CE 1639

Hingmed

Wearable Ambulatory Blood Pressure Monitor

User Manual

WBP-02A

Shenzhen Hingmed Medical Instrument Co., Ltd.

About this Manual

The manual mainly introduces the installation and application method of Wearable Ambulatory Blood Pressure Monitor. Users should read carefully before application (include warnings, contraindications and notes).

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Version Information

This manual may be upgraded due to software upgrading in the future. Users may not get further update for manual upgrading.

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Chapter 1 Preface

1.1 Brief Introduction of Ambulatory Blood Pressure Monitoring

Ambulatory blood pressure monitor is an instrument for monitoring human's blood pressure automatically during certain period (normally 1-2 days) with certain intervals upon actual situation. Blood pressure readings in different periods under different conditions would be analyzed and then blood pressure diagnosis would be given accordingly.

During 24 hours in a day, human blood pressure is not fixed, but fluctuates within a certain scope. Spot measurement of blood pressure in clinic office may not reflect the patient blood pressure situation accurately, especially for the patients whose blood pressure only high on some certain time during a day. The 24-hour ambulatory blood pressure measurement would indicate the whole day blood pressure fluctuation and be able to help finding the patients whose blood pressure only high on some certain time during a day.

It is also important to conduct 24-hour ambulatory blood pressure measurement for those confirmed hypertension patients. Research shows half of hypertension patients who believe their blood pressures were controlled well are found that their blood pressure are still unstable during 24-hours by using ambulatory blood pressure measurement, their blood pressures rise up in the morning and/or in the afternoon, or rises up at night, it means their blood pressure is not controlled ideally. This well explained why confirmed hypertension patients who already taking medication and feel good in blood pressure control still suffer from renal damage. 24-hour ambulatory blood pressure monitoring can help patients to learn their blood pressure fluctuation trend and doctor would be able to provide accurate short, medium or long-term medication solution accordingly. This would help to control their blood pressure well and avoid further damage of target organs e.g. cardio, brain and kidney. Obviously, Ambulatory blood pressure monitoring is superior to spot clinical blood pressure measurement, and gradually becomes an important method to evaluate the treatment effecacy of hypertension.

Compare to clinical or home blood pressure spot measurement, the ambulatory blood pressure monitoring has below strength:

a) Eliminating the measurement contingency and some other affecting factors i.e. emotion, movement, eating, smoking, drinking, etc.

b) Reflecting the 24 hours blood pressure fluctuation accurately upon much more readings covering the whole day.

c) Help to improve hypertension diagnosis quality, i.e. to have borderline hypertension patients getting timely treatment. These patients usually do not feel any symptom at early stage.

d) Providing guidance on medication. In many cases it could be used to evaluate medication effecacy, help to select drugs, and adjust dosage and drug administration time.

e) Providing accordance on target organs damage analysis (especially for organs which used to be caused by hypertension). For instance, the hypertension patients with myocardial hypertrophy, fundus dynamic vascular lesions or renal function changes, the blood pressure difference between day and night is smaller than usual.

f) To predict the time of sudden attack of cardiovascular and cerebrovascular disease in a day. Usually, it is most frequent that the stroke happens due to a sudden rising of blood pressure in early morning.

g) Ambulatory blood pressure measurement is very important for prognosis. Compare with normal blood pressure, patients with high blood pressure in 24 hours have higher mortality and incidence of cardiovascular disease than those with low blood pressure in 24 hours.

For the following hypertension types, Ambulatory blood pressure monitoring is particularly helpful for diagnosis.

1. White-coat hypertension

White-coat hypertension is for the cases that the blood pressure is constantly high in hospital or clinic office but normal out of hospital or clinic office. And this kind of situation is repeatable. White coat hypertension is very common. About 15% of doctor visitors have White-coat hypertension.

2. Masked hypertension

Masked hypertension is for the patient that their blood pressure is only high at certain time during a day and it's difficult to find by using office spot measurement. 24 hours ambulatory blood pressure measurement would be able to ding this kind of hypertension. It is reported that masked hypertension population taking 10% of the whole population nd about 40% of the hypertension patients who are having medication therapy. It is very necessary to have ambulatory blood pressure monitoring for masked hypertension diagnosis for those hypertension patients who are taking medication.

3. Morning surge hypertension

Morning surge hypertension is for the patients that the average blood pressure during the 2 hours after getting up is more than 135/85mmHg. There are two types-"Only morning surge" and "Anti-dippers or Non dipper". The "Only Morning Surge" is for the cases that blood pressure rise suddenly after getting up, and the Anti-dipper or Non-dipper is for the cases that blood pressure is high at both night and early morning. Both cases are risky factors for cardiovascular disease. ABPM can help to identify these two types of cases.

4. Nocturnal Hypertension

To diagnosis nocturnal hypertension, people need to measure their blood pressure at night. A 24ours ambulatory blood pressure monitor is the ideal tool for this kind of diagnosis.

