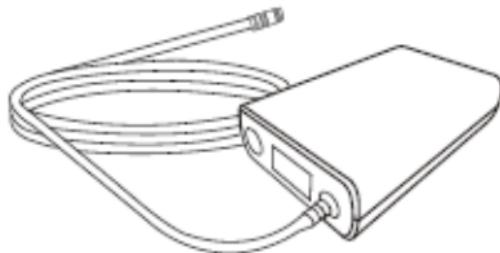


Ambulatory Blood Pressure Monitor

ABPM60



User Manual

Contec Medical Systems Co., Ltd.

Preface

Please read the User Manual carefully before using this product. The operating procedures specified in this User Manual should be followed strictly. This manual describes in detail the operation steps which must be noted, the procedures which may result in abnormality, and possible damage to the product or users. Refer to following chapters for details. Failed to follow the User Manual may cause measuring abnormality, device damage or personal injury. The manufacturer is NOT responsible for the safety, reliability and performance issues of such results due to user's negligence of this manual for using, maintenance or storage. The free services and repairs do not cover such faults either.

Caution: Please read the User Manual carefully before using this product.

For product upgrade, the device you received may not exactly in keeping with the description in this user manual, and we sincerely apologize for that.

Precautions

Please consider the security and validity before putting the product into use:

- Safety classification: internally powered, type BF
- Measurement results should be explained by professional doctor combined with clinical symptoms.

- The reliability of this product depends on whether the operator's operation is in accordance with the operating and maintenance instructions of this manual.
- The intended operator may be the patient.
- No maintenance or repair during device using.

⚠ Warning: Replacement of accessories that are not supplied by our company may result in errors. Any maintenance personnel who has not been trained by our company or other authorized service organization should not attempt to maintain the product.

Responsibility of the user

- The user should read this user manual carefully before operating, and operate it in accordance with the manual.
- Although the device has been designed with a view to safety requirement enough, the user should not neglect the state of the equipment and patient observation.
- The user is responsible to supply the use situations of device to our company.

Responsibility of Our Company

- Our company supplies the qualified product to the user in accordance with enterprise standard.
- Our company performs device repair in warranty period (a year) and maintenance after warranty period.

- Our company responds promptly to the user's request.
- Upon request, our company may provide, with compensation, necessary circuit diagrams, calibration instructions and other information to help qualified technician to maintain and repair some parts, which our company may define as user serviceable.
- Our company is responsible for safety, reliability and performance of the device only in the conditions that:

All installation, expansion, debugging, change, and repair of this device are conducted by our qualified personnel; and,

Applied electrical appliance is in compliance with relevant requirements, and the device is operated under strict observance of this manual.

This user manual is written by our company. All rights reserved.

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Chapter 1 General

- For safety use, to avoid harm or loss to user due to improper use, be sure to observe this **Safety Precautions**.
- For an overall introduction to the patient monitor, please refer to **Device Introduction**.
- For the location of each interface, please refer to **External Interfaces**.

1.1 Safety precautions

Caution

Improper use may result in personal injury or property damage.

Property damage is related to the damage of housing, family property, livestock and pets.

Contraindication

No.

Warning

For the patient with severe blood circulation disorders or blood disease, please use it under the guidance of a doctor. Extrusion of the arm during measuring may result in acute ischemia or erroneous measurement.

 **Warning** 

Noninvasive blood pressure measurements should not be made on sickle cell disease and any patient with skin damage or who is expected to be harmed.

 **Warning** 

For patients with severe coagulation disorders, the implementation of automatic blood pressure measurement shall be determined according to their clinical evaluation, because the rubbing between limbs and cuff may result in a danger of hematoma.

 **Warning** 

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

For infants or patient without the capacity of consciousness and behavior, please use the device under the guidance of a doctor. Otherwise it may cause accident or dissension.

Self-diagnosis and treatment by measure results may be dangerous. Please follow the instructions of your physician, and hand measure results to the doctor who knows your health state for diagnosis.

The device is not intended for use for other purpose except blood pressure measurements, otherwise it may result in accident or malfunction.

Please do use the specified cuff, or the measurement result may be inaccurate.

Do not leave the cuff under over-inflated state for long time, Otherwise it may cause risk.

If liquid splashes on the device or accessory especially when liquid may enter the pipe or device, stop using it and contact the service department. Otherwise it may cause risk.

The disposal of the packaging material should follow the applicable waste control regulations and keep it out of children's reach. Otherwise it may cause harm to the environment or children.

Please use specified accessories and verify if the device and accessories work safely and normally before use. If not, the measurement result may be inaccurate or cause accident.

If the device gets damp accidentally, it should be placed in a dry and ventilated place for a period of time to dissipate moisture. Otherwise the device may be damaged due to moisture.

The device should be stored or transported under the specified environment condition to avoid measurement error.

It is recommended to regularly check if there is any damage on the device or accessories, if there is, stop using it and contact the biomedical engineer of hospital or our representative institution. Do not disassemble, repair or modify the device without permission, otherwise the measurement will be inaccurate.

Measurement error may occur if the device is used on a moving platform.

Possible falling risk if the device is placed on a tilted surface.

Dispose of packaging materials, waste batteries and end-of-life products in accordance with local laws and regulations. User should perform proper treatment to the waste products and materials according to the regulations.

Replacement of accessories that are not supplied by our company may result in errors.

Any maintenance personnel who are not trained by our company or other authorized service organization should not attempt to maintain the product.

The device can only be used for one patient at a time.

If the small parts on the device are inhaled or swallowed, please consult a doctor immediately.

The device and accessories are processed with allergenic materials. If you are allergic to it , stop using this product.

This device is suitable for use with electrosurgical devices, but it should be noted that, when used in conjunction with electrosurgical equipment, patient safety must be the top priority.

Caution

This device has a certain resistance capability to electromagnetic interference, but the use of mobile phones, MRI (Magnetic Resonance Imaging) or other portable and mobile RF equipment may affect the measurement, so when using the device, these equipment should be turned off or away from the device.

The electromagnetic radiation of the device is very low, basically it will not produce energy harm to

human body, or interfere to the surrounding electronic equipment. However, the device will still produce slight electromagnetic radiation, it should keep away from high-precision required equipment.

 **Warning** 

In addition to the transducers and cables sold by our company as spare parts for the internal components of this device, the use of unspecified accessories, transducers and cables will result in increased emissions or reduced immunity to this device.

 **Warning** 

The device should not be used close to or stacked with other equipment, and if it is necessary to do so, please guarantee that the device is functioning properly in its intended configuration.

 **Warning** 

Do not modify this device without authorization of the manufacturer.

 **Warning** 

Active medical device is subject to specific EMC precautions, and therefore it must be installed and used in accordance with these guidelines.

Caution

Basic performance of EMC test: The waveform noise and measurement error in the testing can be automatically eliminated 10 s after harassment end. Before and after the test, the average error of NIBP measurement $\leq \pm 0.67$ kPa (5 mmHg), PR measurement error: ± 2 times/min.

Warning

If the device is operating below the blood pressure measurement range that described in the "Specification" section, it may result in inaccurate results.

Warning

This device may be interfered by other equipment even if other equipment meets the emission requirements of the corresponding national standards.

Caution

If the electrolyte in the battery accidentally entered the eyes, please immediately rinse with plenty of water and go the nearest hospital, because there will be the risk of blindness and other injuries.

Caution

If the electrolyte in the battery accidentally stuck to the skin or clothing, please immediately rinse with plenty of water, or it may cause skin injury.

Caution

The software was developed in accordance with IEC60601-1. The possibility of hazards arising from errors in the software program has been minimized.

All analog and digital equipment connected to this device must be certified to IEC standards(such as IEC60950: Information technology equipment-Safety and IEC60601-1: Medical electrical equipment-Safety), and all equipment should be connected to in accordance with the requirement of the valid version of the IEC60601-1-1 system standard. The person connecting the additional equipment to the signal input and output port is responsible for whether the system complies with the IEC60601-1 standard.

The software is developed in accordance with IEC60601-1-4. The possibility of risks arising from errors in the software program has been minimized.

Refer to the following chapters for the minimum value of patient physiological signals. Operating the device below the minimum value specified in the following chapters may result in inaccurate results.

