried through too.

⚠ **Note** ⚠

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

1.4 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 SpO_2 Sensor and socket for NIBP cuff (**Figure 1.4.1①**)

①the Socket for NIBP cuff

②the Socket for SpO_2 Sensor

Figure1.4.1 Top

At the bottom is the socket for USB, as shown in Figure 1.4.2.

①the Socket for USB

Figure1.4.2 Bottom

1.5 Accessories

A cuff for adult
B a USB data line
C an oximeter probe
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.

Chapter2 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  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..

The

SpO_2

Probe

Figure2.4

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.

Figure2.5

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 2seconds, 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 red symbol of battery will flash in the main interface when the power is low.

The main interface is shown as the follow:

Figure3.1.1 ABPM main menu

Figure3.1.2 Monitoring main menu

⚠ Note ⚠

When the register is full ⚠ will turn up at the top of the screen. The note of the last time 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.

Figure3.2 System menu

[PM SpO_2 SETUP] and [SpO_2 TABLE] are gray in the mode of ABPM. They cannot be set up.

3.2.1 System Setup

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

Figure3.2.1 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 turn up in the main interface. On the other hand, when users select [OFF], the loudspeaker turns off, 

will turns up.

In the [NEW PATIENT] item, if users select [YES], 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]. 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 function is to control the backlight time of the main interface in ABPM.
Under the ABPM, [DEFAULT]and [NEW PATIENT] cannot be set up.
Note: Select NEW PATIENT and when interface displays clearing out the last history archive, shows the patient record is clearing out, never disassemble the battery, otherwise, cause the next saving data error, in this kind of case, it will appear "System Initializing" in boot-strap, you can normally use after system resumes.

3.2.2 BP SETUP

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

Figure3.2.2 BP setup

In PM mode, When users select [ON] in the [AUTO MEASURE] item, the Monitor will measure blood pressure according to the time selected in the [INTERVAL] item. In ABPM mode, [AUTO MEASURE] and INTERVAL can not be set up and become gray.

The interval time (Unit: minute) setup in the [INTERVAL] item can be selected from the following options:

5, 10, 15, 20, 30, 45, 60, 90,120.

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 ALMand DIA ALM can be processed separately.

The adjustable ranges of the high and low limits of the alarm are as follows:
SYS: 40-270mmHg
DIA: 10-215mmHg

3.2.3 SpO_2 SETUP

Select [PM SpO_2 SETUP] in the "SYSTEM MENU". The following menu will pop up.

Figure3.2.3 SpO_2 setup

For the [PULSE SOUND] item, you can choose its state. When the switch turns on, plug in finger and hear Pulse sound in Monitor mode. There are not limit for silence and alarm pause state.

For the [SpO_2 ALM HI/LO] item, you can set up [SpO_2 ALM HI] and [SpO_2 ALM LO]. Alarm occurs when SpO_2 value overflows.

For the [PR ALM HI/LO] item, you can set up [PR ALM HI] and [SpO_2 ALM LO]. Alarm

occurs when PR value overflows.

SpO_2 and PR ALARM analysis alarm limits:

PARAMETERS	Max. HI	Min. LO	Step
SpO_2	100	0	1
PR	250	30	1

3.2.4 Patient Information

Pick the [ABPM INF0] item in the “SYSTEM MENU” to call up the following menu.

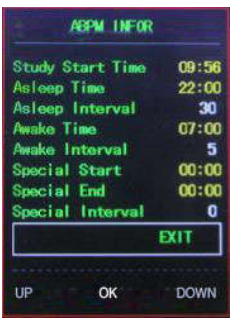


Figure3.2.4 ABPM information

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.

Figure3.2.5 NIBP table

Users can press the UP and DOWN button to see the stored values. Press the MENU will exit. When data is much, long press UP key or DOWN key to appear to quickly turn over page, you can easily and quickly browse all datas.

3.2.6 SpO_2 TABLE

Pick the [SpO_2 TABLE] item in the “SYSTEM MENU” to call up the following menu.