5. Hypotension

Ambulatory blood pressure monitoring is very useful not only on diagnosis of hypertension but also hypotension. Especially, the hypotension could cause dizziness or fainting on elder people who have exhaustion of autonomic nervous when standing, after a meal or after a bath.

Hypotension is divided into primary hypotension and secondary hypotension. Primary hypotension is common in women, which usually impact the patient's life quality. However, only few primary hypotension patients are considered long-term prognosis, because primary hypotension just leads to few vascular disorders. On the other hand, secondary hypotension is usually caused by some normal diseases and is accompanied with dangerous syndromes such as syncope and vertigo, so patients need prevention and therapeutic measures. In this case, the 24 hours ambulatory blood pressure monitor would be very helppful.

Besides above circumstances, 24 hours ambulatory monitor is also very helpful on below cases:

- Childhood hypertension
- Efficacy of anti-hypertensive drug therapy on a 24-hour basis
- Nocturnal hypertension
- Episodic hypertension and/or anxiety disorders
- Resistant hypertension
- Changes in diet and daily routine designed to reduce hypertension
- Hypertension in pregnancy

1.2 Brief Introduction of WBP-02A ABPM

Blood pressure monitor with body position information

Hingmed WBP-02A ABPM is wearable. Comparing traditional ABPM, it's very small, light and is worn on people's arm directly without air tube. The traditional ABPM used to be attached with a 1 meter longer air tube around patient body. WBP-02A has below strength:

1. More comfort for patient as there would be no air tube around patient body.
2. Minimized the ambulatory motion tolerance, improved the measurement consistency.
3. With rechargeable Li battery, ABPM users do not have to cost two AA batteries every day.

Hingmed ambulatory blood pressure monitor has an outstanding feature that it could provide the user's body position when taking blood pressure measurement, which could be very important in clinical research. Most hypertensive diseases, such as dizziness, nausea, brain death, happened under spirit pressure with body movement. Therefore, monitoring patient's blood pressure should not be confined to a calm condition. Blood pressure measurement under ambulatory environment would more closely reflect patient normal blood pressure situation. And that would be extremely helpful on clinical diagnosis.

In addition, blood pressure data with body position information can help doctors to make a good judgment on orthostatic hypertension. Body position hypertension is that some patient would only have high blood pressure under standing or sitting posture, but normal at lying posture. Orthostatic hypertension accounts for 4.2% in domestic hypertension patients and 10% in abroad report. Orthostatic hypertension is characterized by that there is not hypertension in normal and just being found occasionally or in physical examination. Diastolic pressure rising-up and large fluctuation would represent in orthostatic hypertension and the individual could be accompanied by serious palpitation, tiredness, sleep quickly etc. In blood examination, the plasma rennin activity in orthostatic hypertension is higher than that of normal people, even than that of general hypertension patient.

Chapter 2 Safety Requirements

2.1 Intended Use

Wearable Blood pressure monitor of WBP-02A is mainly used to measure blood pressures, which include systolic pressure, diastolic pressure and pulse rate, of patients in different setting intervals within 24 hours (not applicable to children under 3 years old), and the measurement data can be downloaded to computer system through USB cable. Then doctors can use Hingmed ABPM software system analyze the blood pressure readings for diagnosis reference.

Product composition: Main unit, Noninvasive blood pressure cuff, USB cable, battery charger, manuals, quick start, and Hingmed PC software.

The device is Lithium battery inside; Electric shock protection degree: CF type applied part; Operation mode: automatic continuous running.

2.2 Contraindication

- DO not use the monitor near X-ray tomography device.
- DO not use the monitor in the places where inflammable anesthetic exist, it may lead to explode.
- DO not wrap the cuff on the limb being used for IV injection as cuff inflation may block infusion and hurt patient.
- DO not immerse the monitor in any liquid or any detergent, which would cause electrical hazard.

2.3 Warnings

- Cuff shall not be worn on the wound, because inflation pressure may cause further damage.
- When patients wear the monitor, making sure the monitor is not connected with PC or other devices through USB cable.
- DO not apply the monitor on people under 3 years old.
- DO not use the monitor in conjunction with defibrillation equipment.
- It may cause measurement error by using parts not included in the supply listing.
- Make sure the cuff inflation pressure is suitable for the patient. If any abnormity occurs in the monitoring process, please stop measurement immediately, and remove the cuff from the patient or quickly press start/stop button to stop inflating. If the cuff fails to deflate, notice the patient to remove it properly and safely.
- If this device is dampened by accident, put it in a well-ventilated place for drying prior to use.
- Only professional physicians can explain the measured blood pressure values.
- Don’t repair/maintenance while the medical equipment is in use.
- The patient is an intended operator. The patient can only measure, transmit data under normal circumstances, maintain the device and its accessories according to the User Manual.
- Not intended to be sterilized.
- Not for use in an oxygen rich environment.
- No modification of this equipment is allowed.
- It is not intended for use on neonate.
- It is not intended for use pre-eclamptic patients.
- Do not apply the cuff over a wound; otherwise it can cause further injury.
- The application of the cuff and its pressurization on any wrist/arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present.
- Inflate the cuff on the side of a mastectomy.
- Do not inflate the cuff on the same limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
- Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
- The device cannot be used with HF surgical equipment at the same time.