1.2 Device introduction

Working environment:

Temperature:

Working: +5 °C～+40 °C

Transport and storage: -20 °C~+45 °C

Humidity:

Working: 15 %~85 %(no condensation)

Transport and storage: ≤ 95% (no condensation)

Atmospheric pressure:

Working: 700hpa ~ 1060hpa

Transport and storage: 700hpa ~ 1060hpa

Power supply: DC 3.7V

Service life: 5 years or 10,000 times of measurements (within 5 years)

Safety classification: internally powered, type BF defibrillation-proof applied part

The parts of the device (cuffs, extension tubes, enclosures, etc.) in contact with the patient are made of insulating material and the device is protected against electric shock. When high frequency or defibrillation devices are applied to the patient, no special precautions are required.

The device is suitable for adults, for dynamic NIBP monitoring, it can store up to 500 groups of data. The data can be uploaded to the computer analysis software through the interface on device back, realizing editing of data, trend graph and diagnostic information, and statistics, display, parameter settings, printing and other related processings (see the **Software Function** for details).

⚠ Caution ⚠

The monitor can not transmit measurement results in real time, the storage media within the monitor can only store one patient's blood pressure data.

1.3 External interfaces

To facilitate the operation, different interfaces are located in different parts of the monitor.

The operating button is located on the top panel of the monitor. The display of LCD screen includes: current time, the specific pressure value in the cuff, measured diastolic blood pressure, systolic blood pressure, pulse rate, mean arterial pressure and prompt information. The socket of NIBP cuff extension tube is located at the top of the device; the data playback interface is located at the bottom. Top of the device: the button, socket of cuff extension tube

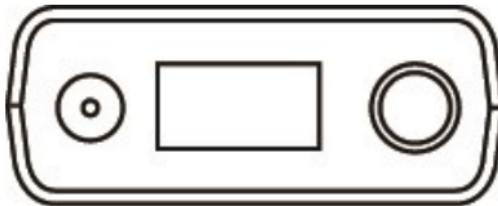


Figure 1.3.1 Top View

Bottom of the device: data playback interface

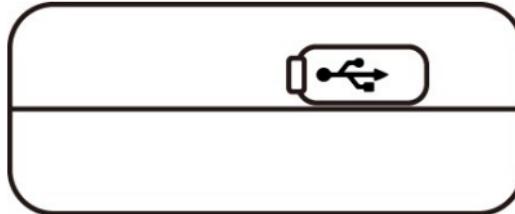


Figure 1.3.2 Bottom View

⚠ Caution ⚠

If the monitor is connected with an USB cable without measuring blood pressure, the monitor will not be able to process blood pressure measurement until the USB cable is disconnected.

When the monitor is measuring blood pressure, if a USB cable is inserted, the monitor will automatically cancel the measurement.

1.4 Accessories

Adult cuff, user manual, extension tube, bag, software,USB data line,lithium batter,Adaptor
(optional)

⚠ Caution ⚠

The device is applicable for adults only.

 **Warning** 

Please use specific accessories provided by the manufacturer, and replace the accessories according to the requirements of the manufacturer, in order to avoid injury to the human body.

 **Caution** 

- The cuff is a consumable. If measurement is taken 6 times per day (three times of every morning and evening), the service life of cuff is approximately 1 year (under our company's test conditions). To get correct measurement results, it is recommended to replace the cuff in time;
- If air leakage occurs, please contact our company to buy a new one. The separately purchased cuff does not include extension tube. Please let us know if you need the extension tube at the same time. If you do not want to buy the extension tube, please do not throw it away, and install it on the new cuff when replacing.
- Portable bag is convenient for user to carry the device. When it is slightly worn, it does not need to be replaced. User can contact our company to purchase depending on demand or when the bag is seriously damaged.

⚠ Caution ⚠

At the end of the service life, the product described in this manual, as well as its accessories, must be disposed in compliance with relative disposal regulations. If you have questions concerning disposal of the product, please contact us or representative institution.

Software information:

Name: ABPM60

Specification: No

Version: V1.0

Naming rule: V<Important enhancive software upgrades> <Enhancive software upgrades> <Corrective software upgrades> <build>

Algorithm:

Name: oscillometric method

Type: new arithmetic

Intended use: to measure blood pressure-related parameters

Clinical function: By sampling and processing the pulse signals of the patient, the algorithm calculates the value of blood pressure.

Chapter 2 Installation

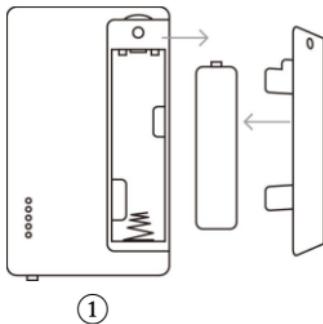
2.1 Open the package and check

Open the package and take out the monitor and accessories carefully. Keep the package for possible future transportation or storage.

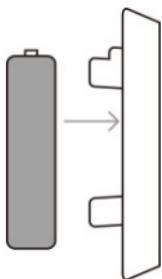
- Check for any mechanical damage.
- Check all the accessories.
- If there is any problem, contact our sales department or agent immediately.

2.2 Battery installation

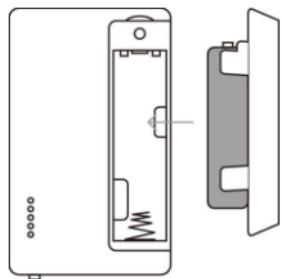
The device is power supplied by one lithium battery. Before use, the battery should be installed in the battery compartment located at the rear of the device. The operation steps are:



①



②



③

①Follow the direction of the arrow to remove the battery cover;

②Install the battery into the battery cover according to the $\oplus\ominus$ polarities;

③Close the battery cover.

Icon “

 Caution 

If the battery is unable to meet the working requirements, the device will make the low battery

prompt, and will automatically turn off if the battery power decreases continuously. Please turn off the device or take out the battery if you are not going to use the device for a long time.

 **Caution** 

If the battery reaches its service life, or battery smell, deform, discolor or distorted appears, please stop using the battery and dispose it in accordance with local regulations. Or it may cause environment pollution.

 **Caution** 

This monitor belongs to internally powered device and can not be connected to public supply network during normal operation but connected to public supply network when charging.

 **Caution** 

Please take the batteries out when not using the device.

 **Warning** 

The battery should not be replaced by inadequately trained personnel, incorrect replacement operations (such as reversed installation, the wrong type of battery installed) may result in dangers of overheating, fire, or explosion.

2.3 Startup

After the battery is installed, the device will automatically turn on, and start the measurement according to the scheme set last time.

⚠ Warning ⚠

Do not use this device for patient monitoring if it is found damaged or an error message appears, please contact your hospital's biomedical engineer or our service engineer for maintenance immediately.

⚠ Caution ⚠

Check all functions that may be used, to ensure the device functions properly.

2.4 Cuff connection

⚠ Caution ⚠

Please refer to Figure 2.4.1~2.4.2 for the correct method of cuff connection.



Figure 2.4.1 Connection between Extension Tube and Cuff

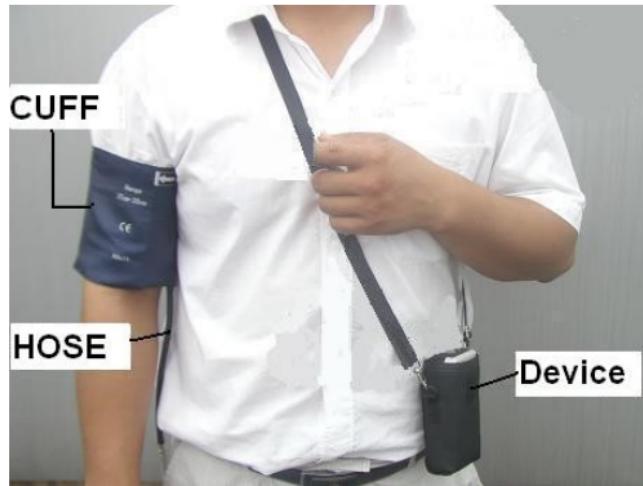


Figure 2.4.2 Wearing of Whole Device

Chapter 3 Display and Buttons

3.1 Display interfaces

Caution

For the first time of turning on the device, all displayable sections should be displayed on the screen, if any section is missing, there may be something wrong with the display screen, please contact us for maintenance.

Correctly install one lithium battery in the battery compartment of the device, and fasten the cover of the battery compartment, the device will display the system time on the screen. (This system time may not be the current correct time, it can be corrected when transmitting the measurement scheme into the device, so the device does not have the time adjustment function.)

The screen also displays the followings: the pressure value during the measuring process, the measurement result, the countdown before taking the next measurement, the battery level, and error messages.