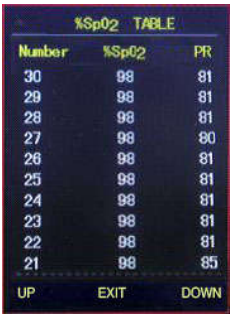


Figure3.2.6 SpO_2 table

Users can press the UP and DOWN button to see the stored values. Press the MENU will be exit. The SpO_2 is measured once per 1s, and the most number of times is 183000. Long press UP key or DOWN key, after a few second, will appear to quickly turn over page, you can easily see all records, the speed of turning over page is more quick than turning over blood pressure data**.**

3.2.7 TREND

Select TREND to enter TREND GRAPH interface, as shown the following figure**:**

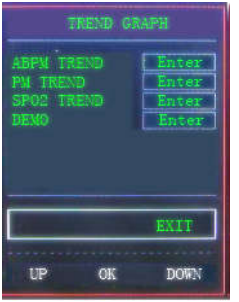


Figure3.2.7 TREND graph

Select ABPM TREND to enter the following interface, display waveform is the measurement data in ABPM mode.

Select PM TREND to enter the same interface, display waveform is the measurement data in PM mode. The time on the left of the horizontal axis topside is the start time for display waveform, the time on the right of the horizontal axis is the end time for display waveform. Via UP key and DOWN key, you can turn over different time segment measurement BP data waveform chart.

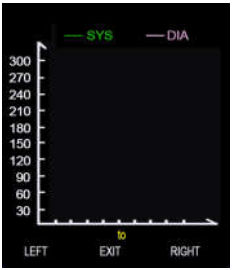


Figure3.2.8 Abpm or PM trend

Select SpO_2 TREND to enter the following interface, as shown in Figure 3.2.10 SpO_2 TREND, Via UP key and DOWN key, you can turn over different time segment measurement SpO_2 and Pulse rate data waveform chart. The time on the left of the horizontal axis topside is the start time for display waveform, the time on the right of the horizontal axis is the end time for display waveform. Press MENU key to enter total trend chart interface (the total trend chart display on the screen which all datas take average value from SpO_2 list, and UP key and DOWN key become gray), as shown in figure 3.2.10 total trend chart interface.

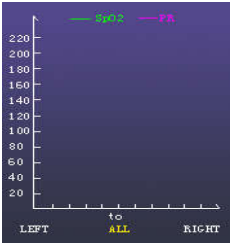


Figure3.2.9 SpO_2 trend

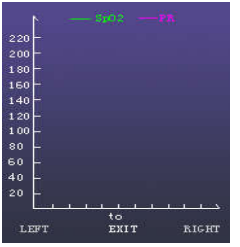


Figure3.2.10 SpO_2 Total trend chart

Select DEMO to enter the following interface, in DEMO mode, press MENU key to exit DEMO

mode.

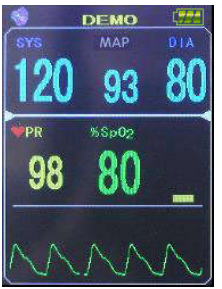


Figure3.2.11 DEMO

⚠ 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 SpO_2 SETUP] and [SpO_2 TABLE] can't be changed in the "SYSTEM MENU".

Chapter4 SpO_2 Monitoring

4.1 What is the SpO_2 Monitoring

SpO_2 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 SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97%. The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

How the SpO_2/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 4mW.
- **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 SpO_2 value and the PLETH waveform can be displayed in the main screen.**

- **The update period of data is less than 5 seconds, which is changeable according to different individual pulse rate.**
- **Please read the measured value when the waveform on screen is equably and steady-going. The measured value is optimal value. And the waveform at the moment is the standard one.**

⚠ Warning ⚠

ES (Electrosurgery) equipment wire and SpO_2 cable must not be tangled up.

⚠ Warning ⚠

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

⚠ Note ⚠

Do not perform SpO_2 measuring and NIBP measuring on same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 value.

4.2 Precautions during SpO_2/Pulse Monitoring

⚠ Note ⚠

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

⚠ Note ⚠

SpO_2 waveform is not proportional to the pulse volume.

⚠ Warning ⚠

Do not use the SpO_2 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, erubescence, 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

SpO_2 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 SpO_2 socket, please pay attention to the direction of the sensor.