2.4 Notice

2.4.1 Battery

- The monitor uses the built-in battery, do not replace it without authorization.
- Connect monitor to USB port of adapter, and then connect adapter to power socket for recharging. The adapter should be with 3C compulsory certification or other compulsory certifications (such as FCC or CE). The specifications of adapter should be: Input: 100-240V~, 50/60HZ ; Output: 5V ⎓ 1A.
- Keep the monitor away from high-temperature places, and avoid direct-sunlight in summer, also, the environmental temperature shall not be over 60 Celsius degree.
- For security, consult after-sale supporter quickly, if the Li-ion cannot be charged or its discharge speed is fast.

2.4.2 Training

- Explain to patients how to stop operation if abnormal measurement occurs, and how to remove the cuff if the patients feel painful or discomfort on arm.
- Keep still during measurment, especially do not move the cuffed arms, and it is better to keep calm, and make the cuff as the same horizontal position as the heart.
- If the cuff-wrapped arm is bending while inflating, then keep bending, do not stretch your arm, otherwise it would cause pressure inside cuff changes rapidly and disturb the measurement.
- Explain to patients how to deal with error operation and common problems.

2.4.3 Blood pressure measurement

- Patient with anticoagulant or patient with coagulation disorder may extravasate on the wrapping cuff position while measurement even the cuff is worn correctly. In fact, no matter what type of the monitor is, such patients would extravasate during the measurement process.
- If cuff fails to inflate in 150 seconds, instruct patients to remove the cuff manually, excessive inflation may block patient's blood flow that makes patient uncomfortable.
- Operating or storing the monitor beyond the specified environmental conditions in Chapter 6 would cause damage.

2.4.4 Energy conservation and environment protection

- Please power the monitor off after measurement is accomplished.
- Please properly handle the scrapped batteries, cuff, cable and main units in compliance with local environmental regulations.

2.4.5 Maintenance

- Please use the accessories supplied by Hingmed, otherwise it may cause measurement errors.
- Maintenance should be conducted only by trained personnel or personnel authorized by Hingmed.
- Error warning: error codes will be displayed on the screen in malfunction situation, see 5.1 troubleshooting for details.

Chapter 3 Product Introduction

3.1 Product Composition

Prior to use please confirm if any accessories are missed, if there is any damage on main unit and accessories, please contact distributors or Hingmed customer service for help.

Hingmed ABPM Packing List

Parts	Qty
Hingmed ABPM	1
Software U-disk	1
USB data cable	1
Quick battery charger	1
Large Adult cuff (22-36 cm)	1
User Manual	1

Optional accessories

Item	Cuff Option
1	Small adult cuff(18-26cm)
2	Middle adult cuff(22-32cm)
3	Extra Large adult cuff(30-43cm)

3.2 Name and Function of Each Component

3.2.1 Monitor



1 OLED screen; 2 Cuff; 3 Backward button; 4 Power on/off and Start/stop button;

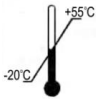
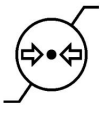
5 Forward button; 6 USB port.

3.2.2 OLED displays



MEM	Quantities of historical memory, it flashes means full of memory
AUTO	Automatic measurement
□□:□□	Showing system time when turning on
	Heartbeat symbol
2015-01-20 15:00	Measurement time of history memory
	Battery volume indication

3.2.3 Symbols used in labeling

Symbol	Description	Symbol	Description
	Type CF		Serial number
	Manufacturer		General Mandatory action sign
	Keep dry		This way up
	Fragile		Disposal in compliance with WEEE Directive
	Stacking limit by number		Temperature limitation
	Refer to user manual	IP22	Ingress Protection (IP) ratings
MD	Medical devices		Date of manufacture
UDI	Unique Device Identification		Use-by date
CE	CE mark	EU REP	EU authorized representative
	Battery level		Atmospheric pressure limitation
Rx Only	Prescription devices	MR	MR Unsafe

Chapter 4 Product Installation and Use

4.1 Battery Installation

The inside battery cannot be dismantled, and cannot be replaced without authorization, when the power of battery is running out, please recharge it on power charger with USB cable.

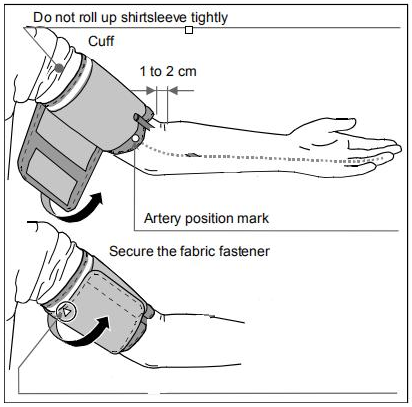
Note: The quick charger attached in WBP-02A package is a special designed quick charger. Please always use this charger for battery charging.

