CE 0197

User Manual

For ABP series ABPM

Suzhou Beneware Medical Equipment Co., Ltd.

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BENEWARE

Revision History

Date	Version	Changes compared to previous issue
March, 2015	1.0	Base version

Contents

1 Summary

The ambulatory blood pressure monitor (ABPM) which came out in the 1960s is a kind of medical device for measuring and recording humans' blood pressure for 24 hours or more. For several decades since its appearance, its technology has been improved and enhanced continuously and it has made contributions at the landmark level to diagnosis and guidance of treatment of humans' high blood pressure. The ambulatory blood pressure monitor overcomes limitations such as the small number of blood pressure measurement in the clinic, observation error and the White Coat Hypertension (WCH). Therefore, it can reflect the actual level and fluctuation of blood pressure objectively.

Compared with sporadic blood pressure, ambulatory blood pressure has the following advantages:

1) It gets rid of contingency of sporadic blood pressure and avoids the influence of emotion, sports, taking food, smoking and drinking etc. on blood pressure, reflecting the condition of blood pressure objectively and truly.

2) Ambulatory blood pressure can obtain more data of blood pressure and can truly reflect the change rule of blood pressure all day long.

3) For patients with slightly high blood pressure or critical high blood pressure who have no symptoms at an early stage, it enhances the detection rate and they can receive timely treatment.

4) Ambulatory blood pressure can provide a guidance to medication. In most cases, it can be used for measuring treatment effect of medicine and help choose medicine, and regulate dose and time of dosing.

5) It can judge whether patients with high blood pressure have the injury of the target organ (which can be damaged because of high blood pressure easily). For patients with high blood pressure who have myocardial hypertrophy, pathology of dynamic vessels of eye ground or the changed function of kidney, their difference of night and day is small.

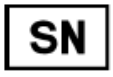
6) Predict the time of sudden attack of cardio-cerebrovascular diseases in a day. Before dawn, when blood pressure rises suddenly, cardio-cerebrovascular diseases are most likely to happen.

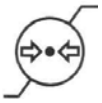
7) Ambulatory blood pressure is of great importance for judging prognosis. Compared with conventional blood pressure, the case fatality rate of people with high blood pressure in 24 hours and their incidence of first cardio-cerebrovascular disease are both higher than people with low blood pressure in 24 hours. Especially for people under 50 whose diastolic pressure ＜16.0kPa (105mmHg) and who have never had attacks of cardio-cerebrovascular diseases, measuring ambulatory blood pressure is more meaningful which can direct pharmacy and predict attacks of cardio-cerebrovascular diseases.

1.1 Safety Standard Requirements

- The device is powered by an internal power source.
- Safety category of the product is type BF applied part equipment. And the specific apply part is cuff rather than the monitor.
- The device applies to patients with normal sinus rhythm.
- The device boasts protection design which avoids excessive pressure of the cuff.
- The device does not provide explosion protection.
- Not suitable for pregnant women or infants weighing less than 10 Kg.
- Power supply of this product is two AA alkaline or Ni-HM rechargeable battery.

1.2 Symbol Description

	Type BF applied part, defibrillator protected.
	Refer to instruction manual/booklet
	USB interface
	Do not dispose of this product as unsorted municipal waste
	Ambulatory Blood Pressure Monitor meets the applicable requirements of the European directive 93/42/EEC
	Date of manufacture
	Manufacture
	Serial number
	Battery polarity
	Authorised representative in the European Community
	Special cautious, one must refer to the instruction manual
	Temperature range. (see Technical Specifications)
	Humidity range. (see Technical Specifications)

	Pressure range. (see Technical Specifications)
	Fragile
	Keep dry.
	Keep away from sunlight.
	This end up.

1.3 Environmental Requirements

Environmental test of the instrument should be in accordance with group II of climatical and mechanical environment tests of IEC 60601-1.

Please refer to “Appendix 1 Technical Specifications” for environmental requirements of operating, storage and transportation.

2 Application Cautions

This instrument can only be used by medical personnel with professional qualifications. For safe and effective use, and to avoid possible damages, please read the instruction manual before use, so as to get familiar with performance of the instrument and fully understand the correct operation method and cautions.

⚠ Caution ⚠:

This device does not apply to people who is suffering from sickle cell disease, has occurred or is expected to occur skin lesions.

⚠ Caution ⚠:

This device can not be used by people who are in severe shock, using heart-lung machine, heart or artery deformity (excluding surgery corrected).

⚠ Caution ⚠:

This device can not be used when parts of the device are not serviced or maintained.

⚠ Caution ⚠:

This device is common equipment of inner power supply BF type application part. When defibrillator is applied to patients, preventive measures of the instrument are unnecessary for it makes no impact on the device when it discharges.

⚠ Caution ⚠:

The device is not suitable for places which use electro-surgery devices.

⚠ Caution ⚠:

The device can't connect with the public power grid.

⚠ Caution ⚠:

This device is applicable to continuous operation and equipped with inner power supply, but can not be used in flammable and explosive environment, such as FLAMMABLE ANAESTHETIC MIXTURE WITH AIR and FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

⚠ Caution ⚠:

Please use AA alkaline battery or Ni-MH rechargeable battery, don't use other power supply, and don't install the wrong battery terminals. Please replace with new or fully recharged batteries after the old new are used up.

⚠ Caution ⚠:

Please use the cuff allocated by the company. During use of the product, don't pull the cuff forcibly or wind or press its airway so that the air circuit will not be blocked.

⚠ Caution ⚠:

Before automatic measurement, during air inflation of the cuff, if the patient's blood circulation is blocked by pressure for a long time or the pressure is excessive because of abnormal conditions, the patient should be directed to stop measurement by pressing the stop button.

⚠ Caution ⚠:

If the cuff can't release air normally because the safety air release function loses efficacy or its air tube is blocked, the patient should be directed to remove the cuff to avoid injury of limbs.

⚠ Caution ⚠:

Don't use in environment with explosive danger or contains anesthetic, volatile substance and other inflammable gas.

⚠ Caution ⚠:

When using this device, please avoid strong electromagnetic interference. Use mobile phone near this product may interfere with measurements. In surrounding area of this product, there should be no high voltage cable, X-ray machine, ultrasonic instrument, electrotherapy machine, etc..

⚠ Caution ⚠:

Avoid contacting with water, don't use and store in places of abnormal temperature or humidity, poor ventilation, or with excessive dust or contain sulfur, saline and alkaline gases and chemical medicines.

⚠ Caution ⚠:

Disinfect this device and its accessories regularly with UV disinfection equipment.

⚠ Caution ⚠:

The host and its accessories (especially the battery) should not be discarded casually when in discard processing, please let the qualified company or government department to handle after strict sterilization.

⚠ Caution ⚠:

Pregnant women or infants weighing less than 10 Kg should not use the device.

⚠ Caution ⚠:

No modification of this device is allowed.

3 Structure Characteristics and Working Principle

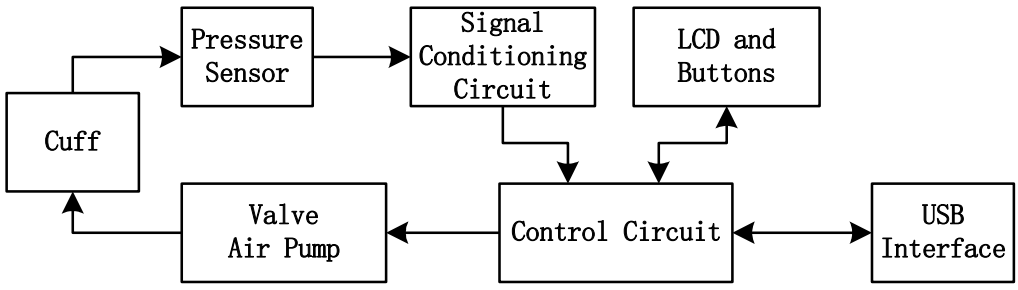
3.1 Electrical Schematic Diagram and Compendium of the Principle

3.1.1 Electrical Schematic Diagram and Parts List

Electrical schematic diagram and parts list is only for qualified maintenance station or personnel recognized by our company.

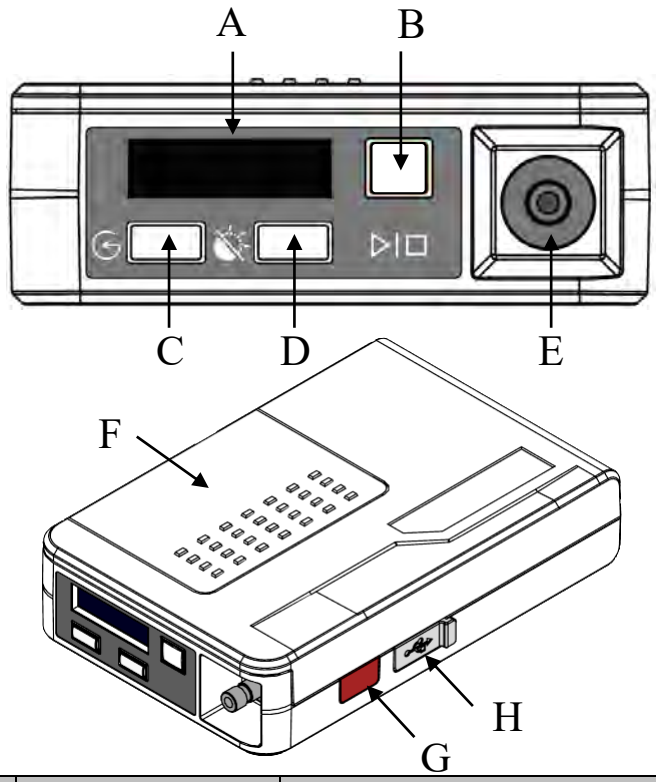
3.1.2 Compendium of the Principle

The monitor includes cuff, pressure sensor, signal conditioning circuit, control circuit, LCD, buttons, valve, air pump and USB interface. The control circuit controls the pump and the valve to pump and release air of the cuff. The pressure sensor converts pressure signals of the cuff into electric signals and offers them to the signal conditioning circuit for pretreatment. The control circuit adopts pressure signals after pretreatment and works out the measured value of blood pressure and stores the measurement result in the internal storage medium. Users can interact with the monitor through LCD and the buttons, and connect with PC through USB interface for data transmission. The device does not contain corrective factors related to changes in environment.