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

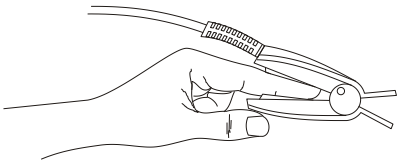


Figure4.3 Mounting of the sensor

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.

Chapter5 NIBP Monitoring

5.1 Introduction

- **The Non-invasive Blood Pressure (NIBP) module measures the blood pressure using the oscillometric method .It is that: using the blade to block artery blood, checking the oscillometric wave during degassing for sure that it was not affected by the operator's subjective factors or the disruption of the environmental noise.**
- **There are two modes of measurement available: manual and automatic .Each mode displays the diastolic, systolic and MAP blood pressure.**
- **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 ⚠

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

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

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.

Plug in the air hose and switch on the system.

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.

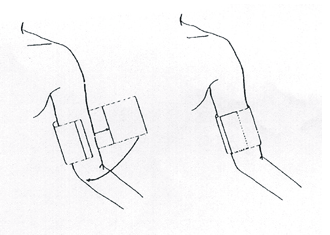


Figure 5.2 Applying Cuff

⚠ 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 3 m
Child	18 ~ 26 cm	10.6 cm	
Infant	10 ~19 cm	8cm	
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.**

1. **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.**

2. **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	Sensor 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 cannot 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.

⚠ Warning ⚠

This product is calibrated before leaving factory, The calibration of the NIBP measurement is necessary for every two years (or as frequently as dictated by your Hospital Procedures Policy).

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-wash or hand-wash, 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.

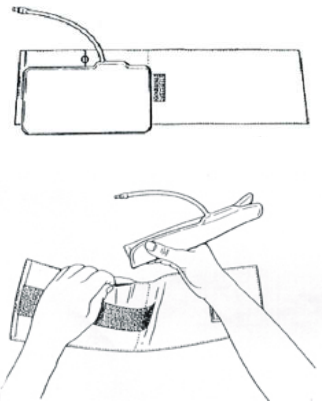


Figure5.4 Replace Rubber Bag in Cuff

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 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°C~60°C; Humidity: ≤95%

5.6 Key of Symbols

Signal	Description
	Refer to instruction manual/booklet
SYS	Systolic pressure
MAP	MAP pressure
DIA	Diastolic pressure
%SpO_2	The pulse oxygen saturation (%)
PR	Pulse rate (bpm)
	Close the sound
	Open the alarm sound indication
	Close the alarm sound indication
	Type BF defibrillator proofed applied parts
SN	Serial number
	1. the finger clip falls off (no finger inserted)] 2. Probe error 3. Signal inadequacy indicator

IPX1	**Ingress of liquids rank**
CE 0123	**This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.**

Chapter6 Installation of the software

- **Demand of editor**
- **Installation of software**

6.1 Demand of Editor

Processor: Pentium IV 1.8G or more
Operation System: Win2000/XP/Vista
EMS memory: 256M and up
Hard Disk: 40G or more
Display: 17 inch or more
CD-ROM
Resolution of printer: 300 DPI or more

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 Patient_Monitor_Setup.exe.
   Follow the instructions in the screen.

Note: After installing Patient_Monitor_Setup, open the instrument, plug in USB, the computer pop up a dialog box, select "Auto install", the installation is successful, until drive installation finishes.

Chapter7 Introduce 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 configurations, such as thresholds**.**

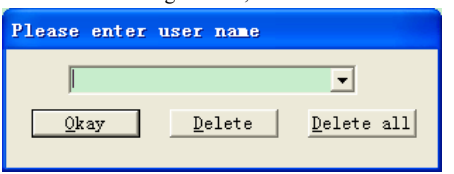


Figure7.1.1 User Register

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.

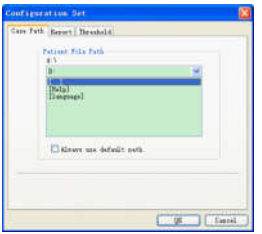


Figure7.1.2 Set file path

"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 users configuration information are finished, the main interface is entered, as the following pictured displayed:

Figure7.2 The main operating interface

1. Menu bar The main operating menu of this software
2. Tool bar 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 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.