4.2 Wear The Monitor

With the special integration design, you can wear the Hingmed WBP-02A ABPM on your arm. Press the middle button for about 5 seconds to power on/off the monitor.

4.2.1 Wear cuff correctly

1) Apply the cuff to your bare upper arm.
2) Position the lower edge 2-3 cm (1 inch) above the elbow crease.
3) Align the "Φ"  marker with the brachial artery (inner arm pulse point).
4) Adjust the main unit to the external position as illustrated.





✧ **Notes:**

- **An improperly sized cuff may lead to measurement errors and compromise accuracy.**
- **Do not place the cuff on injured skin.**
- **Before applying the cuff, cover the area with a clean cloth or protective film to prevent cross-contamination.**

4.2.2 Start for single measurement

Press “start/stop” button to start a measurement (the middle button), it only measures one time, after measurement, user can read the data on OLED screen, also, user can click forward button or backward button to read history data.

For automatic measurement, please refer to sections 4.3-4.4 of this user manual.

4.2.3 Ready for use

For a 24 hours ambulatory blood pressure study, a good preparation of patient is important.

- Patient should try to avoid overstress, excitement and muscle tightened.
- When start inflating, patient should keep the measurement arm away from body slightly, and do not move the arm during measurement.

- During 24 hours programmed monitoring, patient may press the button of “start/stop” to start/stop measurement at any time. (Only when the button function is set as enable to use).
- DO not remove the cuff in the process of measurement, if the cuff slips below the elbow or falls off, please rewrap it to the right position.
- History data would not be lost if battery power is run out, or monitoring stopped by manually powered off.
- Guide patient to record the events that affect measurement obviously during measurement.
- Make sure that patient know how to check the monitor. The monitor should be dry and avoid falling and bumping.
- If monitor or cuff causes excessive pain or abnormal pain, patient should remove the cuff and power off the monitor.

4.3 Installing Software System

4.3.1 Hardware requirements

Computer with CD drive, minimum display resolution: 1024*768, one USB port.

4.3.2 Software requirements

Microsoft Windows 2003, Windows XP or above versons

4.3.3 Software installation

Hingmed ABPM software components include:

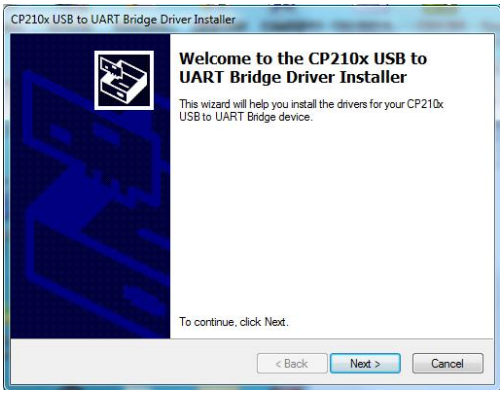
- Hingmed ABPM Software Instruction
- Hingmed ABPM PC software U-disk

Insert the installation USB disk into a valid computer USB interface, and then follow the following steps:

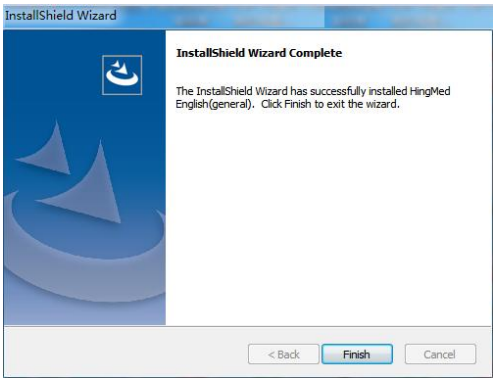
a) Open “My computer” or “Computer”;

b) Click on the removable disk and run the setup installation software under the included U disk directory file;

c) First, you are prompted to accept the terms of the license agreement. After selecting, follow the prompts → "Next" → "Next". After the installation process, you can customize the program installation path as needed, or click "Next" directly to install. After the installation is completed, the screen shown in Figure 1 below will pop up. When the main program installation is completed, you will be prompted to install the device driver as shown in Figure 2. After the driver installation is completed, click the “ Finish” button.



（Figure 1）



（Figure 2）

● After installation, the software icon will appear on your computer desktop. When this icon appears on your computer, it means that you have installed the blood pressure management software for the ambulatory blood pressure monitor.

4.4 Execute Ambulatory Blood Pressure Study

4.4.1 Communication with Hingmed ABPM

After installing the PC software, your computer should be able to communicate with monitor for programming and performing a Ambulatory Blood Pressure Monitoring study.

4.4.2 Connect monitor to computer

a) Plug Micro USB connector of the data cable to the USB port of the monitor.		b) Plug USB connector of data cable to USB port of your computer.	