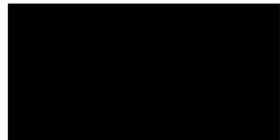


Figure 3.1.1 Main interface



Figure 3.1.2 Measurement results

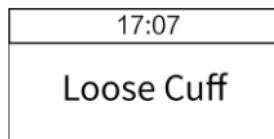


Figure 3.1.3 Error message



Figure 3.1.4 Version information

⚠ Caution ⚠

When the memory is full, the number of records displayed in the main interface is 500 in red font, and the earliest record will be overwritten if the memory overflows.

When using the USB cable to connect the device with the computer, the device displays the version information, as shown in Figure 3.1.4.

3.2 Button functions

When transmitting the measurement scheme into the device, if the “Manual Measure” switch is set to on, and press the button in the main interface, the device will start a measurement. Pressing the button again during measuring can stop the measurement. When you press and hold the button, the device will give a prompt, and if you long press the button again within 3s, it will turn off, otherwise, the device returns to the main interface.

When an error occurs during measuring, the screen will display an error message and the

buzzer will beep, as shown in Figure 3.1.3 (see section 4.3 for the explanation of error message codes).

When the measurement result is outside the set normal range, the measurement result will be displayed in red font and the buzzer will beep.

If the prompt sound switch is set to on when transmitting the measurement scheme into the device, the device will generate the prompt sound when an error message is displayed. Pressing the button can turn off the prompt sound.

Chapter 4 NIBP Monitoring

4.1 Overview

- The NIBP measurement adopts Oscillometric method.
- Measurement mode: manual/auto mode. The measured value of SYS, MAP, DIA and PR can be displayed in every mode.
- In "Manual" mode, the device only takes the measurement once.
- In "Auto" mode, the device takes the measurement circularly. Time interval can be set as 5/10/15/20/30/40/60/90/120/180/240 min.

Caution

- Do not speak or move when measuring, and avoid any muscle movements.
- Do not use any mobile devices, such as a mobile phone, near the device during measurement.
- The position of the cuff will cause changes in the measurement results.
- Do not touch the monitor, cuff and extension tube during the measurement.
- For information on contraindications for NIBP measurements, refer to section 1.1 Safety Precautions.
- The device has dual over-pressure protection function in both hardware and software, if the airbag is over inflated, the device will reset and deflate immediately. If the over inflation lasts long,

immediately disconnect the cuff from the device and cut off the power.

- Use this device in an environment where temperature and humidity are appropriate, as this may cause measurement error.
- If the measurement interval is short, please pay close attention to the battery power, and replace the battery in time when the device prompts for low battery, otherwise the 24-hour ambulatory blood pressure monitoring may not be achieved.

4.2 NIBP monitoring

⚠ Warning ⚠

Do not apply the cuff to a limb that has an intravenous infusion or catheter. This could cause tissue injury around the catheter when infusion is slowed or blocked during cuff inflation.

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

The effect of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure due to connection tubing kinking;

Due to blood flow interference, too frequent measurements can cause injury to the patient.

Need to check by observation of the limb concerned that operation of the Automated sphygmomanometer does not result in prolonged impairment of the circulation of the blood of the

patient;

Do not use the cuff on the injured area, otherwise it will cause more serious damage to the injured area.

Do not use the cuff on the site where intravascular treatment is being performed or with catheter connection, otherwise it may cause temporary blockage of blood flow and then cause injury to the patient.

Do not use the cuff on the side of the mastectomy or lymph node clearance;

The pressure by cuff may cause temporary weakness of some functions of the body. So do not use monitoring medical electrical equipment on corresponding arm.

Do not move during measuring, or the blood flow of patient may slow down.

The device needs 2 hours to recover from the lowest storage temperature to reach its performance of intended use.

The device needs 4 hours to recover from the highest storage temperature to reach its performance of intended use.

1. Insert the inflation tube to the cuff interface, connect the device to the power supply.

2. Follow the method described below to apply the cuff to the patient's upper arm.

Δ Make sure that the cuff is fully deflated.

Δ Choose proper cuff size for the patient, ensuring that the symbol φ is just above the appropriate

artery. The cuff should not wrapped too tight around the limb, otherwise it may cause extremities ischemia.

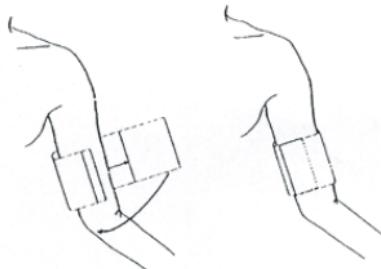


Figure 4.2 Cuff Wearing

⚠ Caution ⚠

The inflatable part of the cuff should be long enough to encircle 50~80% of the limb. Use of improper size cuffs may result in erroneous readings. If the cuff does not fit, use a relative larger cuff to reduce the error.

Cuff applicable range: 25~35cm

- 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.

- Connect the cuff to the inflation tube. 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, plus 0.75 mmHg (0.10 kPa) for each centimeter of difference.

If it is placed lower than the heart level, minus 0.75 mmHg (0.10 kPa) for each centimeter of difference.

Measurement Way:

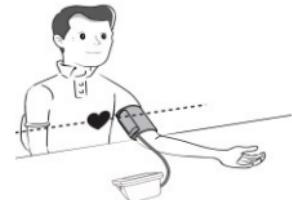
Measurement in quiet and relaxing state.

1. Adopt a comfortable sitting position, use back and arms to support the body.

2. Place your elbow on a table, the palm faces up and the body is relaxed.

3. The cuff is level with your heart.

4. Feet flat on the floor, and do not cross your legs.



⚠ Advice ⚠

Try to measure your blood pressure at the same time each day with the same arm and the same pose for consistency.

The high and low location of cuff will cause changes in measure results.

Do not touch the sphygmomanometer, cuff and windpipe during measure.

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

Remain still 4~5 minutes before measurement.

Do not talk and movement during the measurement. Relax the body, do not let the muscle activity.

Do not use precision instrument near the Sphygmomanometer.

⚠ Warning ⚠

If the time interval of ambulatory blood pressure monitoring is set too long, the patient's arm or limb wearing the cuff may appear purpura, ischemia and nerve damage. When monitoring a patient, it is necessary to often check patient's limb distal color, warmth and sensitivity. Once any abnormality is observed, change the location of the cuff or stop the measurement immediately.

⚠ Caution ⚠

If there is any doubt about the accuracy of the reading, examine the vital signs of the patient by possible means before checking the monitor's function.

⚠ Warning ⚠

If liquid is inadvertently splashed on the device or its accessories, especially when the liquid may enter the tube or device, please stop using and contact with qualified maintenance personnel.

Measurement Limitations

The oscillometric method has certain limitations depending on the patient's condition. This measurement method relies on the searching of regular pulse waves generated by arterial pressure. If the patient's condition makes it difficult to use such method, the measured value will become unreliable and the time of measurement will increase. User should be aware of that the following conditions may interfere with the measurement method, making the measurement unreliable or the measurement time prolonged. In this case, the measurement method is impossible due to the patient's condition.

■ Patient Movement

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

■ Cardiac Arrhythmia

Measurements will be unreliable or may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

■ Heart-lung Machine

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

■ **Pressure Changes**

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

■ **Severe Shock**

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

■ **Heart Rate Limitation**

Measurements can not be made if the heart rate is below 40bpm and above 240bpm.

■ **Obese patients**

The thick fat layer will lower the accuracy of the measurement, because the arterial oscillation will be hard to reach the cuff due to the damping of fat.

The BP value measured in the following situations may be different:

- After eating (within 1h), or having drinks containing alcohol, caffeine or black tea;
- After smoking, taking exercises or bathing;
- Talks or body moves during measurement;
- Patient is nervous, excited or in unstable emotion;
- Adopts wrong posture, such as bend down (lean forward) or cross legs;

- A sharp increase/decrease in room temperature, or measurement temperature changes constantly;
- Measured on a moving vehicle;
- Long term continuous measurement.

4.3 NIBP error messages and causes

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

	measuring process.	
Overpressure	Cuff pressure is over the scope, ADU 300 mmHg.	Check the cuff to make sure it is not blocked or squeezed.
Saturated signal	Movement or other factors may lead to too big signal amplitude.	Check the connection of air tube to make sure it is not squeezed. Patient should keep quiet and then take a new measurement.
Air leakage	Possible air leakage in the valve or airway	Check the air tube and the cuff.
System failure	Possible failure caused by pump, air valve or pressure sensor.	Please contact us.
It spends too much time	The time for a single measurement exceeds the maximum measurement time (adult: 180s).	Check the connection of air tube and tighten the cuff.