3.2 Name and Function of Each Part

3.2.1 Structure Description of the Monitor



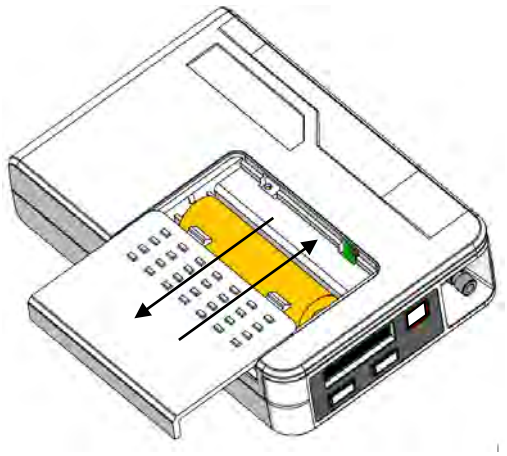
Designator	Name	Instruction
A	LCD	User interactive display interface
B	Function key 1	Corresponds to icon ▷|□, mainly used for starting and stopping measurement
C	Function key 2	The corresponding icon, be mainly used for playing back data
D	Function key 3	The corresponding icon, be mainly used for switching the timing mode or entering/quitting USB communication mode
E	Metal air nozzle	Connect with self-lock metal quick connector of the connecting conduct of the cuff
F	Battery cover	Sliding battery cover
G	Infrared window	Infrared communication window
H	USB port	Mini USB port, be used for connecting

		with PC

4 Operating Instruction

4.1 Install Batteries

Open the sliding battery cover above the monitor and put two AA batteries in the battery compartment. Pay attention to positive and negative electrodes of the battery and don't use new and old batteries together.



4.2 Start up the Monitor

After installing the batteries, the ambulatory blood pressure monitor will be turned on automatically; if the monitor is shut down, press  button for about 3 seconds. The buzzer will send out two short sounds of "beep" and the monitor will be turned on again.

4.3 Shut down the Monitor

When the monitor is turned on, press  button for about 3 seconds. The buzzer will send out one long sound of "beep" and the monitor will be shut down. If the monitor will not be used for a long time, please take out the batteries.

4.4 Automatic measurement

After turning on the monitor, it will start the mode of automatic measurement.

Time interval of automatic measurement will be decided according to the method set with PC communication device last time. 3 seconds before every measurement, its buzzer will send out one short sound of “beep” and counting of 3 seconds backward will be displayed on the display screen and then, measurement is started. During measurement, the display screen will give real-time display of pressure of the cuff.

4.5 Manual Measurement

During time interval of automatic measurement, press  button for a short time. With “beep” of the buzzer, one time of manual measurement is started. Prompting methods of sound and vision of automatic and manual measurement are the same.

4.6 Stopping Measurement

During measurement of the monitor, press  button for and the monitor will stop the current measurement and release air to reduce pressure of the cuff quickly.

4.7 Wakeup Display

When the monitor is not used for over one minute during time interval of automatic measurement, it will shut down the clock display automatically to reduce power consumption. The display screen will display three “.” in sequence. Just press  button for a short time to wake up the display screen to display the clock again.

4.8 Switching Interval of Day and Night Measurement

If the automatic measurement mode of the monitor is “Sleeping Mode”, during time interval of automatic measurement, press  button for a short time to switch between time intervals of day and night measurement. Patients can only switch the day into the night from 18:00 to 23:59. After that, they can only switch back to the day from 0:00 to 17:59.  button is invalid in other automatic modes.

4.9 Static Pressure Test

The ambulatory blood pressure monitor offers the testing mode of static pressure.

In this mode, the display screen of the monitor will display real-time pressure of the cuff measured by the pressure sensor. Users may test its performance with this mode. The way to enter the testing mode of static pressure and the operating method of the mode are as follows:

- After starting up the monitor, in the automatic measurement mode, press and hold and button at the same time for about 5 seconds until there is one short sound of "beep" of the buzzer. The display screen will display the title of "Static Test". Under it, there are 2 options, "Start" (corresponding to button) and "Option" (corresponding to button). Choose "Start" to enter the testing mode of static pressure.
- In the static pressure test mode, options change into "Pump" (corresponding to button) and "Valve" (corresponding to button). Press "Pump" and users can control the air pump to increasing pressure. Release the button and air inflation is stopped immediately. Press "Valve" and the valve will release air. Within 2 seconds when pressing the button, the air releasing speed is slow for fine adjustment of pressure. After pressing for over 2 seconds, the valve will release air quickly. Release the button and the valve will be closed again.
- Press button to exit the testing mode of static pressure. And stop air inflation and open the valve for releasing air.
- In the testing mode of static pressure, the pressure safety mechanism of the monitor is still effective. If it has detected that pressure exceeds 300mmHg for over 3 seconds or the pressure maintains more than 15mmHg for over 150 seconds, it will forbid air inflation compulsively and open the valve for air release. If users need pressurized measurement again, they must press "Valve" first to close the valve again.

4.10 Pressure Calibration

The ambulatory blood pressure monitor offers the function of pressure calibration. Users may use one triple air tube to connect the monitor and the air pump with the calibrated pressure gauge to calibrate pressure measurement of the monitor.

The way to enter the pressure calibration mode and the operating method in the mode are as follows:

- In the mode of automatic measurement, press and hold  and  button at the same time for about 5 seconds until there is one short sound of "beep" of the buzzer. The display screen will display the title of "Static Test". Under it, there are 2 options, "Start" (corresponding to  button) and "Option" (corresponding to  button). Choose "Option" and the title is changed into "Calibration". Then choose "Start" button to enter the pressure calibration mode.
- In the pressure calibration mode, options change into "Next" (corresponding to  button) and "Valve" (corresponding to  button). Increasing pressure of the air passage should be carried out by the external air pump. Press "Valve" and the valve will release air. Within 2 seconds when pressing the button, the air releasing speed is slow for fine adjustment of pressure. After pressing for over 2 seconds, the valve will release air quickly. Release the button and the valve will be closed again. The external valve can control pressure as well. According to the target pressure indicated by the display screen is 250mmHg, adjust pressure with the air pump and the valve. When reading of the external pressure gauge is 250mmHg, press "Next" for a short time to complete pressure calibration of 250mmHg and enter into the next calibration point. After calibrating three target points, 250 mmHg, 150 mmHg and 50 mmHg, calibration will be stopped automatically and it will return to the automatic measurement mode. **The calibration result only takes effect after the monitor is started up next time.**
- Before completing calibration of three calibration pressure points, if users press  button for a short time, it will exit the pressure calibration mode and the calibration result will not take effect.
- In the testing mode of static pressure, **the pressure safety mechanism of the monitor will be suspended**.

5 Setting of Automatic Measurement

5.1 Model Support

The ABP series can support as many as three kinds of measurement mode: ABP-010 and ABP-011 only support one measurement mode (Auto Mode); ABP-020 and ABP-021 support 3 measurement modes (Fixed mode, Auto mode and Sleep mode)

5.2 Fixed Mode

In fixed mode, the monitor will carry out automatic measurement regardless of time interval such as day and night. Time intervals include seven kinds, 5, 10, 15, 20 or 30 minutes and one hour or two hours. For this setting, the LCD screen of the monitor will display  in the left.

5.3 Auto Mode

In auto mode, the measurement interval of the monitor in the day is 15 minutes while that at night is 30 minutes each time. According to time frame of day and night of PC set by users, the monitor will switch measure interval automatically. In time range of the day, the LCD screen will display  in the left and display  in time range of the night.

5.4 Sleep Mode

In this mode, the measurement interval of the monitor in the day is 15 minutes while that at night is 30 minutes each time. Patients need to switch between day and night manually. Press  button for to switch measurement interval of day and night. In time range of the day, the LCD screen will display  in the left and display  in time range of the night. After initialization, the monitor enters this mode and the default is daytime.

6 Use Step

6.1 Install the Ambulatory Blood Pressure Analysis Software

6.1.1 Computer Requirements

- **Basic Configuration**

  CPU：Intel Pentium 4, 1.8GHz

  RAM：512MB

  Hard Disk：10GB

  Screen：VGA color display with resolution of 1024 * 768

  Printer：2M RAM, 600 dots per inch

  Operating System：Windows XP

- **Recommended Configuration**

  CPU：Intel Pentium, Dual-Core 2.93GHz

  RAM：2GB DDR3

  Hard disk：SATA 320G（7200 RPM）

  Screen：23-inch LCD monitor with resolution of 1920 *1080

  Printer：more than 2M RAM， 600dpi

  Operating System：Windows 7

- **Space Requirements of Computer Hard Disk**

1. Space requirements of computer hard disk for installing software
2. Space requirements of computer hard disk for software operation
3. Space requirements of computer hard disk for storing patient’s data

6.1.2 Environment Requirements of Ambulatory Blood Pressure Analysis Software

1. The software should be placed in a relatively dry and clean room.

2. Avoid exposure to magnetic, shock, moisture and direct sunlight environment.

3. Attention to electrostatic protection. The static electricity of body can reach several thousand volts. If the static electricity is applied to the software, it will affect the normal operation of the software even damage the electronic components. Therefore, it is recommended that the staff chair and foot need to use anti-static mat before installing the software, and the room should maintain a certain humidity which can prevent static interference.

6.2 Startup the Software

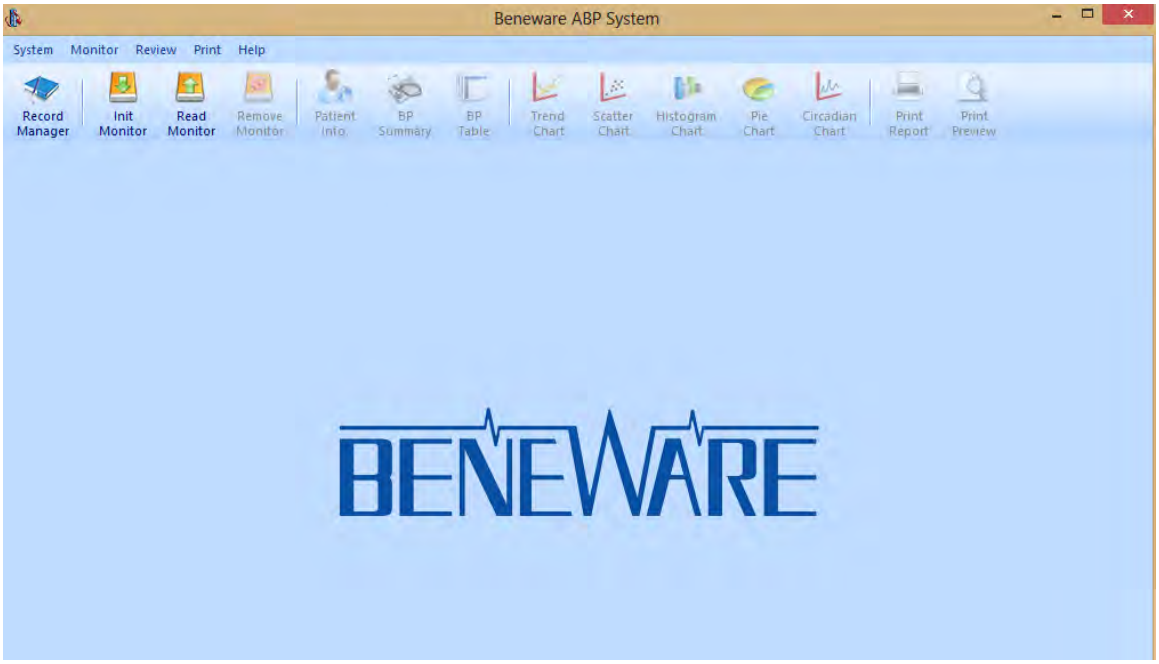
1、 Power on the host and enter the Windows operating software interface.

⚠Caution⚠:

- **The power connected to PC is required to meet the safety specifications prescribed by the standards EN60601-1.**

2、Double-click the icon“  ” on the desktop and open the software.