4.4.3 Programming automatic measurement

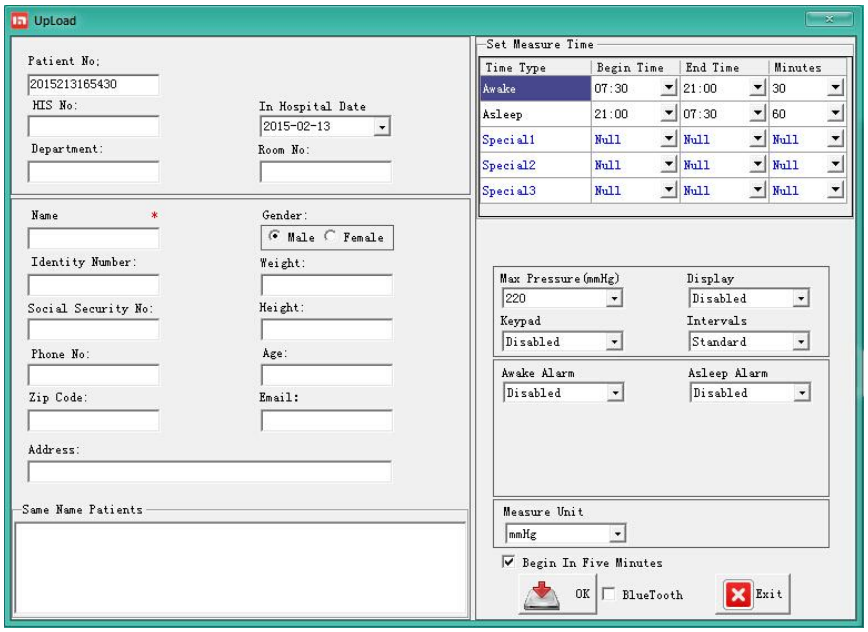
After successful connection, open the software to start programming.

a) Click “Program” in the toolbar;

b) Input the related information in the programming interface as below Figure ;

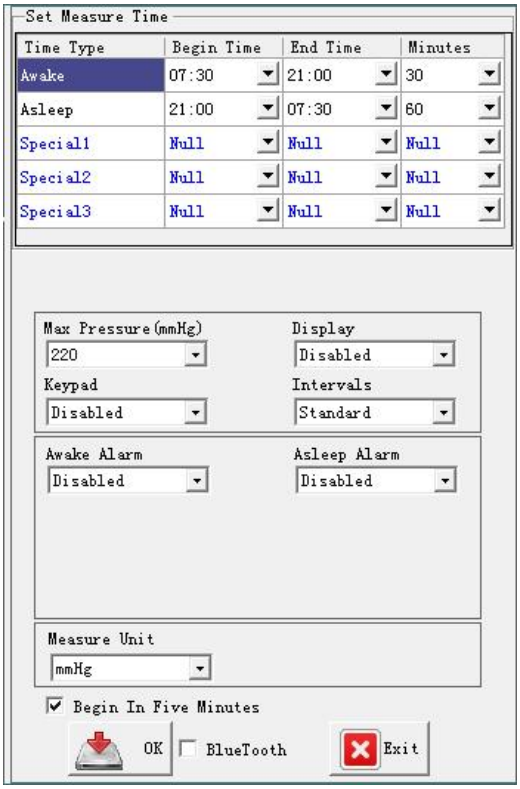
c) Click “OK” to program;

d) There would be a bar indicates the programming progress.



The measurement parameters could be adjusted as follows:

● Enter into the programming interface and set the parameters as the following figure.



●The parameters setting (see the following table):

Time type	Daytime, Nighttime, Special time
Maximum pressure	120-280mmHg
Keyboard	Enable / Disable
Display	Enable / Disable
Daytime alarm	Enable / Disable
Nighttime alarm	Enable / Disable
Maximum systolic blood pressure for alarm	100-200mmHg
Minimum systolic blood pressure for alarm	60-90mmHg
Minimum diastolic blood pressure	90-180mmHg
Minimum diastolic blood pressure	30-70mmHg
Unit	mmHg/Kpa
Intervals	Standard / Fixed

4.4.4 Start monitoring

- Check whether the monitor work well or not before patient wearing the monitor .
- Make sure the screen can display the time.
- Press the “start/stop” button or wait for 5 minutes (If “Begin in five minutes” was selected in the program) to verify the first time of measurement is no problem, then allow patient to leave.

4.4.5 Finish measurement

If the measurement is accomplished, take it off from the patient.

4.4.6 Retrieve data

1. Connect the monitor to computer through USB port;

2. Open Hingmed ABPM software;

3. click “Read” to transmit the data, the data will be shown on the screen automatically after successful “reading”, and then you can analyze the data on the software.

Note: Data will be missed after next programming operation if they are not uploaded to computer.

4.4.7 Analysis and reporting

The data could be stored in computer and an independent file will be created include patient name, ID etc. Click “Print review”, and select the content upon the option, then you will get the BP report on the screen. Click” Print” to print the report. Click “PDF” to get a PDF format report. See the following Figure a to Figure c.