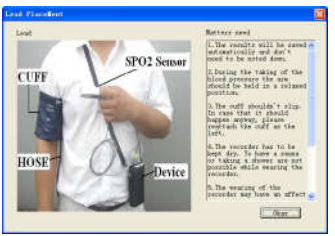


Figure7.3 Wear

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:

1. Press the shortcut key 

, or from the menu select "Upload", the following dialog box will appear.

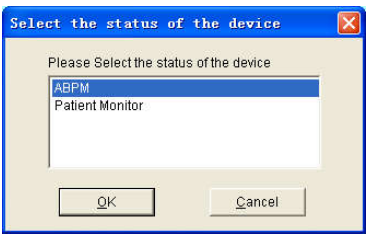


Figure7.4.1 Select the status of the device

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

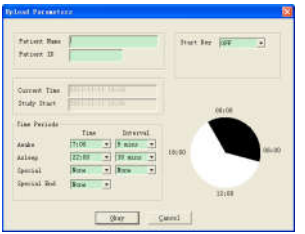


Figure7.4.2 Upload test parameters

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 choose is "Patient Monitor" the following dialog box will appear.

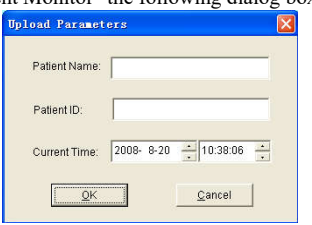


Figure7.4.3 Upload test parameters

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

Figure7.4.4 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 

, 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).

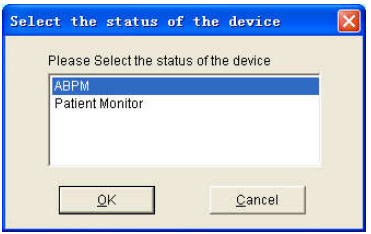


Figure7.5.1 Select the status of the device

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

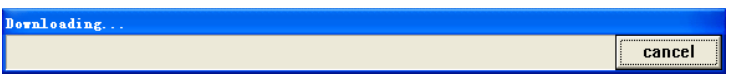


Figure7.5.2 Downloading progress bar

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

7.6 Choose Patient Data to Edit

Press shortcut key 

, or from the menu select "File" and select "Open data" the

following dialog box will appear:

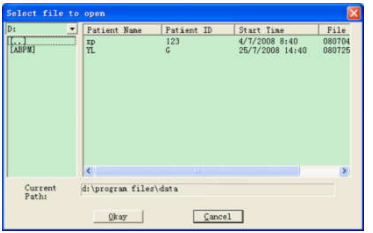


Figure7.6 Patient file select

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:

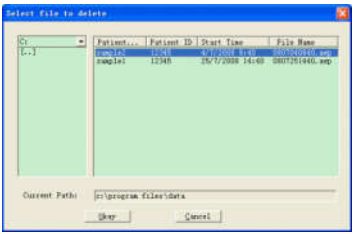


Figure7.7 Data file delete

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.

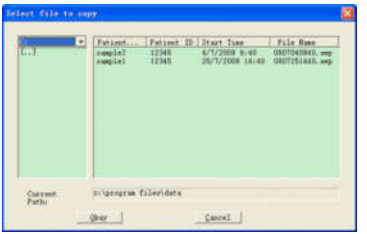


Figure7.8.1 Data file copy

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 directory to copy to.

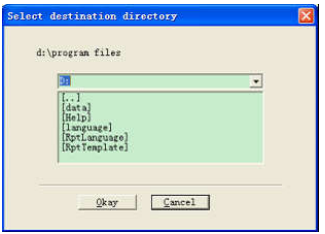


Figure7.8.2 Backup path settings

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 

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

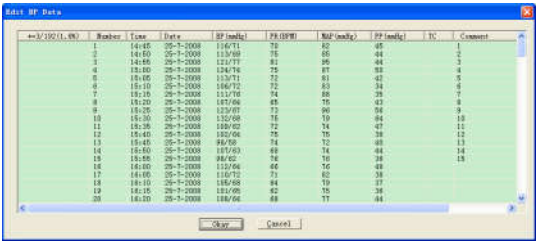


Figure7.9 Data edit page

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

*=3/192(1.6%): 192 represents the total data sum, 3 represents the data amount deleted, 1.6% 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.