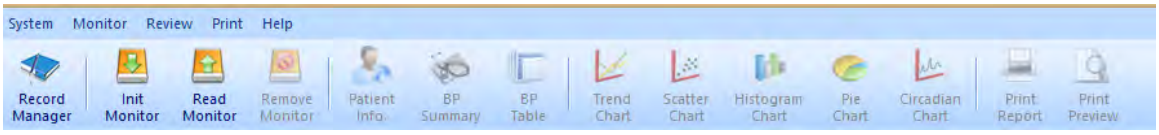
3、 After starting the software, the main interface of the software shown in the following figure will appear.



6.3 Introduction of the Main Interface

The function of main interface can be summarized into the following four areas: the menu bar, toolbar, information area and status bar (from top to bottom).

The toolbar contains four functional groups with a total of 14 buttons, namely: open; initialize the device, reading data, eject the device; patient information, summary data, blood pressure list; trends charts, relevant charts, histograms, pie charts, circadian rhythm; print the report, and print preview.



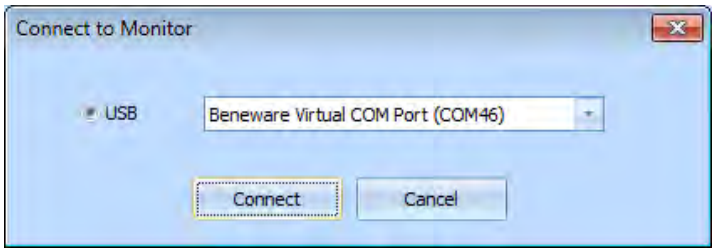
The function of button in the toolbar is shown in the following table:

Function Group	Button	Function Introduction
File	**open**	Open the blood pressure record
Device	**initialize the device**	Fill in the patient information and initialize the recorder
	read data	Read the patients' data
	eject the device	Eject the device which will establish a connection
View	**patient information**	Observe or modify patient information
	summary data	Aggregated results of blood pressure data
	blood pressure list	Record list of blood pressure
	trends charts	Trends charts of blood pressure
	relevant charts	Relevant charts of blood pressure
	histograms	Histograms of blood pressure
	pie charts	Pie charts of blood pressure
	circadian rhythm	Circadian rhythm of blood pressure
Print	**print report**	Print report
	print preview	Print preview

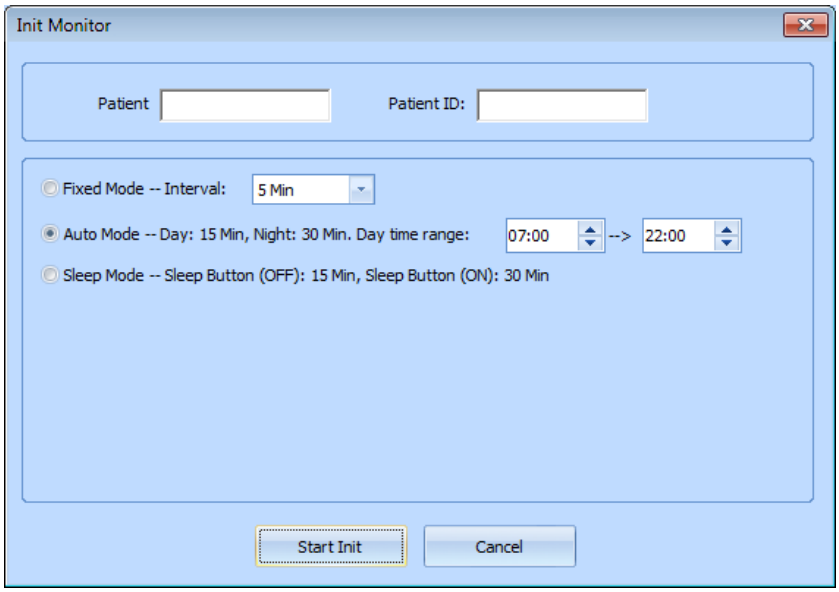
6.4 Initialize the Monitor

1) Connect the monitor with PC.

2) Press button for about 3 seconds to enter USB communication mode. Click "**Init Monitor**". The following interface will appear and then click "**Connect**".



3) Input patients' information. After choosing and setting the measurement mode, click "**Start Init**". After the software points out initialization is completed, click "**Ok**".



Caution :

- High frequency of use may cause congestion of measurement site. In auto mode, the default measurement interval of the monitor in the day is 15 minutes while at night is 30 minutes each time. It is recommended that user had better choose reasonable use frequency under the guidance of doctor.

4) Choose "**Remove Monitor**" and end data connection between the monitor and PC. Press button for about 3 seconds to quit USB communication mode and remove the data wire.

6.5 Work Steps of the Monitor

6.5.1 Preparations

To ensure the reliability of the equipment, please make the following preparations before use:

1. **Check limb and select the appropriate portion of the upper arm for blood pressure measurement.** Sleeves shall not be bounded on the incomplete skin or damaged tissue site. Cuff can not be tied to the limb for intravenous infusion, or other position whose circulation is impaired or damaged;

⚠ Caution ⚠:

- Using the inflatable cuff for blood pressure measurement will exert the patient a certain pressure on the measurement site. Doctor should refer the actual situation of the patient to decide whether the patient is suitable for blood pressure measurement;
- This monitor does not apply to people who is suffering from sickle cell disease, has occurred or is expected to occur skin lesions.
- Since the limb with bundled cuff has risk of hematoma , it is necessary to judge whether the automatic blood pressure measurement is applicable for users with severe thrombotic disorders by observing the clinical circumstances;
- Patients who are suffering from severe blood circulation disorders or blood diseases should use this device under the guidance of a doctor;
- Do not install cuff on the body with intravenous infusion or catheter. When the cuff is aerated, the infusion is slowed or blocked, which may cause tissue damage around the catheter;
- Do not use the cuff to make a blood pressure measurement on the arm on the side of a mastectomy;
- Do not use monitoring equipment simultaneously on the same limb;
- Do not squeeze the windpipe on the cuff;
- Make sure that the windpipe connecting blood pressure cuff and the monitor is not tangled;

- In the automatic measurement mode, the friction between cuff and limb may cause purpura, ischemia and nerve damage if the time is too long. Therefore, it is necessary to check the patient's distal color, warmth and sensitivity frequently. If any abnormality is observed, the cuff should be placed in another location or stop blood pressure measurement immediately;
- Only use attachments specified by the manufacturer. Using other accessories may cause damage to the monitor or not achieve the desired effect claimed in this specification.

2. Check the cuff. If the cuff is aging, tearing or appears closed lax, obstruction, signs of material deterioration or visual pollution, it should be replaced. Squeeze the air out of the cuff and tie to the patient's arm;

3. Connect cuff, air tube and the interface of ambulatory blood pressure monitor accessory. Make sure that the connection is reliable and completely closed to ensure the airline's patency;

4. For patient whose cuff is worn on the upper arm, make sure that the marker Φ on the cuff has matched the position of artery. The cuff used for measurement applies to patient whose arm circumference between 24~32cm.Do not wrapped the limb too tightly, or it may cause discoloration, limb ischemia;

5. Connect ambulatory blood pressure monitor and ensure a full charge;

6. Before using the monitor, the patient's posture is recommended as follows:

⑴ comfortably seated

⑵ legs uncrossed

⑶ feet flat on the floor

⑷ back and arm supported

⑸ middle of the cuff at the level of the right atrium of the heart

7. Users are responsible for reading instruction manual or consulting with the company before using equipment to confirm the matchability between cuff

and equipment.

To ensure the correction of measurement results, it is recommended:

(1) The air tube should not be bent in any position when the patient places the cuff. Therefore, air tube should be in the upper arm extension projecting upward. The placement of air tube should ensure an unrestricted movement of the arm;

(2) The lower edge of the cuff locates at about 2 cm above the elbow position of the patient;

(3) The cuff should contact arm closely. The gap between the cuff and the arm should be able to insert a finger;

(4) 5 min should elapse before the first reading is taken and patient should not talk during the measurement procedure;

(5) Medical staff conduct a manual measurement to confirm whether the installation of ambulatory blood pressure monitor and accessory is successful.

⚠ Caution ⚠:

- Remain the cuff at the same level with the position of user's heart, otherwise it will affect the results of blood pressure measurement;
- Make sure that the monitor is placed in the professional portable package when patients use the monitor;
- The results can be affected by patients' physiologic condition or exercise. Keep the body in a quiescent state in the process of blood pressure measurement, otherwise it will affect the accuracy of blood pressure measurement;
- Use the cuff correctly in accordance with the mark on it. Marker line of the cuff must be in the range of markup;
- To ensure the accuracy of the measurement, calibration of the monitor should be performed once a year;
- Diabetes, high cholesterol, high blood pressure disease will accelerate atherosclerosis, or even lead to peripheral circulation disorders. If the blood pressure values are abnormal, please consult a doctor promptly.

6.5.2 Some Other Recommendations for Patients

During the monitoring period, it is recommended that:

- Wear loose, comfortable tops or shirt.
- Avoid swimming and bathing during monitoring.
- Since vibrations may affect ambulatory blood pressure measurements, operating heavy equipment or power tools should be avoided.
- Press the function key 1  in the process of blood pressure measurements will cancel the current blood pressure monitoring .Then the cuff will deflate.
- Do not touch or squeeze the cuff and pipe in the process of blood pressure measurement.
- Be careful not to disconnect the pipe when patients disrobe at bedtime.
- Patients can make another manual blood pressure measurement if headache, dizziness or other symptoms appear.
- Driving or taking cars is not recommended.
- Intense emotions will increase the blood pressure. Patients should not make a measurement in a state of tension.
- Please keep quiet and do not talk while the monitor is working.
- Do not remove the cuff.
- Do not wet the monitor.
- Do not remove the battery from the monitor.

6.5.3 Cuff Usage

The cuff is used as follows：

1. Confirm the cuff is deflated completely;
2. Place the cuff in the position close to the patient's upper arm and guarantee the mark on the cuff is right above the proper artery;
3. Cuff wrapping should be tied tight, however, some gaps need to be left to prevent venous reflux during the monitoring period;

⚠ Caution ⚠:

- Improper placement of cuff may affect the accuracy of measurement.
- The limb used for manometry should be placed on the same level with the patient's heart position.

6.5.4 Monitor Start

1) Open the battery cover, install two AA batteries and cover them to guarantee normal starting of the device.

2) Connect the connector of the cuff with the air nozzle of the monitor. The monitor will carry out work according to the set measurement mode.