Chapter 5 Cleaning and Maintenance

Be sure to observe the precautions and correct use in the manual. Otherwise, our company will not assume responsibility for product quality.

⚠ Warning ⚠

- Remove the batteries before cleaning the device or peripheral equipment. The accessories must be separated from the main body and cleaned independently.
- Do not squeeze the rubber hose on the cuff.

Cleaning

- In order to prevent damage to the device, do not allow water or cleaning fluid to enter into the device socket.
- If the surface of device body, accessories and peripheral equipment get dirty, please use a dry soft cloth to wipe, do not wipe the interior of device.
- If the surface of device body, accessories and peripheral equipment are particularly dirty, use a soft cloth moistened in water or neutral detergent to wipe.

Maintenance

- Please clean the device and its accessories frequently.

The device should be inspected and calibrated regularly or according to the hospital's

inspection requirements (recommended period is 1 year). The inspection can be carried out by the state-designated inspection agency, or by professionals. The product has a static pressure detection mode for inspection. Please contact our after-sales service if you need to enter the mode.

Cleaning of Reusable blood pressure cuff

The cuff can be sterilized under high pressure in the conventional hot air oven and disinfected by gas or radiation disinfection method, or sterilized by immersing in the decontaminating solution. But remember to take away rubber bag when adopting such method. The cuff can be machine-washed and hand-washed, but can not be dry-cleaned. Hand washing may exceed its service life. Take out the rubber bag before washing the cuff and re-install it in the cuff after the cuff is washed and dried completely.

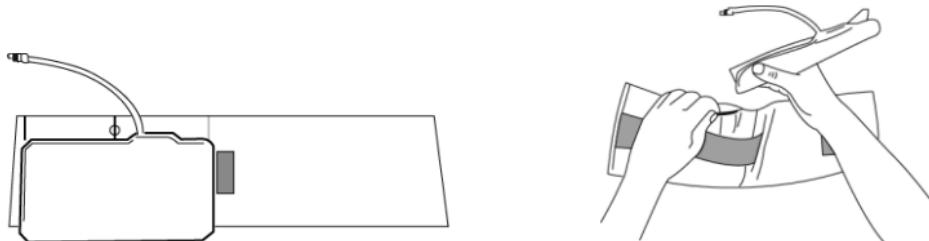


Figure 5-1 Replacement of Rubber Bag

When re-installing rubber bag in the cuff, first put the rubber bag at the head end of cuff, and in this way, rubber hose and large opening at the long end of cuff will be in a line, next vertically roll up rubber bag and insert it in the large opening of cuff, then hold the rubber hose and cuff and shake the whole cuff till rubber bag is installed properly. Lead rubber hose in the cuff and thread it through hole lining.

Storage method:

 **Suggestion** 

Do not expose the device in direct sunlight for long time, otherwise the display screen may be damaged.

The basic performance and safety of the device are not affected by dust or cotton wool in home environment, while the device shall not be placed where with high temperature, humidity or plenty of dust.

Aged cuff may result in inaccurate measurement, please replace the cuff periodically according to the user manual.

To avoid device damage, keep the device out the reach of children and pets.

Avoid the device close to extreme high temperature such as fireplace, otherwise the device performance may be affected.

Do not store the device with chemical medicine or corrosive gas.

Do not place the device where there is water.

Do not place the device where with slope, vibration or impact.

Chapter 6 Hardware requirements

CPU: 2.5GHz or higher

OS: Windows XP or higher

Memory: 1G or above

Hard drive: 250G or above

Display: 1024*768 or higher

USB: at least 2

Printer resolution: optimal 600dpi

Chapter 7 Software Functions

7.1 Registration

Double click the software icon, a dialogue box for entering user account pops up:

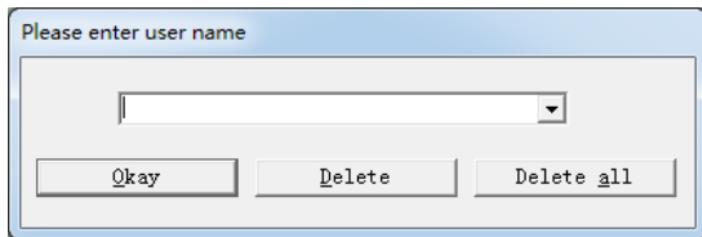


Figure 7.1 Registration

Please input your name, then click "Okay" to enter the main interface. Click "Delete", you can delete one registered user information, click "Delete all", you can delete all the registered user information.

7.2 Main interface

After finishing the registration, enter the main interface as shown below:

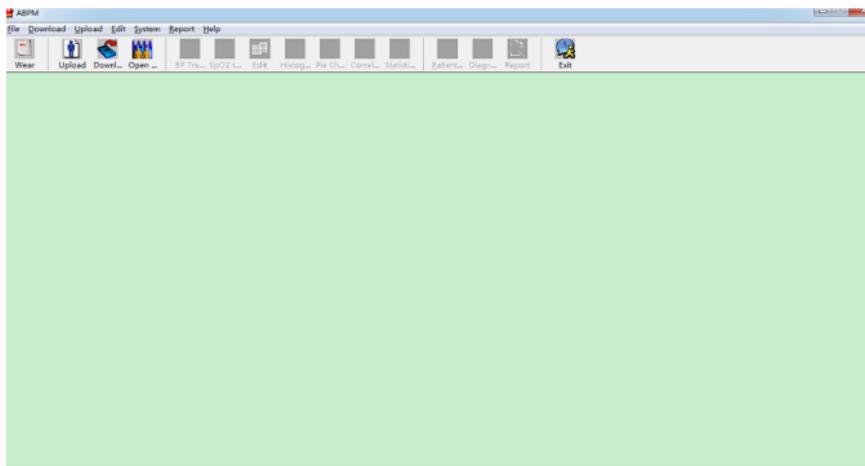


Figure 7.2 Main Operating Interface

1. Menu: The main operating menu of this software
2. Toolbar: Shortcut keys for functions of frequent use
3. The middle area is used to display graphs. After choosing the case to be edited, the data analysis graph, including trend graph, histogram, pie chart and fit line will be displayed here.

7.3 Collection scheme setup

Click the shortcut key  or  in the menu, a dialogue box "Upload Parameters" will appear:

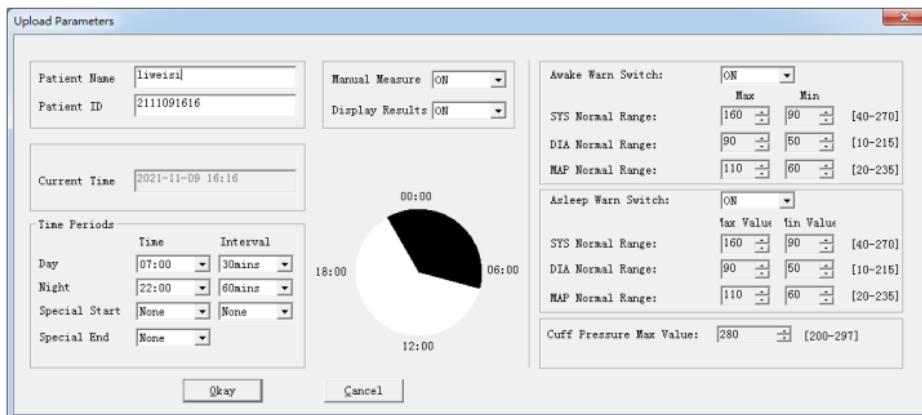


Figure 7.3.1 Setting of Collection Parameters

As shown above, doctors could set the parameter according to patient's condition and the need of

diagnosis. The monitor is able to finish the collecting task as your settings. Specific parameters are explained as follows:

Patient Name: name of the patient

Patient ID: It is an unique number used to identify the patient. The purpose is to prevent the occurrence of the same name patients.

Manual measure: to support manual collecting, which means the measurement can be achieved by pressing the button on the device.

Beep main switch: to turn on/off the master switch of prompt sound

Awake Beep Switch: to turn on/off the prompt sound when the patient is in non-sleep state, the prompt range is determined by the four parameters below

Asleep Beep Switch: to turn on/off the prompt sound when the patient is in sleep state, the prompt range is determined by the four parameters below.

Current Time: current system time.

Settings of parameters in time period:

Day: non-sleep condition of the patient;

Night: sleep condition;

Special Start and **Special End** are optional items. You can set the data collection for special time periods.

Interval refers to the time interval of collection. To minimize the impact of sleep patients, generally collection interval during sleep condition is set to be longer.