PR: Pulse rate.

MAP: Mean pressure.

PP: Pressure difference between high and low blood pressure.

TC: error code (refer to chapter 8)

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 

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.

Figure7.10.1 Color filler type BP trend

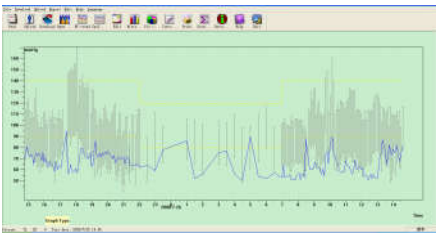


Figure7.10.2 Dotted line type BP trend

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, pulse 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.

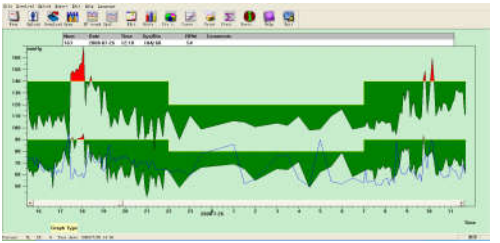


Figure7.10.3 Stretch BP Trend (time axis)

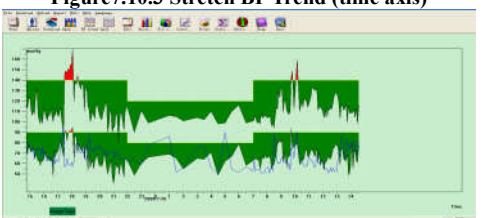


Figure7.10.4 Shrink BP Trend (time axis)

Figure7.10.5 Stretch BP Trend (y-axis)

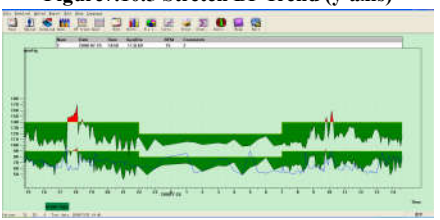


Figure7.10.6 Shrink BP Trend (y-axis)

SpO_2 Trend Edit

Press the short cut key, will appear the SpO_2 trend interface.

Figure7.10.7 SpO_2 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 SpO_2 and pulse value according to the time. Along with the mouse move, the value will change accordingly.

The SpO_2 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 "SpO_2 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.

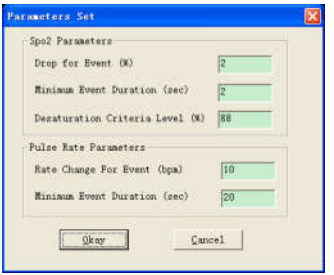


Figure7.10.8 Analysis parameters settings

The setup in the dialog box above indicates:

SpO_2 (desideration) event: the SpO_2 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 

, or from the menu select "Report" and the select "View

Statistics" will pop-up the following dialog box.

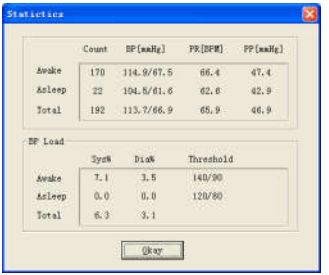


Figure7.11 BP statistics information

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.

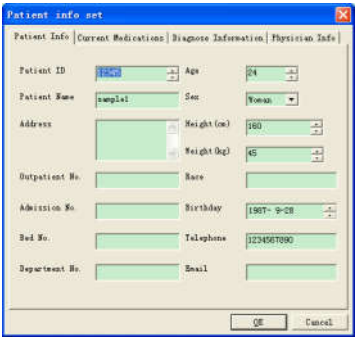


Figure7.12 Edit patient's information

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: wake time and sleep 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.