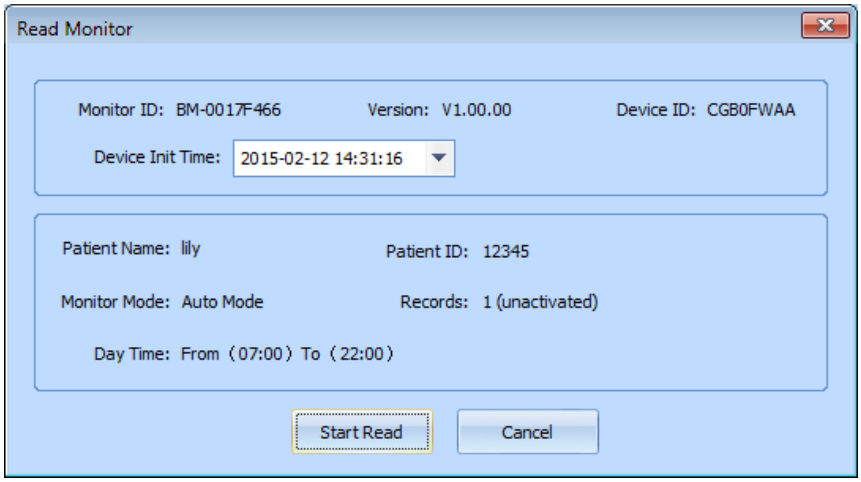
3) After measurement, take down the cuff and the monitor from patients and take out the batteries.

6.6 Data Playback

1) Connect the monitor with PC.

2) Press  button for about 3 seconds to enter USB communication mode. Open the ABPM software and click "**Read Monitor**". Choose the corresponding USB interface of the monitor and click "**Connect**".

3) Confirm registered information of patients and click "**Start Read**".



4) After reading data, choose "**Remove monitor**" and end connection between

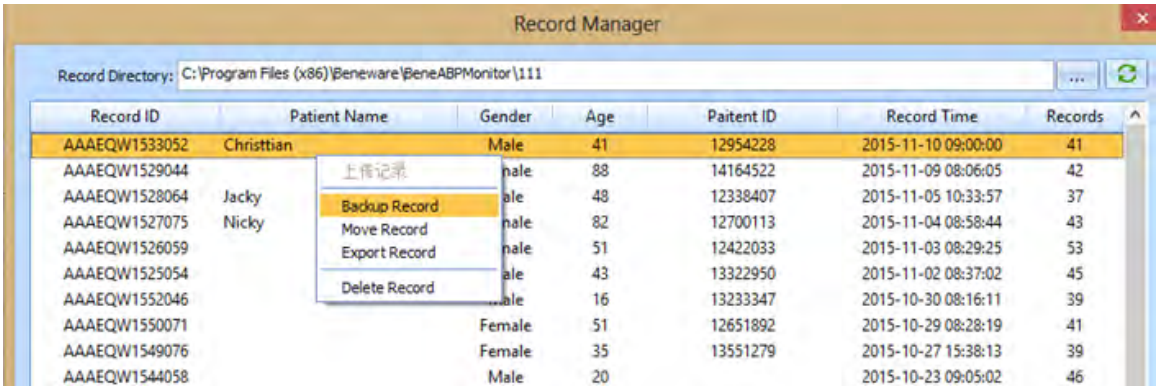
the monitor and PC. Press  button for about 3 seconds to quit USB communication mode and keep the monitor and the cuff in a safe place.

6.7 Data Analysis

6.7.1 Open Blood Pressure Record

Click the button" 

" in the toolbar to pop up record management dialog which is shown in the chart below.



Click the **[...]** button on the top right of the screen to pop up the "**Browse for Folder**" dialog box. After selecting the folder and clicking "**OK**" button, you can switch record folder path. In this case, the list of records will be updated.

Select a record and right-click the record list, a drop-down menu shown in the above illustration will pop up: backup record, remove record, export record, delete record.

（1）Backup Record

Click "**Backup Record**" will pop up "**Browse for Folder**" dialog box. Select the destination folder to be backed up and click on the "**OK**" button will save the data files to the selected backup files folder.

（2）Remove Record

Click "**Remove Record**" will pop up "**Browse for Folder**" dialog box. Select the destination folder to be transferred and click on the "**OK**" button will remove the records files from the current folder to the selected folder. In this case, the record in

the list will disappear.

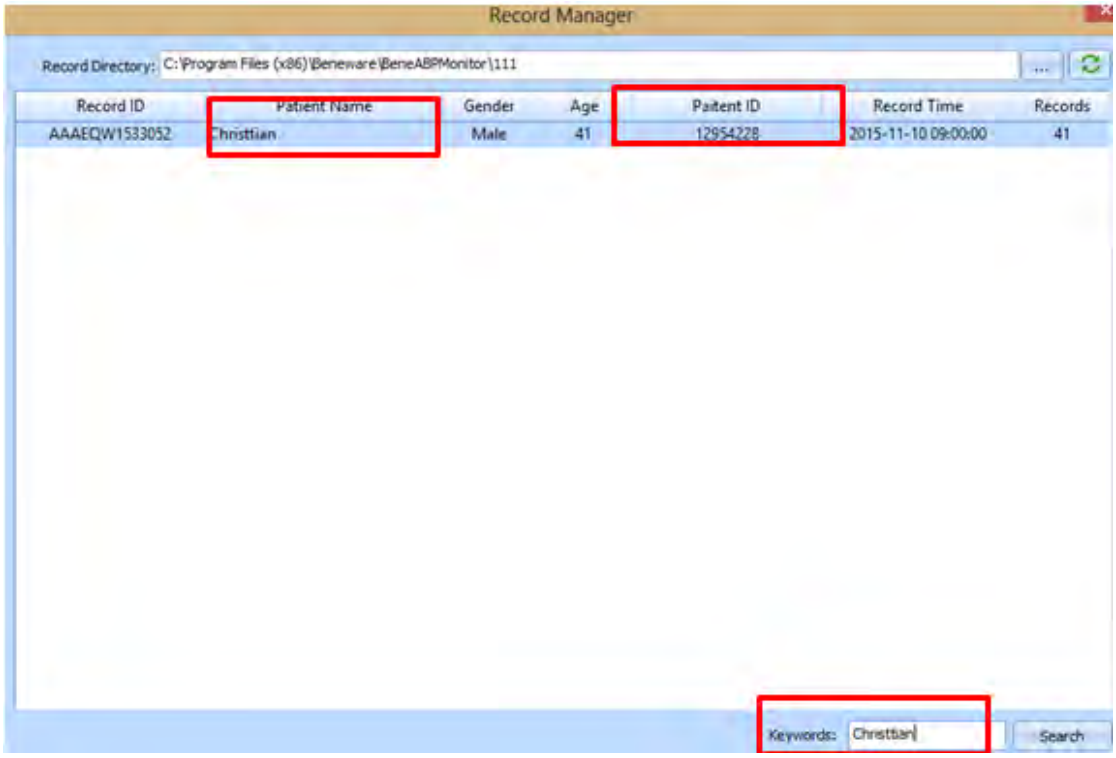
（3）Export Record

Click the "**Export Record**" will pop up "**Save As**" dialog box. Select the destination folder you want to export and click the "**Save**" button will save the current blood pressure inventory data to the selected folder in the form of excel.

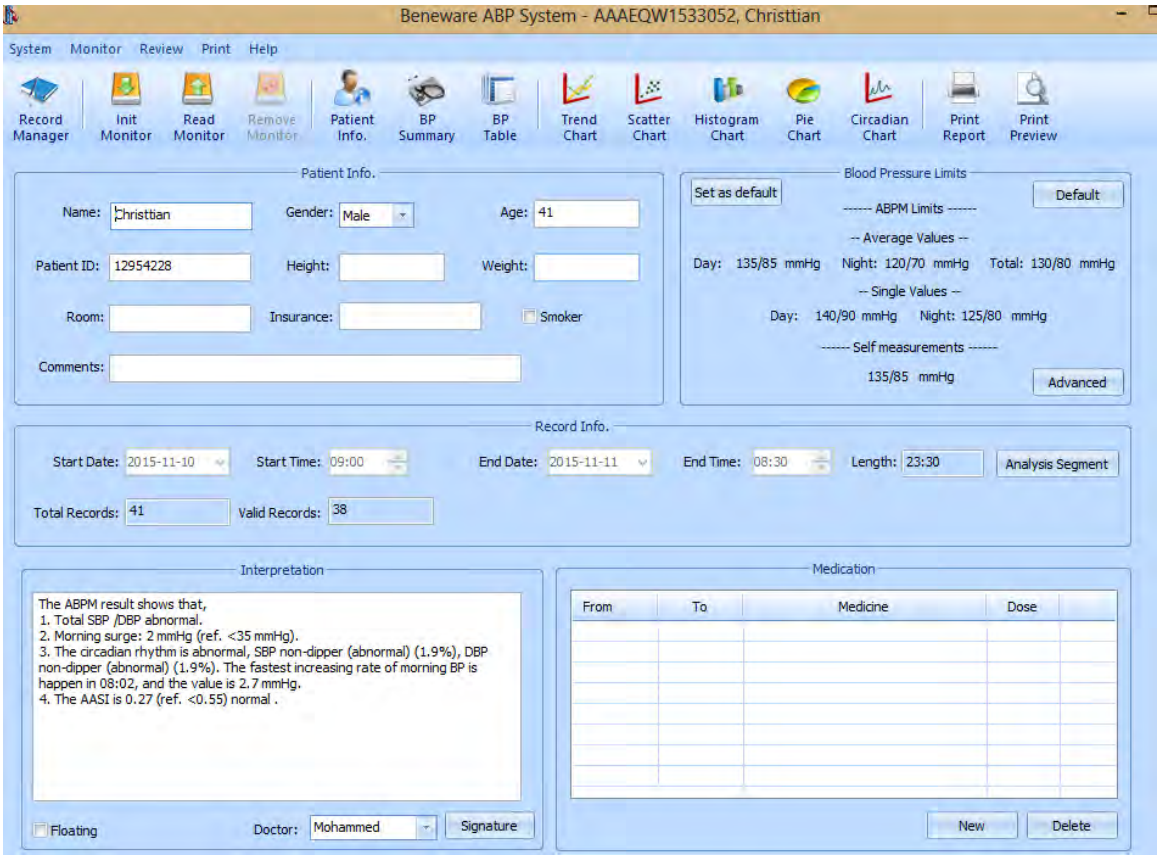
（4）Delete Record

Click the "**Delete Record**" will delete data documents of the record. In this case, the record in the list will disappear.

Entering a keyword at the lower right corner of the "**records management**" dialog box and clicking on the "**Find**" button will get matched keyword in the "**patient's name**" and "**patient ID**" from the record list.



Double-click a selected record to open record data. Meanwhile, the software enters the "**Patient Information**" interface automatically which is shown in the following figure.



6.7.2 Patient Information

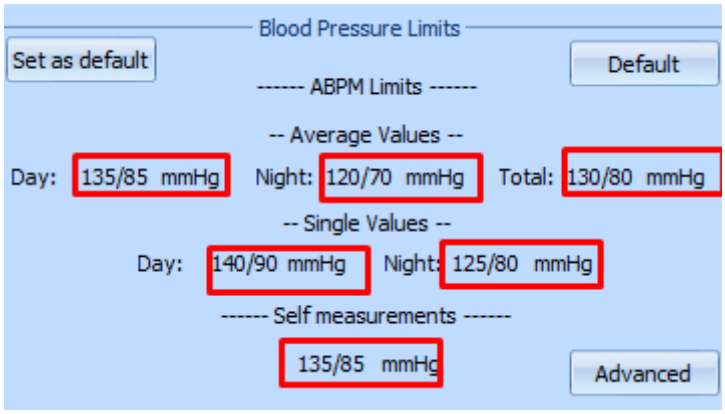
As shown above, the patient information interface is divided into five sections: patient information, normal range of blood pressure, recording information, medication and conclusions. Patient information, normal range of blood pressure as well as the analysis range can be modified.