Take the above picture as an example: the range of awake time in the day is 7:00-22:00, the range of asleep time in the night is 22:00-7:00 (next day), the interval of the awake time is 30 minutes, and the interval of the asleep time is 60 minutes.

The range of daytime duration, nighttime duration and special testing duration are displayed in graphic form on the screen, which facilitates the parameter setting.

After setting the parameter, click "Okay" to upload the scheme. If the parameter is set correctly, and the monitor and computer are connected well, the data will start uploading. Uploading progress is shown as below:

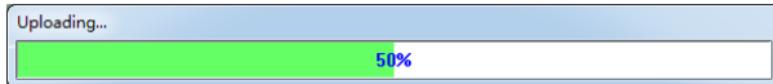


Figure 7.3.2 Uploading Progress Bar

7.4 Download

Before downloading, please make sure that:

The device has been connected to PC correctly;

The device is in power-on state;

The device is not connected  patient when connecting with the PC.

Click the shortcut key  **Down...**, or select "Download"→"Do Download" in the menu, after identifying the device, an interface for editing patient information appears on the software, in which you can edit the basic information of patients. After downloading a case, the patient information will be saved in the case file. The patient information editing interface is shown as below:

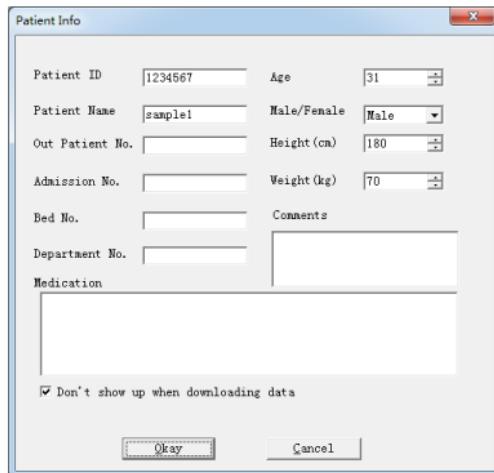


Figure 7.4.1 Patient information

Click "Okay" to start downloading the data, the process bar is shown as below:

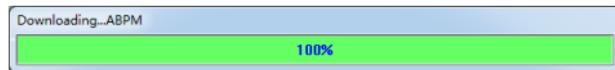


Figure 7.4.2 Downing Progress Bar

7.5 Path of case file

User can choose the storage path of case files, select "System" in the menu, then select "Set File Path", the interface is shown as below:

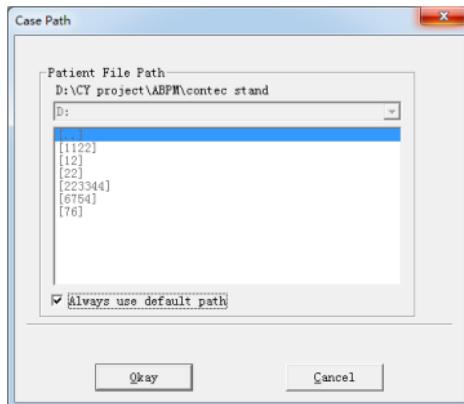


Figure 7.5 Case file path

7.6 Case select

Before editing, choose a case file first. Click the shortcut key  or select "File" → "Open data" in the menu to enter case selection interface as shown below:

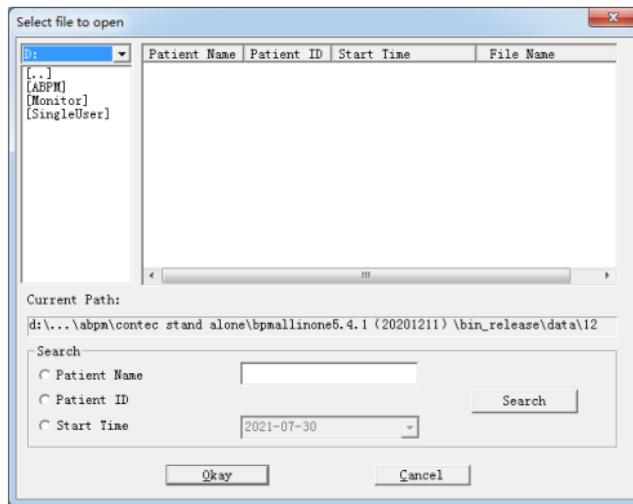


Figure 7.6 Case Selection

In the interface, you are able to select the file folder for data storage, if there are files in the folder,

all the file information will be listed, including: patient name, patient ID, start time and file name. Choose the file you want to edit, then click "Okay".

7.7 Delete

If some cases are not necessary any more, you can delete them. Select "File" → "Delete data" in the menu, the deleting interface will appear, which is similar to case selection interface, shown as below:

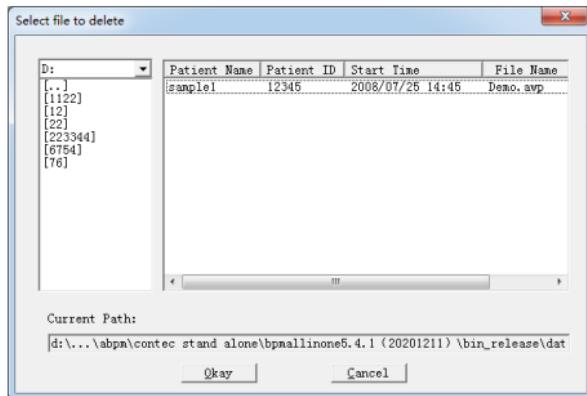


Figure 7.7 Select a Case for Deleting

You are able to delete one single file or multiple files at the same time; to delete multiple files, you

need to press "Ctrl" on the keyboard and select the files you want to delete, after that, click "Okey", an alert dialogue box will pop up, then click "Okay" to delete. If you want to cancel, please click "Cancel".

7.8 Backup

Sometimes, you may want to save one original copy before you edit a file, then you need to backup the case file. The software provides such function. Select "File" → "Copy data" in the menu to open the data backup interface, as shown below:

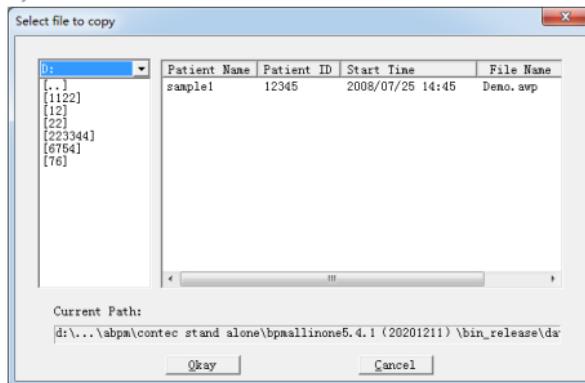


Figure 7.8.1 Select a Case to Backup

After selecting the file, click "Okay", a dialog box of file path setting appears, as shown below, in which you can set the path of backup file, after that, click "Okay" to save.

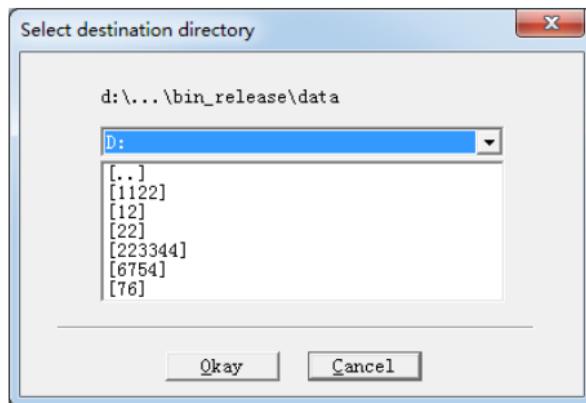


Figure 7.8.2 Backup Path Setting

7.9 Blood Pressure Data



You can edit each data record. Click the shortcut key **Alt** or choose "Edit" → "BP data" in the

menu, the data editing interface as shown below will be displayed:

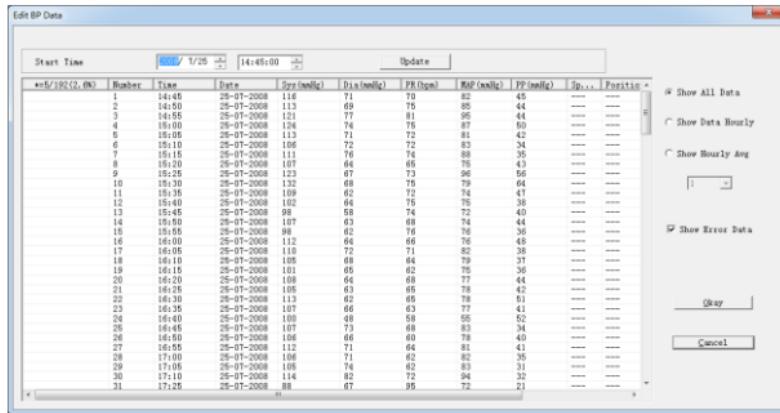


Figure 7.9 Data Editing Interface

In this interface, you can view the details for each data. In which,

$*=5/192(2.6\%)$: 192 stands for data sum, 5 stands for the number of deleted data, 2.6% stands for the present of deleted data.