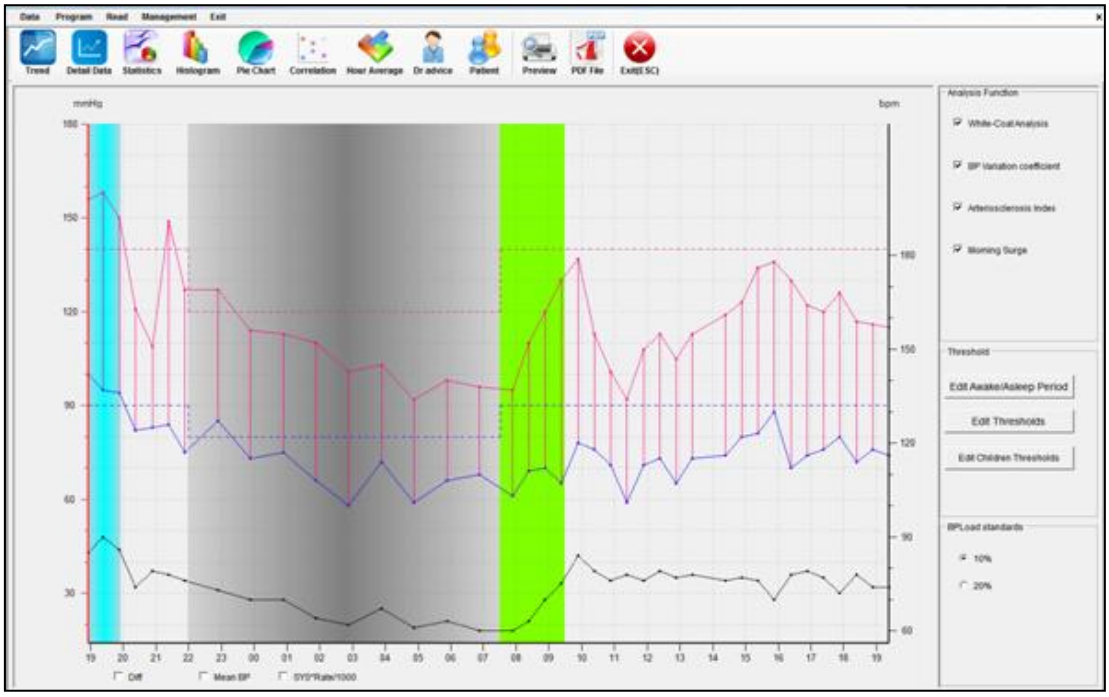


Figure a: Historical data curves of ambulatory blood pressure

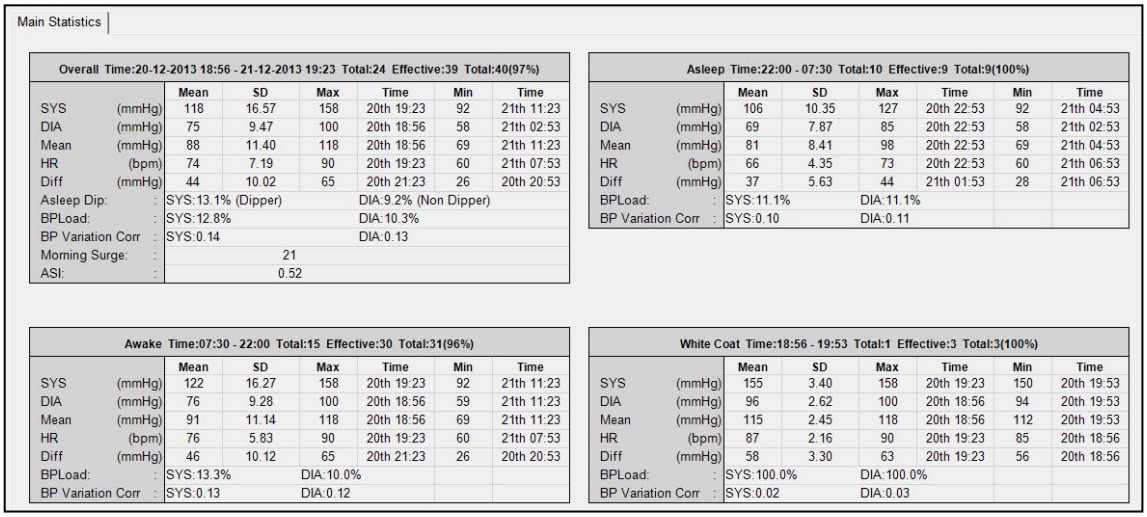


Figure b: Statistics of historical data of ambulatory blood pressure



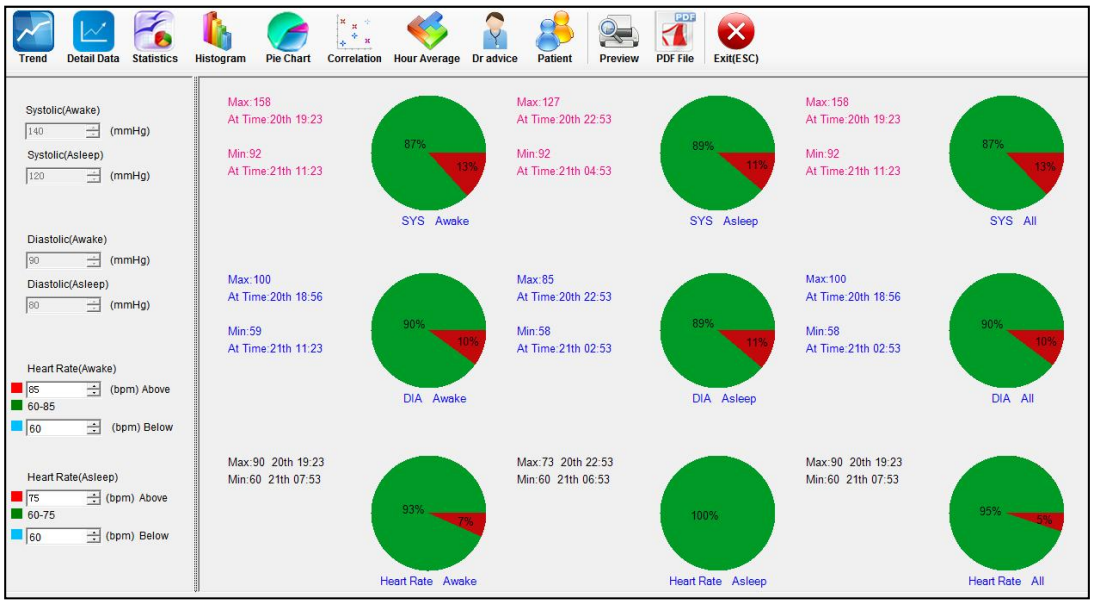


Figure c: Ambulatory blood pressure history data analysis summary map

Note:

1. **For operation details of PC software of Hingmed Wearable Ambulatory Blood Pressure Monitor, please refer to < User Guide of PC software >;**
2. **Programming the monitor will delete the history data in the monitor, so please make sure that the history data has been retrieved and stored;**
3. **The monitor could store maximum 300 readings. When storage is full, the monitor can’t save data normally until next programming;**
4. **Last programming will be valid till next programming.**

Chapter 5 Troubleshooting and Maintenance

5.1 Error Codes and Corrective Actions

Error Code	Description	Resolution
EC01	Cuff is too loose, maybe loose winding or disconnected cuff	Retighten cuff or keep it on proper arm position when inflation
EC02	Air leakage, maybe valve leakage or air tube leakage	Tighten metal connector and check the cuff. If leakage is not still resolved, contact agent or dealer
EC03	Air pressure error, maybe unable to open valve	Check whether the valve can work normally
EC04	weak signal，maybe week pulse or loose cuff	Check whether the cuff is too loose, tighten it if necessary.
EC05	Pressure beyond the limit，maybe the pressure of subject beyond the limitation	Press “start/stop” button to measure again. If still cannot work properly, change to another monitor.
EC06	Excessive exercise，maybe there is too much motion tolerance or interruption	Keep calm while measurement and do not move the arm with cuff
EC07	overpressure，cuff pressure beyond 290 mmHg	Press “start/stop” button to measure again. Change to another larger scale monitor if it still does not work well.