（1）Patient Information

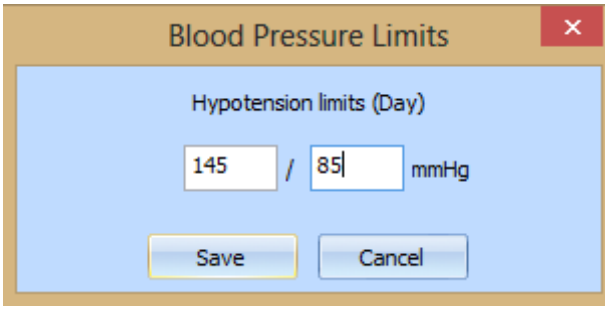
The section is used to fill in the patient information.

（2）Normal Range of Blood Pressure

The value of normal reference range in the ambulatory blood pressure monitoring of average, single measurement and manual measurement can be set as shown in the figure below.

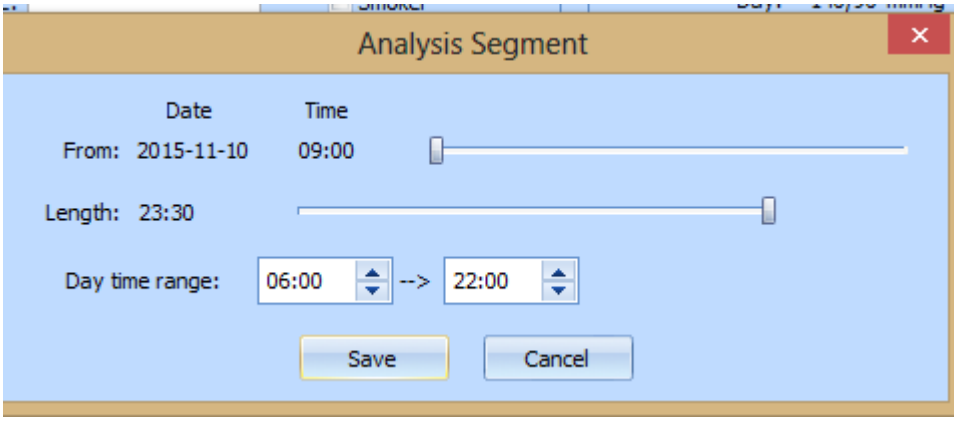


Left-click on the tagged value shown in the above figure will pop up "**normal blood pressure**" dialog box. For example: click the value "**145/85**" in "**Mean / day**" will pop up the setting dialog box of average blood pressure normal range during the day. Change the value in the input box and click on "**save**" button will modify the normal range of average blood pressure during the day.



（3）Record Information

As shown in the chart below, record information shows the related information of the current record. Click "**analysis section**" button will pop-up "**analysis section**" dialog box. The start time and duration of record during analysis can be changed by dragging the slider.



（4）Treatment

Remark the patient’s medication information. User can add new information or delete the original treatment information through the "**add**" and "**delete**" button.

（5）Conclusions

After analyzing the blood pressure by software, user can make a diagnosis by referencing the findings and fill in the diagnostic information.

In the "**Patient Information**" screen, user can change the analysis results of patient's blood pressure by setting the normal range of blood pressure and analysis section, which will be reflected specifically in the data summarization, blood pressure list, trends, correlation charts, histograms, pie charts and circadian rhythm. At the same time, patient information, medication, conclusions and other information will be displayed in the report printed.

6.7.3 Data Summarization

Click the button " 

"to enter the interface of data summarization which is shown in the following figure.

Total (2015-11-10 09:00 --> 2015-11-11 08:30)

	Min	Average	Max	STDEV	CV
SBP (mmHg)	134 (11:30)	154 < 130	194 (09:01)	11.21	0.07
DBP (mmHg)	73 (10:00)	106 < 80	144 (09:01)	12.42	0.12
MBP (mmHg)	98	123	157	10.04	0.08
HR(BPM)	58 (10:00)	94	122 (07:00)	16.37	0.17

Above limits (SBP): 93.8% Above limits (DBP): 93.8%

Nocturnal reduction rate - SBP: 1.9% DBP : 1.9% Morning BP: 150/112 mmHg

Total Records: 41 Valid Records: 38 Valid percents: 92.7% (>90%)

Day (06:00 --> 22:00)

	Min	Average	Max	STDEV	CV
SBP (mmHg)	134 (11:30)	155 < 135	194 (09:01)	11.12 < 17	0.07
DBP (mmHg)	73 (10:00)	106 < 85	144 (09:01)	11.63 < 13	0.11
MBP (mmHg)	98	123	157	9.73	0.08
HR(BPM)	58 (10:00)	97	122 (07:00)	15.38	0.16

SBP > 140 mmHg: 90.9% (<25%) DBP > 90 mmHg: 90.9% (<25%)

Total Records: 33 Valid Records: 31 Valid percents: 93.9%

Night (22:00 --> 06:00)

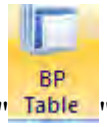
	Min	Average	Max	STDEV	CV
SBP (mmHg)	136 (04:00)	152 < 120	169 (23:00)	11.34 < 13	0.07
DBP (mmHg)	82 (02:00)	104 < 70	128 (23:00)	15.35 < 10	0.15
MBP (mmHg)	109	125	143	11.06	0.09
HR(BPM)	64 (04:00)	84	110 (23:00)	16.48	0.20

SBP > 125 mmHg: 100.0% (<25%) DBP > 80 mmHg: 100.0% (<25%)

Total Records: 8 Valid Records: 7 Valid percents: 87.5%

The interface displays the analysis results of blood pressure in the whole day, daytime and nighttime.

6.7.4 List of Blood Pressure Record

Click the button " 

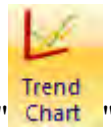
"to enter the interface of list of blood pressure record which is shown in the following figure.

No.	Date	Time	SBP	DBP	MBP	HR	State	Exclude	Comment
1	2015-11-10	09:00	168	113	136	118	Moderate artifact	-	Manual
2	2015-11-10	09:01	194	144	157	117	Idle	-	
3	2015-11-10	09:30	140	90	121	120	Heavy artifact	-	
4	2015-11-10	10:00	151	73	98	58	Heavy artifact	-	
5	2015-11-10	10:30	155	106	119	101	Moderate artifact	-	
6	2015-11-10	11:00	144	102	116	90	Idle	-	
7	2015-11-10	11:30	134	86	112	70	Idle	-	
8	2015-11-10	12:00	134	94	112	97	Moderate artifact	-	
9	2015-11-10	12:30	157	110	120	106	Idle	-	
10	2015-11-10	13:00	156	99	110	102	Heavy artifact	X	
11	2015-11-10	13:30	154	99	111	105	Heavy artifact	-	
12	2015-11-10	14:00	154	99	111	106	Heavy artifact	-	
13	2015-11-10	14:30	160	113	125	99	Moderate artifact	-	
14	2015-11-10	15:00	160	103	124	76	Idle	-	
15	2015-11-10	15:30	160	104	122	89	Heavy artifact	-	
16	2015-11-10	16:00	144	102	125	82	Idle	-	
17	2015-11-10	16:30	160	116	127	104	Idle	-	
18	2015-11-10	17:00	163	112	129	98	Idle	-	
19	2015-11-10	17:30	0	0	0	0	Error, Code: 5	x	
20	2015-11-10	17:33	151	103	126	94	Moderate artifact	-	
21	2015-11-10	18:00	158	112	129	112	Idle	-	
22	2015-11-10	18:30	147	100	116	101	Moderate artifact	-	
23	2015-11-10	19:00	159	107	121	96	Heavy artifact	-	
24	2015-11-10	19:30	160	111	126	98	High artifact	-	
25	2015-11-10	20:00	158	110	125	106	Heavy artifact	-	
26	2015-11-10	20:30	158	110	125	114	Heavy artifact	-	
27	2015-11-10	21:00	164	111	129	106	High artifact	-	

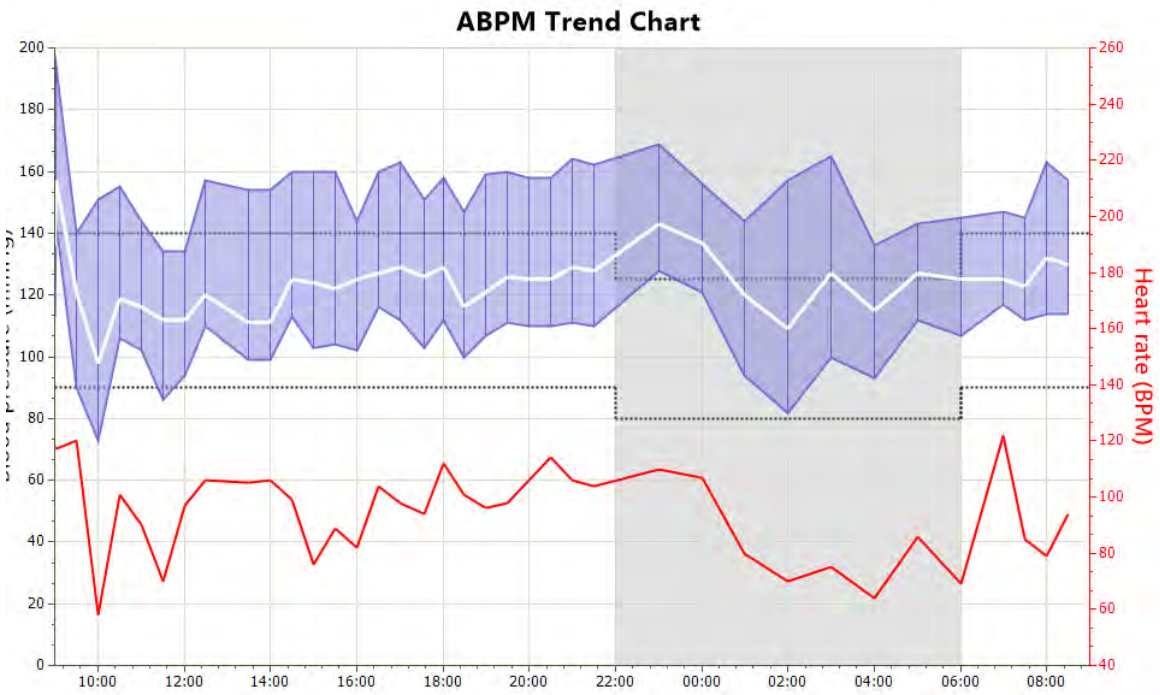
The interface of "**List of Blood Pressure Record**" records the blood pressure values in each period of time (starting time of analysis can be set in the "**Analysis Section**" of patient information interface).In the list of blood pressure record, data in red background indicates that blood pressure is out of the normal range (reference value is set in "**Normotensive Range**" in patient information interface). Data in gray background is the blood pressure data in nighttime while data in white background data is blood pressure data in daytime (the start time of day and night can be set in" **Initialize Device**").