Number: the serial number of data collecting.

Time: collecting time.

Date: collecting date.

Sys (mmHg): the high blood pressure value, its unit is mmHg;

Dia (mmHg): the low blood pressure value, its unit is mmHg;

PR (bpm): value of pulse rate, unit is bpm.

MAP (mmHg): the average pressure value of high blood pressure and low blood pressure, unit is mmHg.

PP (mmHg): pressure difference between high and low blood pressure, unit is mmHg.

Position: displays the posture status if this function is available

TC: error code

Comment: notes for the data.

These data can be edited. '*' means that the data is deleted (it will not be displayed in trend graph or in the record statistic). You can delete/add the '*' by clicking the left mouse button in its area. Also, in the comment column, you can add notes for the data, and these information will be shown in the trend graph.

By clicking buttons, you can display all data or hourly average value, or display by hour.

7.10 Trend Graph

After selecting a case, its trend graph will be shown on the computer automatically. In other



interfaces, clicking the shortcut key  could enter its interface. There are two types of trend graphs: trend for color filler style and trend for dotted line style. The trend shows as follows:

Figure 7.10.1 Color Filler Style

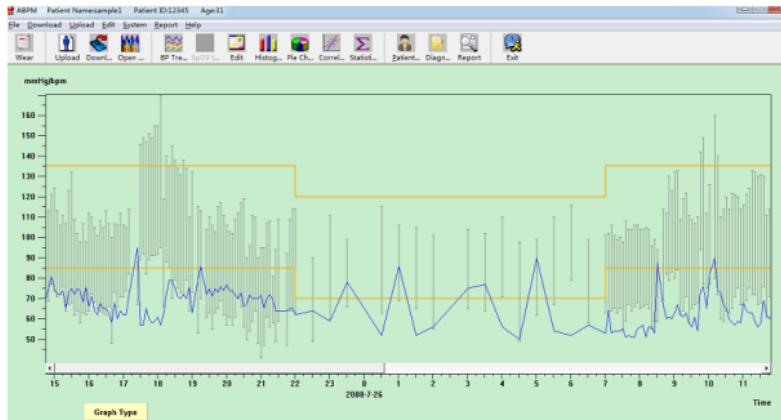


Figure 7.10.2 Dotted Line Style

Click the "Graph type" to switch between the two different trend graphs. When the cursor moves to the displaying area, data information that the mouse pointing will be shown on the top of the screen, including number, time, date, high/low BP value, PR, comment, etc. You can click the left mouse button to delete/add necessary data point. If the distance between the two data points is too short and the cursor cannot be moved to one of the points, move the cursor to the x-axis, press the left mouse button and drag the mouse to right, then the trend graph will be shown in a stretching form; and if

drag the mouse to left, the trend graph will be shown in a shrinking form. When the trend graph is stretched, you can control the movement of trend graph by scrollbar if it exceeds the displaying area, until you could observe the data you wanted. Similarly, you can also move the cursor to the y-axis, press the left mouse button and drag the mouse up/down to achieve stretching/shrinking display.

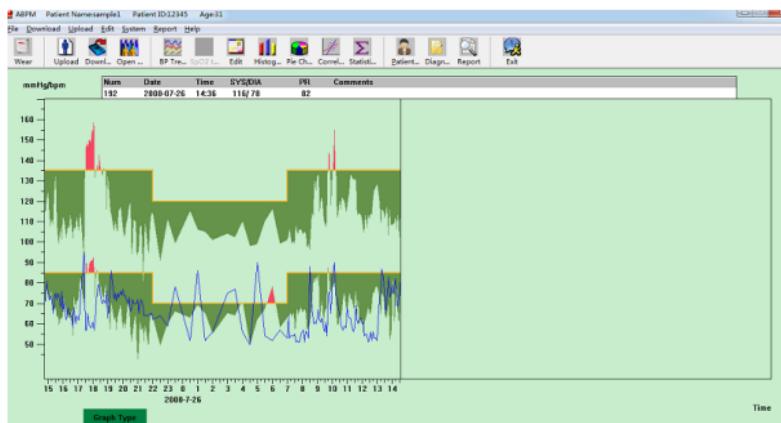


Figure 7.10.3 Trend Graph Shrink (x-axis)

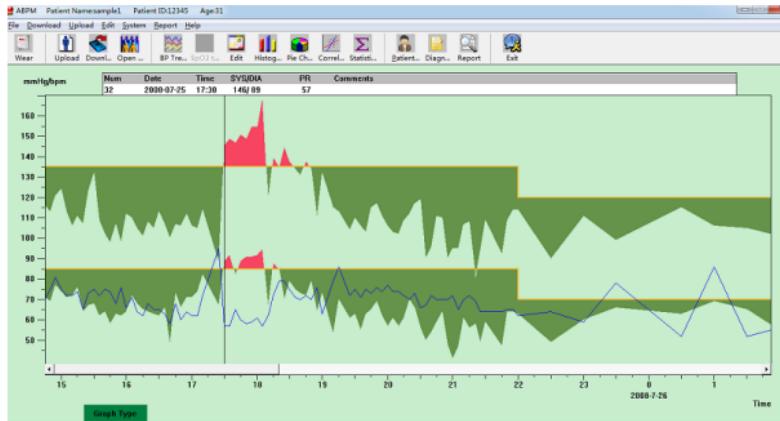


Figure 7.10.4 Trend Graph Stretch (x-axis)

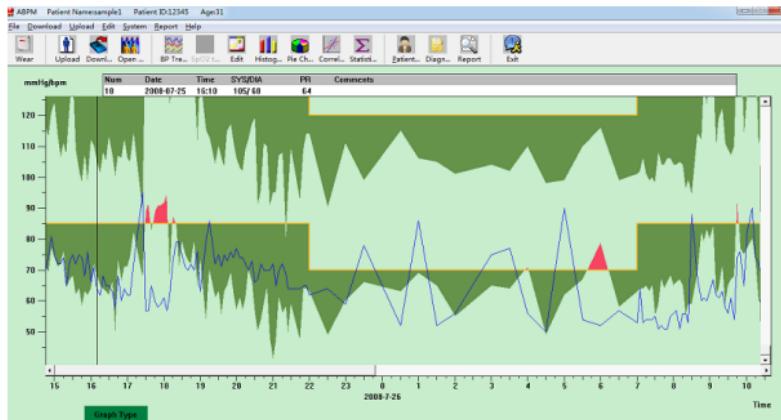


Figure 7.10.5 Trend Graph Stretch (y-axis)

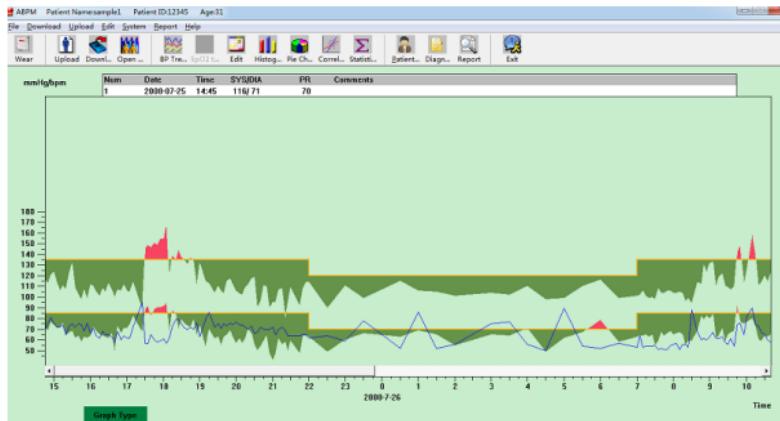
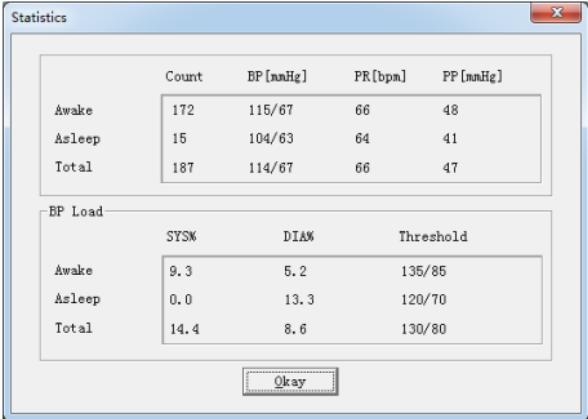


Figure 7.10.6 Trend Graph Shrink (y-axis)

7.11 Statistics information

Click the shortcut key , or choose "Edit"→"View statistics" in the menu, a dialog box for data statistic information will pop up, as follows:



The dialog box is titled 'Statistics'. It contains two tables: one for 'BP' and one for 'BP Load'.