EC08	Artifact/Erratic Oscillometric Signal	Keep quiet, Press “start/stop” button to measure again.
EC09	overtime：one time measurement takes more than 120s.	Keep calm, Press “start/stop” button to measure again.
EC10	Measurement aborted	Keep calm, Press “start/stop” button to measure again.
EC11	System error	Restart，If the error occur frequently, service is required.
EC16	Cuff pressure beyond the max pressure setting	Reprogramming in PC software and set the inflation limit to higher level.
EC32	System error	Press “start/stop” button to measure again.

EC33	Cuff pressure above 15mmHg ,cannot have another measurement	Restart after cuff pressure down to below 15mmHg
EC34	Start a measurement right after last one, cuff pressure is still above 15mmHg.	Restart after cuff pressure down to below 15mmHg
EC35	No response from monitor when press the start/stop button	Press “start/stop” button to measure again.
EC36	Measurement result is not available	Press “start/stop” button to measure again.
EC37	Overtime (beyond 180s)	Press “start/stop” button to measure again.
EC48	Memory is full, can no longer measure	Upload and program the machine to release the memory.
EC66	Unable to power off during nighttime period	Reprogram via software and set the nighttime start time 3 hours later than the current time to enable normal shutdown.

* If the errors cannot be fixed by yourself, please call distributor or service of Hingmed.

5.2 Troubleshooting

5.2.1 No response from buttons / unable to operate

● Cause: During software programming, the Keypad is set to “Disabled”. After the first automatic measurement, the device will lock the keys automatically, and manual button operation will no longer trigger measurements. This is designed to prevent accidental operation and avoid disrupting the measurement schedule.