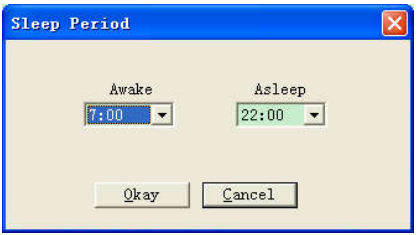


Figure7.13 Sleep period dialog box

7.14 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 then select "Thresholds" will appear the following dialog box.

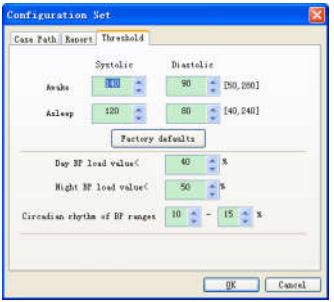


Figure7.14 Thresholds dialog box

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

, will appear the following interface:

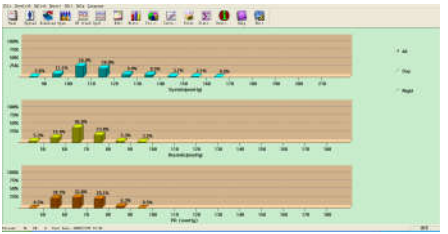


Figure7.15 Histogram

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

7.16 Pie Chart

Press the shortcut key 

, will appear the following interface:

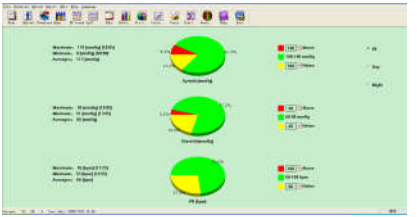


Figure7.16 Pie chart

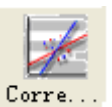
You can adjust to show the percentage of above normal value, normal value and below normal value. On the left, some statistics can be displayed, such as BP value, PR maximum, minimum, and average value etc.

All: Show all BP data statistics.

Day: Show only daytime statistics**.**

Night: Show only nighttime statistics.

7.17 Correlation Line

Press the shortcut key 

, will appear the following interface:

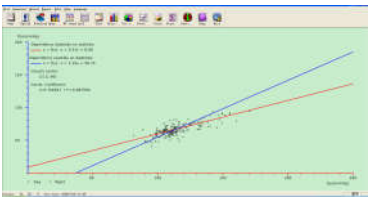


Figure7.17 Correlation line

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 useful 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:

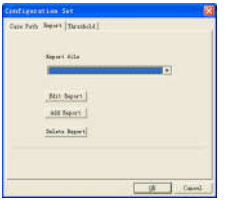


Figure7.18.1 Configure Report

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

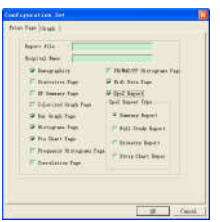


Figure7.18.2 Edit Report

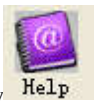
You can select all pages or some of them for printing. Only when the data file include SpO_2 data and you checked the "SpO_2 Report" could print SpO_2 report.

Of course you can also click "Add Report" adds 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 "Report", you can preview the page you selected.

When you sure you want to print the report, press shortcut key 

or from menu select "Report" and then select "Print".

7.19 Help

Press shortcut key 

will pop up help document.

Chapter8 Troubleshooting Guide

Code	Description 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
89	cuff overpressure	Check for blocked or kinked air hose.
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 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer of the user of the Patient Monitor should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Patient Monitor 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 Patient Monitor 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 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Patient Monitor 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 Patient Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Patient Monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Patient Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz

			$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 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 meters (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 Patient Monitor is used exceeds the applicable RF compliance level above, the Patient Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Patient Monitor.
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 Patient Monitor			
The Patient Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Patient Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Patient Monitor 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 $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
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 meters (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.

CONTEC™

Contec Medical Systems Co., Ltd.

Address: No.112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei Province, PEOPLE'S REPUBLIC OF CHINA
Tel: 0086-335-8015430
Fax: 0086-335-8015588
E-mail: cms@contecmed.com.cn
contec88@gmail com
Website: http://www.contecmed.com

EC REPRESENTATIVE

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537, Hamburg, Germany
Tel: +49-40-2513175
Fax: +49-40-255726
E-mail: shholding@hotmail.com

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