Click the "**Exclusion**" column will make "-" into "×", which will dimmed and abate the data. Then click again will change "×" back to "-"and the data become active. "**Exclusion**" operation will affect the analysis results of recorded data.

6.7.5 Trend Chart

Click the button " 

"to enter the interface of trend chart which is shown in the following figure.

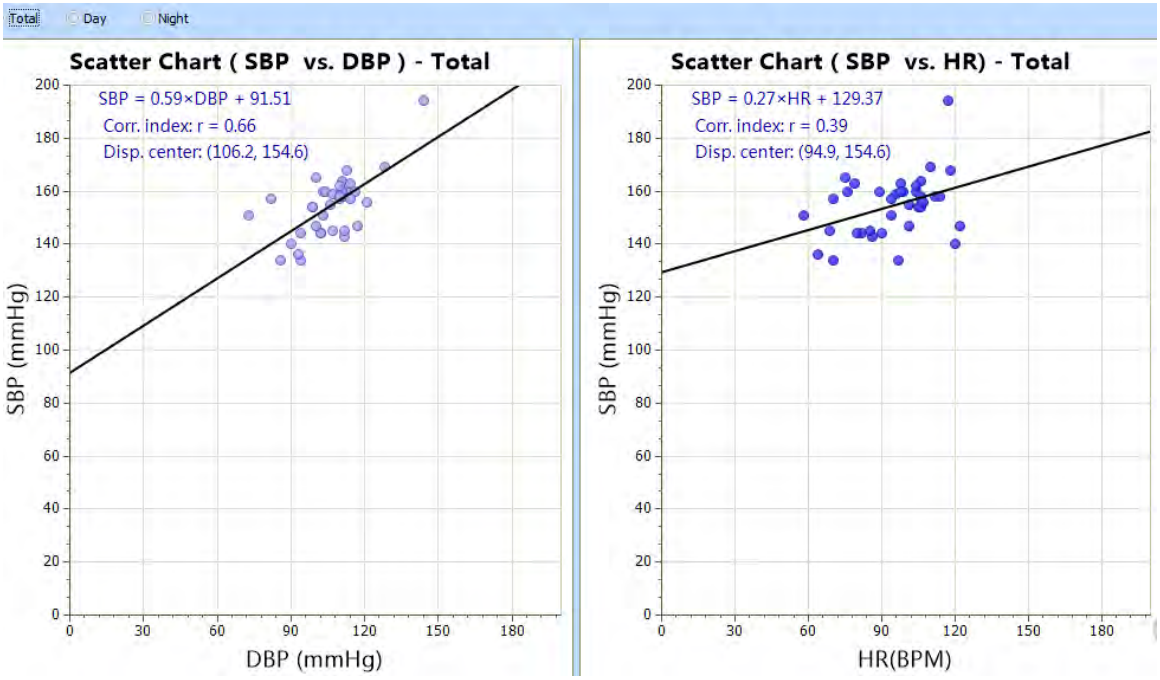


Trend chart of blood pressure reflects the tendency of systolic, diastolic, average pressure and heart rate in the corresponding time in the list of valid data. Click in the plot will appear a defining line, which marks the status, systolic blood pressure, average pressure, diastolic blood pressure and heart conditions at the moment of time.

6.7.6 Correlogram

Click the button " 

"to enter the interface of correlogram which is shown in the following figure.

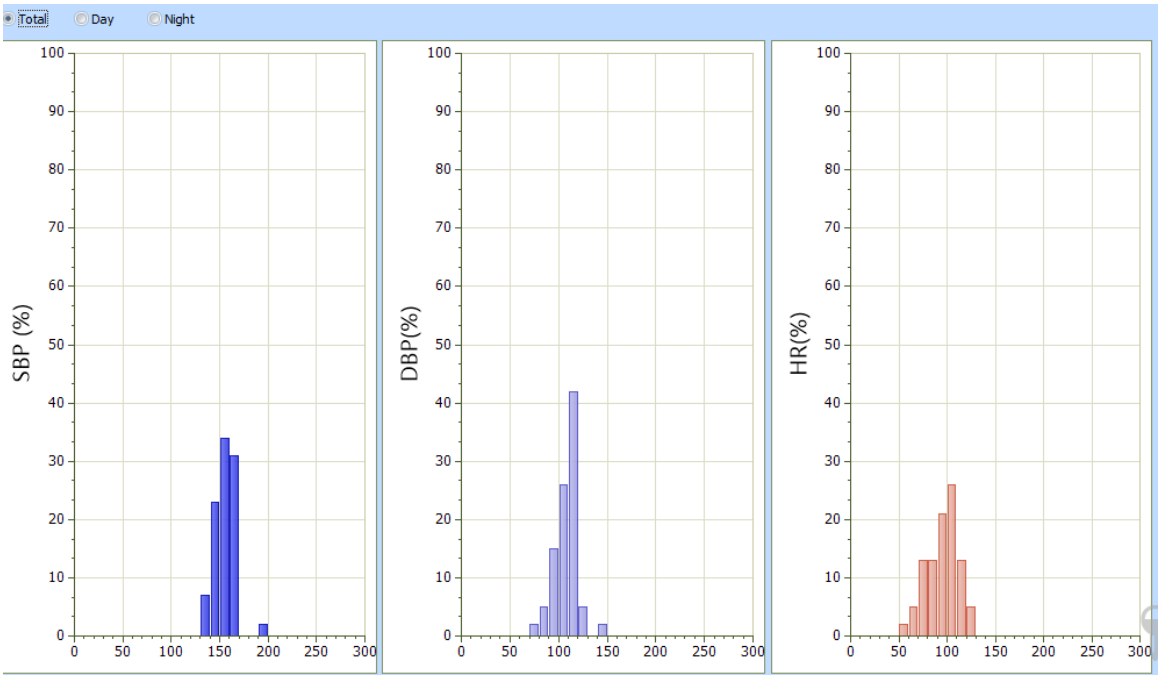


Correlogram reflects the distribution of systolic and diastolic blood pressure, as well as the distribution of systolic blood pressure and heart rate. This figure is mainly used as a reference to judge atherosclerosis.

6.7.3 Histogram

Click the button " 

"to enter the interface of histogram which is shown in the following figure.



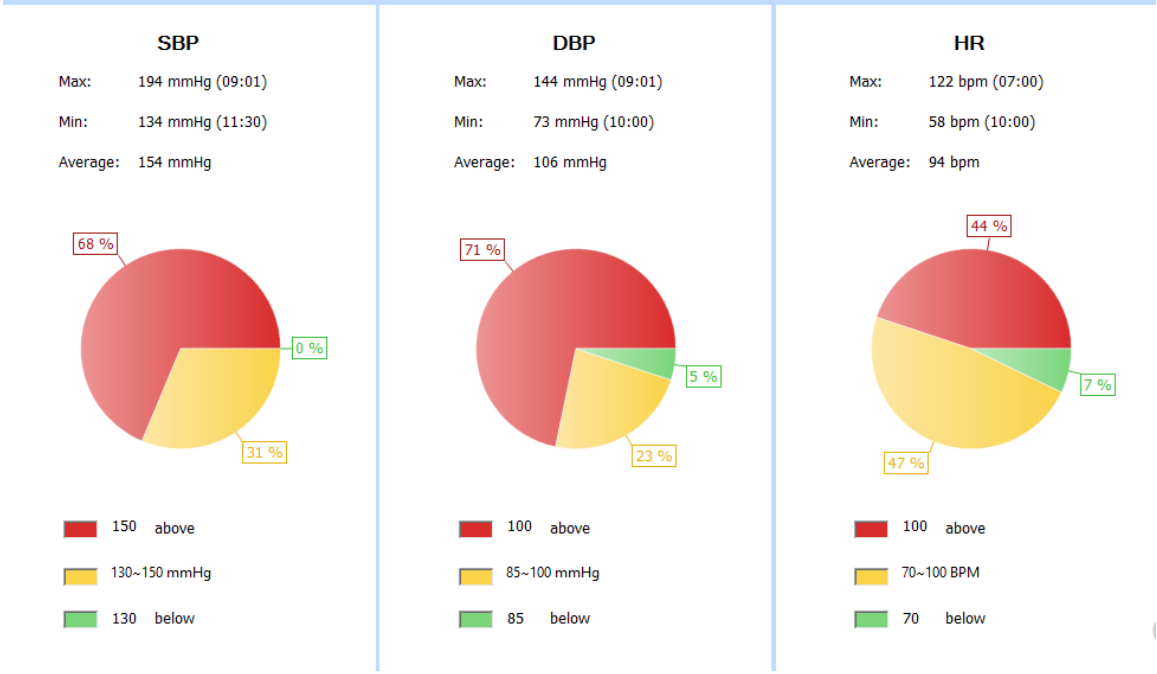
Histogram reflects the percentage distribution of systolic pressure, diastolic

blood pressure and heart rate in each range interval.

6.7.3 Pie Chart

Click the button " 

"to enter the interface of pie chart which is shown in the following figure.

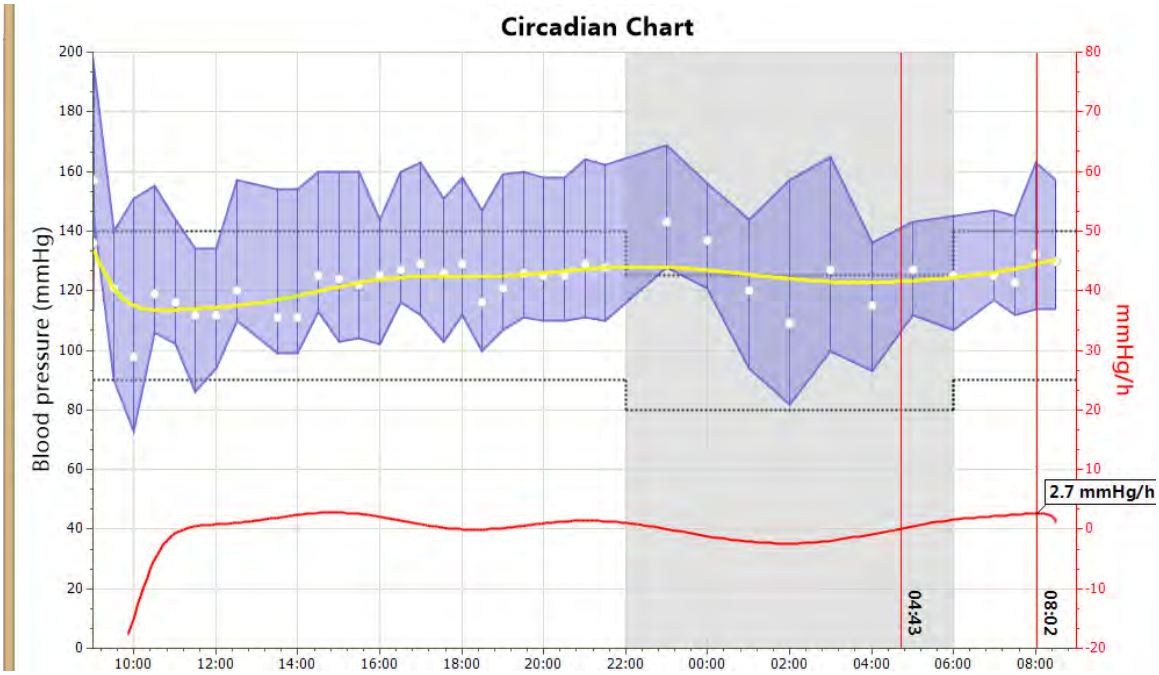


Pie chart reflects the distribution percentage of systolic and diastolic blood pressure and heart rate in different range situation intuitively. In the chart below, the range of values red and green represented can be modified by clicking the number. After modification, the red and green distribution area of the pie chart will change.