	Count	BP [mmHg]	PR [bpm]	PP [mmHg]
Awake	172	115/67	66	48
Asleep	15	104/63	64	41
Total	187	114/67	66	47

	SYS%	DIAM%	Threshold
Awake	9.3	5.2	135/85
Asleep	0.0	13.3	120/70
Total	14.4	8.6	130/80

At the bottom is an 'Okay' button.

Figure 7.11 BP Statistics Information

The upper half of above figure shows the average value of the data. The lower half shows the percentage of data that exceeds the alarm limit. And the data 135/85, 120/70, 130/80 respectively represents the limit value of high/low pressure in the awake/ sleep/ whole day condition. The unit is

mmHg.

7.12 Diagnostic information



Click shortcut key **Diagn...**, or select "Report"→"Diagnose" in the menu, as shown below:

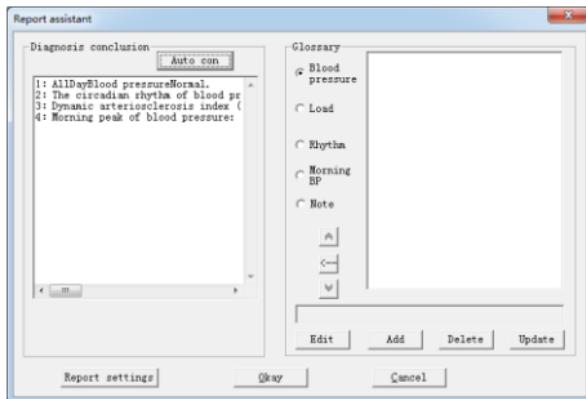


Figure 7.12.1 Diagnosis information

Click "Auto con" button, the software will automatically analyze the current case and display the diagnosis conclusion. The conclusion has several items, which can be set by user. Click "Report

settings" to select "Analyze item", a dialogue box for choosing analysis items pops up, shown as below:

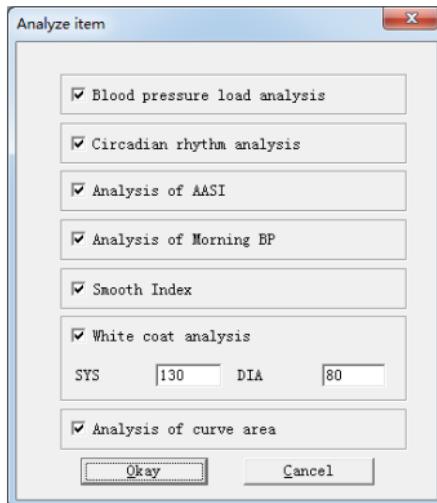


Figure 7.12.2 Analysis items

Also, you can choose to edit the diagnosis conclusion by your own, and edit, delete, add, and update the analysis items.

7.13 Sleep period setup

Setup of sleep period includes: day time and night time. This is necessary because the patient may not sleep or wake up at the exact time set in the collection scheme when patient data is being collected. After setup, the software will recalculate the data, and update trend graph and recalculate the statistic information automatically. Select "System"→"Sleep Times" in the menu, a dialogue box shown as below will appear:

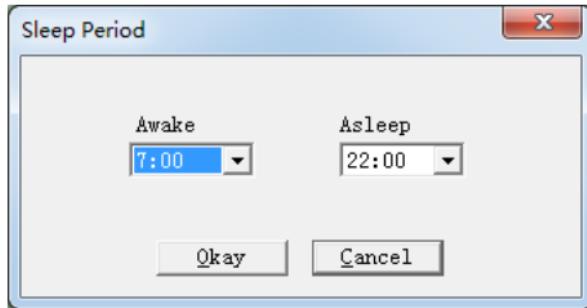


Figure 7.13 Sleep period Setting

7.14 Alarm limit setup

The alarm limit of blood pressure can be set, after that, the trend graph will update

automatically, and the statistic data will be recalculated. Select "System"→"Threshold" in the menu, a dialogue box of BP alarm limit will pop up, as shown below:

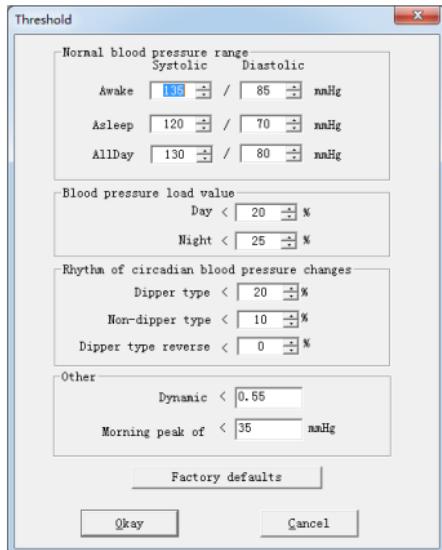


Figure 7.14 BP Alarm Limit Setting

In the day time, the default alarm limit of high/low blood pressure is 135mmHg/85mmHg; in the night time, the default alarm limit of high/low blood pressure is 120mmHg/70mmHg; in a whole day, the default alarm limit of high/low blood pressure is 130mmHg/ 80mmHg.

Besides, the setting includes the followings:

The normal range of "Day BP load value", default setting is less than 20%;

The normal range of "Night BP load value", default setting is less than 25%;

The normal range of "Circadian rhythm of BP ranges", default setting is 10%~20%

The AASI is less than 0.55 in normal condition.

The MBPS larger than 35mmHg indicates blood pressure elevation.

7.15 Histogram



Click the shortcut key **Histo...**, a histogram analyzing blood pressure and pulse rate will show up, as following:

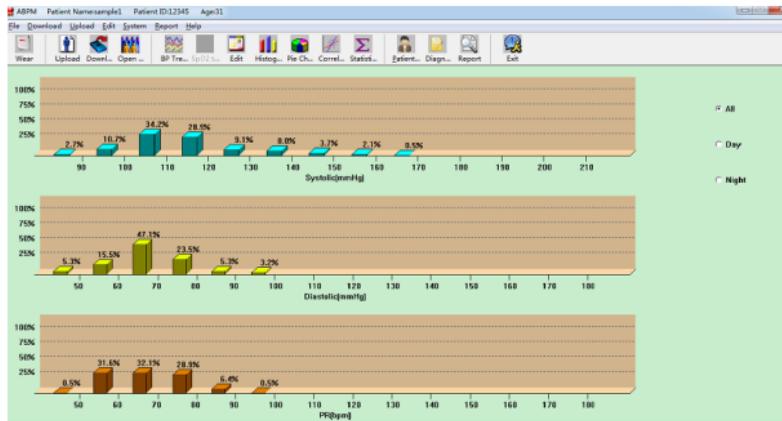


Figure 7.15 Histogram

The three values (SYS, DIA, PR) can be displayed for each time period by selecting "All", "Day" and "Night" on the right side.

7.16 Pie Chart



Click the shortcut key **Pie C...**, a pie chart analyzing blood pressure and pulse rate will show up, as

following:



Figure 7.16 Pie Chart

Pie chart interface is divided into four parts. The first part displays the maximum/ minimum/ average value for the measured data; the second part is the pie charts; the third part provides corresponding settings for the pie charts on the left; the fourth part has three options of "All", "Day", "Night", the analysis of values for each time period can be shown individually.