6.7.3 Circadian Rhythm

Click the button " 

"to enter the interface of circadian rhythm which is shown in the following figure.

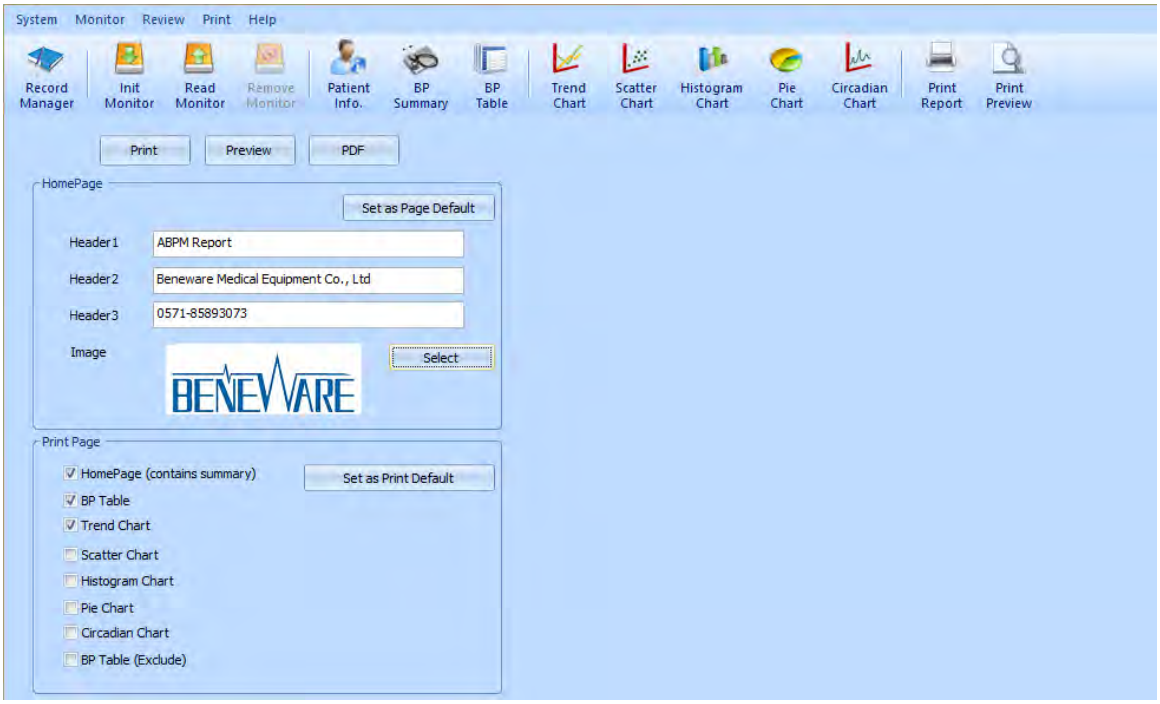


Circadian rhythm chart reflects the hourly changes in blood pressure. Therefore, you can get the dangerous period of patient's blood pressure. In this figure, yellow curve is a trend line of average pressure change; red curve represents the difference between the highest and lowest blood pressure values; three defined vertical red line shows the time zone of fastest rise of blood pressure from the night to the morning which is also called dangerous zone of patients.(in the figure: 04:33 is the starting time of dangerous zone; 08:50 is the end time; growth rate of blood pressure peaked at 07:02 when the pressure growth is 8.3mmHg/h; duration of dangerous interval is 04: 17h).

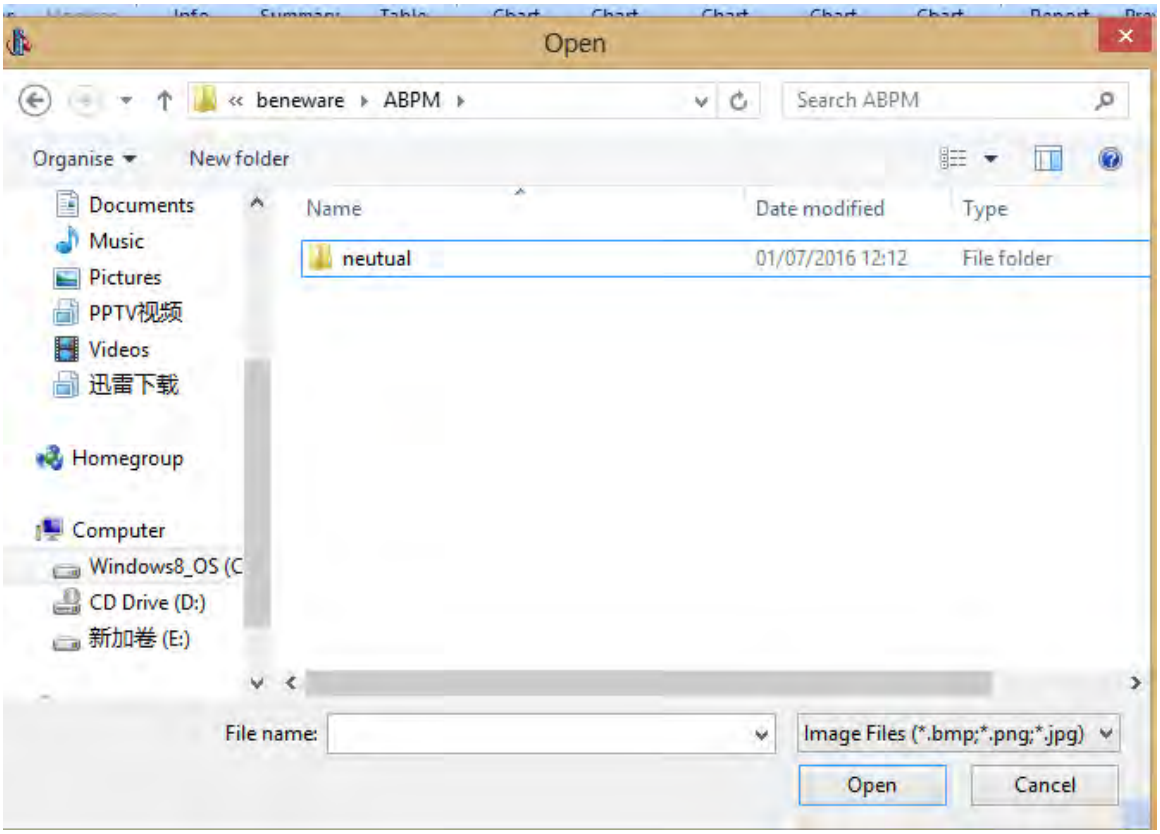
6.7.3 Print Report

Click the button " 

"to enter the interface of print report which is shown in the following figure.



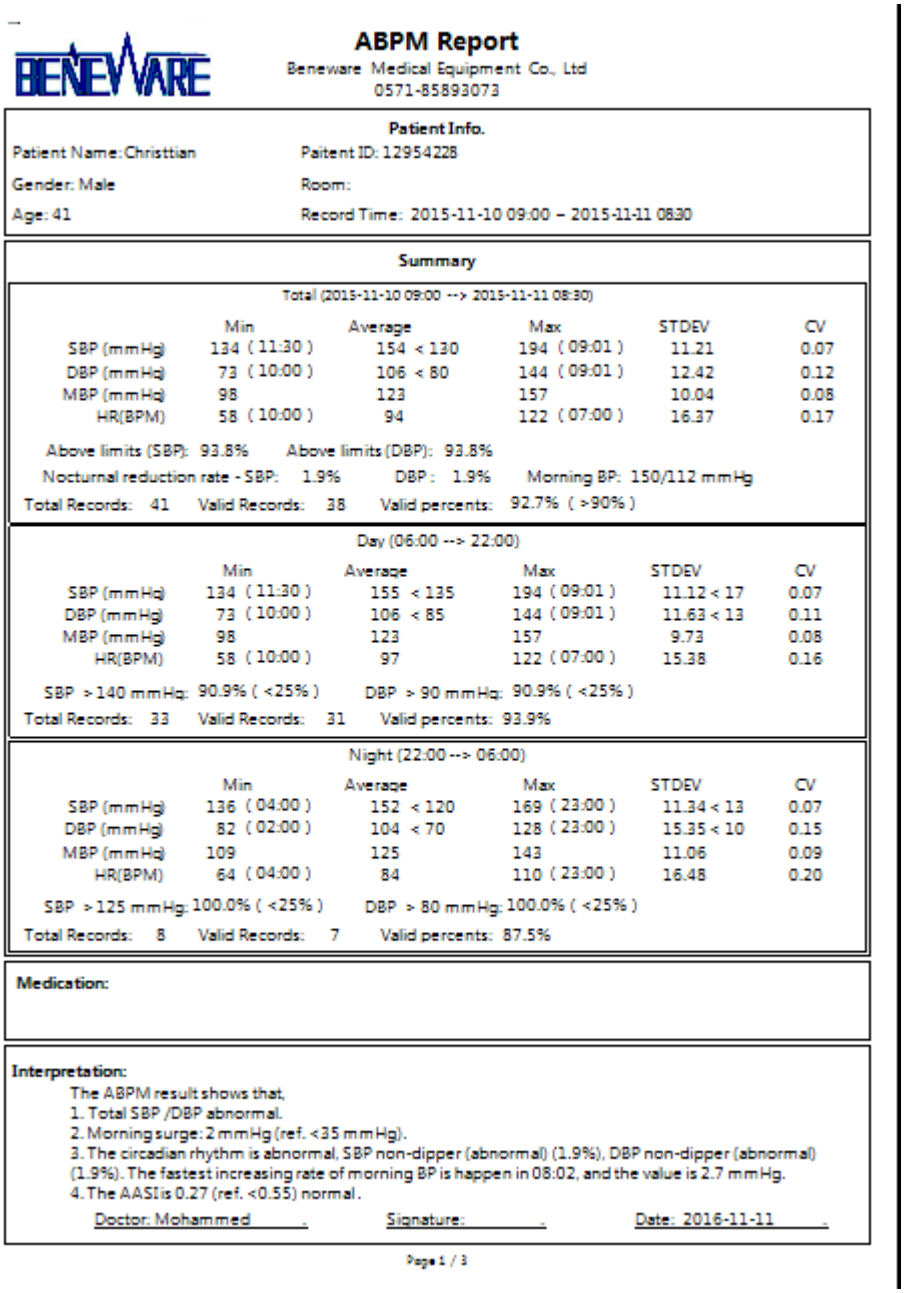
Among them, the "**Home Report**" can change page report title and image titles. Click the "**Select**" button to pop up the "**Open File**" dialog box when you want to set an image title.



Select an image file and click the "**Open**" button to set the image as a title in the report. The software supports BMP, PNG and JPG image file.

In the "**Selection of Printing Page**", you can choose the printing page. If you uncheck the options on that page, the page will not be printed.

After finishing setting, you can enter the print preview screen by clicking on the "**Print Preview**" button or "**Preview**" button in the toolbar.



ABPM Report

Beneware Medical Equipment Co., Ltd
0571-85893073

Patient Info.

Patient Name: Christtian — Paitent ID: 12954228
Gender: Male — Room:
Age: 41 — Record Time: 2015-11-10 09:00 – 2015-11-11 08:30

Summary

Total (2015-11-10 09:00 --> 2015-11-11 08:30)

	Min	Average	Max	STDEV	CV
SBP (mmHg)	134 (11:30)	154 < 130	194 (09:01)	11.21	0.07
DBP (mmHg)	73 (10:00)	106 < 80	144 (09:01)	12.42	0.12
MBP (mmHg)	98	123	157	10.04	0.08
HR(BPM)	58 (10:00)	94	122 (07:00)	16.37	0.17

Above limits (SBP): 93.8% Above limits (DBP): 93.8%
Nocturnal reduction rate - SBP: 1.9% DBP : 1.9% Morning BP: 150/112 mmHg
Total Records: 41 Valid Records: 38 Valid percents: 92.7% (>90%)

Day (06:00 --> 22:00)

	Min	Average	Max	STDEV	CV
SBP (mmHg)	134 (11:30)	155 < 135	194 (09:01)	11.12 < 17	0.07
DBP (mmHg)	73 (10:00)	106 < 85	144 (09:01)	11.63 < 13	0.11
MBP (mmHg)	98	123	157	9.73	0.08
HR(BPM)	58 (10:00)	97	122 (07:00)	15.38	0.16

SBP > 140 mmHg: 90.9% (<25%) DBP > 90 mmHg: 90.9% (<25%)
Total Records: 33 Valid Records: 31 Valid percents: 93.9%

Night (22:00 --> 06:00)

	Min	Average	Max	STDEV	CV
SBP (mmHg)	136 (04:00)	152 < 120	169 (23:00)	11.34 < 13	0.07
DBP (mmHg)	82 (02:00)	104 < 70	128 (23:00)	15.35 < 10	0.15
MBP (mmHg)	109	125	143	11.06	0.09
HR(BPM)	64 (04:00)	84	110 (23:00)	16.48	0.20

SBP > 125 mmHg: 100.0% (<25%) DBP > 80 mmHg: 100.0% (<25%)
Total Records: 8 Valid Records: 7 Valid percents: 87.5%

Medication:

Interpretation:

The ABPM result shows that,
1. Total SBP /DBP abnormal.
2. Morning surge: 2 mmHg (ref. <35 mmHg).
3. The circadian rhythm is abnormal, SBP non-dipper (abnormal) (1.9%), DBP non-dipper (abnormal) (1.9%). The fastest increasing rate of morning BP is happen in 08:02, and the value is 2.7 mmHg.
4. The AASI is 0.27 (ref. <0.55) normal.

Doctor: Mohammed Signature: Date: 2016-11-11

Page 1 / 3

In this case you can view the printed page. The report can be printed by clicking on the "**Print**" button.

7 Error and Troubleshooting

The following table lists the error messages generated by monitor and provides

solutions to these troubles.

Error Message	**Failure Analysis**	**Solutions**
LCD displays “Not Activated!”	The device is not activated	Sent the equipment back to the manufacturer's service center.
LCD displays “OVER PRESSURE” Buzzer beeps	Overpressure	Pipe may be clogged, check the pipe and re-measured
LCD displays “BATTERY LOW!” Buzzer beeps	Insufficient power supply	Use new batteries
LCD displays “RECORD FULL!”	The record is Full	Read the data and initialize the device
LCD displays “ERROR”	Heavy move	Check the patient's condition, keep the patient’s arm stationary and measure again
	The cuff is loose or not connected	Use the cuff correctly by referring to the product specification
	Leakage in the air tube	
Others	Others	Restore factory default settings

If the failures can not be solved, please contact Suzhou Bai Hui Hua Ye Precision Instrument Co., Ltd. Service Department.

8 Care and Routine Maintenance

8.1 Maintenance Cycle

For safety of the operator and the patients, it is recommended to conduct an overall maintenance and safety inspection to this product every quarter.

The monitor should be calibrated once every two years at least. Pressure calibration must be carried out by technical personnel who have had professional guidance and training.

8.2 Maintenance Measures

8.2.1 Cautions and Maintenance of Battery

As battery has self-discharge phenomenon, long term disuse will cause over discharge of the battery and thus be damaged. Therefore when this product is out of use for a long time (more than a month), the battery should be dismounted from the machine, and store in dry and cool place along with the recorder.

Immediately replace it with a new battery in case of low battery capacity.

While replacing battery, only the same type one is applicable. Please don’t put the replaced battery into fire, otherwise it may explode! Don’t disassemble the battery and don’t let metal materials contact with the electrodes!

8.2.2 Cautions and maintenance of the cuff

Users should check integrity of the cuff regularly.

For the cuff, a product which can be used repeatedly, doctors must clean it regularly (Doctors may clean it with clean water and sterilize it with hydrogen peroxide. After drying it in the air, keep it in a safe place.)

Caution: While changing accessories such as the cuff and the battery, only ones of the same model can be used.

9 Accessories and List

No.	Name	Quantity	Function and Instruction of Accessories	Remark
1	Monitor	1	ABPM monitor	
2	Cuff	1	Adult cuff	
3	CD	1	Analysis software	
4	Pouch	1	Soft pouch of the monitor	
5	User manual	1	Operating instructions of the device	
6	Qualification certificate	1	Product quality certificate	
7	Packing list	1	Packing lists of accessories and auxiliaries	

10 Warranty and After-sales Services

- When using the instrument, the user should fill out the *Warranty Card* according to the contents and send back to our company in time. On this basis, Our company will establish user archives and collect use information regularly, helpful in providing continuous and targeted high quality service to customers.
- No parts of this monitor or its accessories could be repaired by user, thus the user shouldn't dismount and repair it at will; Generally, our company won't provide circuit, working principle or other technical materials, but if the user really needs these materials, please contact with our company's Technical Department. Damaged parts may cause danger, thus it needs to be repaired or replaced with new parts immediately, please contact with Technical Service Center of our company in time. The recorder and relevant accessories are warranted according to the following stipulated terms:

Part type	Warranty period
Monitor	Two-year
Cuff	One-year
Pouch	One-year

- Our company may fulfill the warranty commitment in the forms of door to door service, telephone guidance, and express delivery to the company.
- Even within the free warranty period, the following repair will be charged:

  ①Fault or damage caused by improper use of the user;

  ②Fault or damage caused by fall while moving after purchase;

  ③Fault or damage caused by repairing, transforming, dismounting that are conducted by personnel beyond our company;

  ④Fault or damage caused by fire, natural disasters, etc. after purchase;

  ⑤Fault or damage caused by connecting to other equipment;

  ⑥The warranty sealing tape is damaged;

⑦The user smears, alters equipment serial number, lead wire serial number without being authorized.

- Our company is irresponsible for other equipment faults caused directly or indirectly by faults of this product.
- In case the warranty tag be damaged, our company is entitled to be exempted from 12-month free maintenance services.
- For charged maintenance beyond the warranty period, it is advised to continuously apply the "Maintenance Contract System". Please refer to the Technical Service Center of our company for details.
- Please use the original factory accessories while changing auxiliaries of this machine.
- The normal safety use term of monitor is five years, no contraindication.

After-sales Services

If you have any problem in application, please contact the manufacturer or the local distributor immediately.

After-sale servicing unit (manufacturer):

Suzhou Beneware Medical Equipment Co., Ltd.

Address: 7F, No.8 Building, Software Park,
Suzhou Science and Technology Town,
Suzhou, China

Post Code: 215163

Tel: +86-512-66806855 **Fax: +86-512-66806855**

Website: www.beneware.net **E-mail: service@beneware.net**

Appendix 1 Technical Specifications

Function	
Interactive Interface	LCD, Keypad
Measurement Range	Pressure: 0~299mmHg Heart Rate: 30~200bpm
Sensor Accuracy	Pressure: ±3mmHg
Method of Measurement	Oscillometry with continuous deflation
Record Capacity	200 records (ABP-010,ABP-020) 400 records (ABP-011,ABP-021)
Data Interface	USB
Physical Specifications	
Dimension	113 x 75 x 26 mm
Weight	168g without battery
Ingress Protection	IPX0
Collision	Still works in case fall on hard surface from 50mm height in any axial direction
Operating Environment	
Temperature	5°C to +40℃
Humidity	≤80% non-condensing
Pressure	800 ~ 1060hPa
Storage and Transport Environment	
Temperature	-20°C to +55°C
Humidity	≤95% non-condensing
Pressure	560 ~ 1060hPa
Battery	
Type	Two AA (LR6) alkaline or high capacity Ni-HM batteries
Supply Voltage	2.4~3.2V

Appendix 2 Electromagnetic Compatibility

An electronic device can either generate or receive electromagnetic interference. Testing for electromagnetic compatibility (EMC) has been performed on the monitor according to the international standard for EMC for medical devices (IEC 60601-1-2). This IEC standard has been adopted in Europe as the European Norm (EN 60601-1-2).

<table>
<tr><th colspan="3">Electromagnetic Emissions</th></tr>
<tr><td colspan="3">The monitor is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should assure that it is used in such an environment</td></tr>
<tr><td>Emission Test</td><td>Compliance</td><td>Electromagnetic Environment: Guidance</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Group 1</td><td>The monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The monitor is suitable for use in all establishments, including domestic establishments. The recorder has no connection to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic Emissions IEC 61000-3-2</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Not applicable</td></tr>
</table>

Electromagnetic Immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	Complies	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply line +/- 1 kV for input/ output lines	N/A	The monitor does not have AC or DC power lines.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	N/A	The CardioTrak Holter Recorder does not have AC or DC power lines.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	N/A	The monitor does not have AC or DC power lines.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Complies	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

<table>
<tr><th colspan="4">Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliance Level</td><td>Electromagnetic Environment: Guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6
Radiated RF
IEC 61000-4-3</td><td>3 Vrms 150 kHz to 80 MHz 3 V/m
80 MHz to 2,5 GHz</td><td>3 Vrms 3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of the monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance
$D = 1.2\sqrt{P}$
$D = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$D = 2.3\sqrt{P}$ 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">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 surfaces, objects, and people. Additional notes are on following page.</td></tr>
</table>

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the monitor: for equipment and systems that are not life-supporting

The monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 $D = 1.2\sqrt{P}$	80 MHz to 800 MHz $D = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $D = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12.0	12.0	23.0

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 the absorption and reflection from structures, objects, and people.

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