7.17 Fitting line



Click the shortcut key **Corre...**, the fitting line of blood pressure data will appear, as shown below:

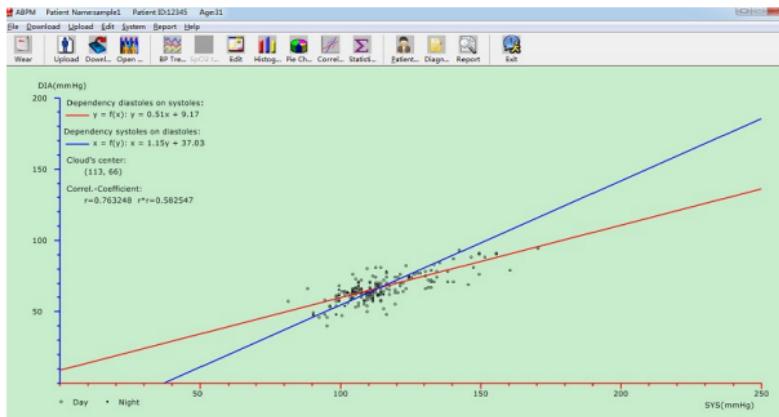


Figure 7.17 Fitting Line

Red represents systolic blood pressure; blue represents diastolic blood pressure. The empty circle is the blood pressure value measured during the day and the filled circle is the blood pressure value

measured at night.

Histogram, pie charts and fitting line help to observe the data.

7.18 Report print

The software supports printing in A4/B5 paper. If you want to print a report, first select "Start" → "Printers and Faxes" → "default printer driver icon" in the system, click the right mouse button, choose "Properties" → "Printing Preferences" → "Paper", select A4/B5 as the paper size. Then open the software, click "Report" → "Select Printer", the printer selection interface will pop up. In this interface, you can select the printer you are connected to, as well as the default paper size for printing. If the default paper size of printer is A4 (B5), the software will print according to A4 (B5) size.

When you finish the editing of blood pressure data, patient diagnostic information, etc., the software will generate a series of analysis reports. You can choose all reports or several of them for printing.

Select "System" → "Configurate Report" in the menu, the following dialog box will pop up:

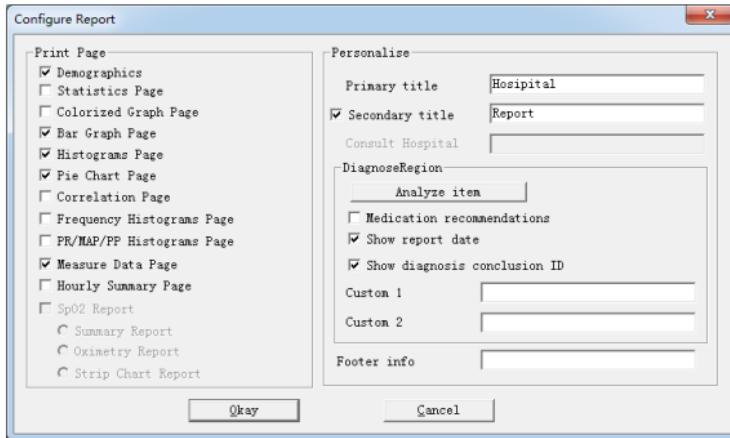


Figure 7.18.1 Report Configuration



Click the shortcut key **Report**, or select "Report"->"Report" in the menu, it will directly go to

the print preview interface. Operator could see the printing result of the page that just selected. Print preview interface as follows:

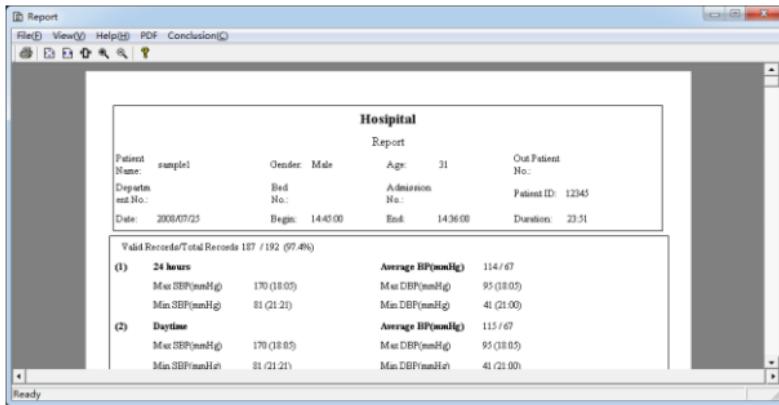


Figure 7.18.2 Print Preview

Make sure that there are no mistakes in the report, click  on the top left corner of the interface, the attribute interface of printer will pop up, then click the "Okay" button, print job will be sent to the printer for printing.

7.19 Help

Click "Help"→"Help Document" in the menu to pop up the help information, which gives a brief description of each function, and facilitates you to quickly know how to use the software.

Chapter 8 Transport and Storage

- The packed device can be transported by general vehicle or according to the order contract.
The device can not be transported with mixture of toxic, hazardous, corrosive materials.
- The packed device shall be stored in a well-ventilated room without corrosive gases, and room environment shall be:
 - Temperature: -20 °C~+55 °C
 - Humidity: ≤95% (no condensation)

Chapter 9 Buttons and Symbols

Signal	Description	Signal	Description
	Attention! Please refer to the accompanying document (the user manual).		Attention! Please refer to the accompanying document (the user manual).
SYS	Systolic pressure	DIA	Diastolic pressure
MAP	Mean blood pressure	PR	Pulse rate (bpm)
SN	Serial number	EMC	Electromagnetic compatibility
	Free of natural rubber latex	P/N	Material code of manufacturer
ADU	Adult	INFO	Information
ABPM	Ambulatory Blood Pressure Monitor		Type BF defibrillator proofed applied parts
	Class II equipment		Open the prompt sound indication
	Batch code		Use by date

	This way up		Fragile, handle with care
	Keep dry		Storage atmospheric pressure limitation
	Storage temperature limitation		Storage humidity limitation
	Manufacturer		Date of manufacture
	Batteries Power		Pulse rate (bpm)
	Waste disposal mark, this symbol indicates that the waste of electrical and electronic equipment can not be disposed as an unclassified municipal waste and must be recovered separately.		Recyclable

Chapter 10 Product Specification

Name	Ambulatory Blood Pressure Monitor
Operating mode	Continuous operating
Display	0.96" color LCD Display
Measurement method	Oscillometric method
Working modes	Automatic
Measurement range	Pressure: 0 ~ 300 mmHg (0 ~ 40 kPa) Number of pulse: 40 beats/minute~240 beats/minute
BP measurement range	SYS 30 mmHg~270 mmHg(4.0~36.0 kPa); DIA 10 mmHg~220 mmHg(1.3~29.3 kPa);
Overpressure protection	$297 \pm 3 \text{ mmHg}$ ($39.6 \pm 0.4 \text{ kPa}$)
Resolution	1 mmHg
Cuff Pressure Accuracy	Static pressure: $\pm 3 \text{ mmHg}$ ($\pm 0.4 \text{ kPa}$)

Error	The blood pressure value measured by this device is equivalent to the value measured by auscultation method, its error meets the requirement of IEC 80601-2-30:2018 .
Transport	Transport by general vehicle or according to the order contract, avoid pounded, shake and splash by rain and snow in transportation.
Storage	The packed device shall be stored in a well-ventilated room without corrosive gases, temperature within -20 °C~+55 °C, relative humidity no more than 95%.
Temperature	Working: +5 °C~+40 °C Transport and storage: -20 °C~+55 °C
Humidity	Working: 15%~85%(no condensation) Transport and storage: \leq 95% (no condensation)
Atmospheric pressure	Working: 700 hpa ~ 1060 hpa Transport and storage: 700 hpa ~ 1060 hpa
Battery service life	Under the condition of room temperature 23°C, arm circumference 270mm and measuring normal blood pressure value, a fully

	charged lithium battery can support measurements 100 times or more.
Rated voltage	DC 3.7 V
Rated Power	10 VA
Dimensions	113(L)*67(W)*26 mm(H)
Unit Weight	180 gram(with batteries)
Safety classification	Internally powered equipment, type BF defibrillation-proof applied part
Service life	5 years of measurement
Date of manufacture	See the label

Chapter 11 After-sales Service

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

Guidance and manufacturer's declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer of the user of the <i>device</i> should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The <i>device</i> uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The <i>device</i> is suitable for use in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF	3 V/m 80 MHz to	3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">80 MHz to 800 MHz</p>

IEC 61000-4- 3	2.5 GHz	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: center;">800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.	
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is	

affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

**Recommended separation distances between
portable and mobile RF communications equipment and the device**

The *device* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *device* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *device* as recommended below,

according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)	
	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.23
0.1	0.37	0.74
1	1.17	2.33
10	3.69	7.38
100	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.