● Solution: Connect the device to a computer and set the Keypad to “Enabled” in the programming interface. After reprogramming, manual button operation will restore measurement functionality.

5.2.2 Screen shows only time / asterisk, no blood pressure values

● Cause: During programming, the display function is set to “Disabled”. In this case, the device continues recording data in the background, and normal measurement is not affected.

● Solution: Connect the device to a computer and set the “Display” to “Enabled” in the programming interface to show measurement results.

5.2.3 Screen shows “MEM”, device cannot continue measurement

● Cause: Device memory is full (maximum 1000 readings), no new data can be stored.

●Solution: Upload historical data to the computer. After completion, reprogram the device to continue measurement.

5.2.4 Automatic stop during inflation with no error

● Cause: Low battery or battery aging, triggering low-power protection.

● Solution: Charge the device using the original charger for approximately 120 minutes. Retry after full charging. If the issue persists, contact the manufacturer or distributor.

5.3 Maintenance and repairing

5.3.1 Inspection and safety maintenance

Visually check if there is any broken or damages on enclosure and cuff. If any damage is

found, do not use the monitor. Please contact the distributor or the after-sale service department of Hingmed.

5.3.2 Monitor maintenance

After use, it is important to perform preventative maintenance to ensure the safe and efficient operation of the monitor for long-term.

● It is recommended that the monitor should be verified every two years.

● DO not disinfect, immerse the monitor in any fluid, or attempt to clean with any liquid detergents, cleaning agents, or solvents. You may use a soft, damp cloth to remove dirt and dust from the monitor. If the unit does become immersed in water, do not use it and contact the distributor or our service department.

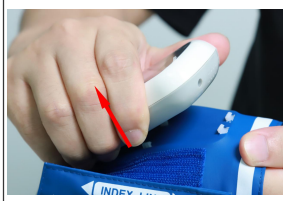
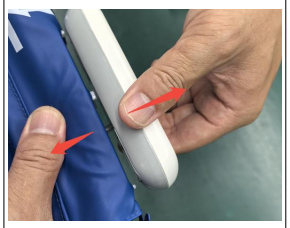
● DO not clean the enclosure and cuff with strong alkali or acid or strong disinfectant.

● Take down the monitor from the cuff, use a mild detergent to clean the cuff and bladder, remove the bladder (with fixing board on it) from the cuff before washing, and hang them for drying. After drying, put the bladder into the cuff, install the monitor onto the cuff.

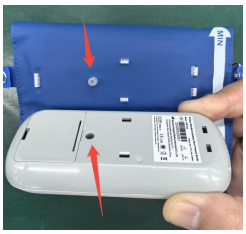
See the following steps to take down the monitor from cuff:

5.3.3 Removal and installation of monitor and cuff

a) Separation from cuff

Step	Illustration	Description	Step	Illustration	Description
1		Remove the inner clip on the side with the screw first. Preparation: Hold both sides of the upper edge of the monitor with one hand and grip the edge of the cuff sleeve with the other hand, as shown by the arrow.	2		Carefully pull the two cuff clips out diagonally from the corresponding slots on the upper edge of the monitor.
3		Remove the two clips connecting the monitor and cuff at the center position.	4		Carefully remove the cuff clip near the USB port from the slot in the bottom housing of the monitor.
5		Air connector removal: Keep the monitor and cuff parallel. As shown in the illustration, apply gentle force in opposite directions to slightly separate the monitor from the air connector.	6		Hold the monitor with one hand and the cuff with the other. Keeping them parallel, apply additional force and separate the air connector in the direction indicated by the arrow to complete cuff removal.

b) Assemble

Step	Illustration	Description	Step	Illustration	Description
1		Install the air connector first. As shown in the illustration, align the cuff clip with the corresponding slot on the monitor, and insert the cuff air connector into the corresponding port on the monitor.	2		Install the clips at both ends. Align the two end clips of the cuff with the corresponding slots on the monitor.
3		Hold both ends of the monitor with both hands. Position your thumbs near the end clips of the cuff and apply gentle pressure to secure the clips into the corresponding slots on the monitor.	4		Install the center clips last. Position your thumbs near the center clips of the cuff and apply gentle pressure to secure the clips into the corresponding center slots on the monitor. Finally, check that the cuff is properly installed.

5.3.4 Battery replacement instructions

Step	Illustration	Description	Step	Illustration	Description
1		Remove the battery cover：Place the device as shown in the diagram. Press down at the area marked by the red box to take off the battery cover.	2		Take out the old battery：Pull the battery out of the battery compartment. As highlighted in the red frame, the wires attached to the battery connect to the device's main board via terminals.Use tweezers to grip the female terminal on the power cord, then pull it off the male terminal on the main board .
3		Install the new battery：Grip the female terminal with tweezers and insert it into the male terminal on the main board.Keep the red wire on the outer side.	4		Bend the wire at a 90° angle to the terminal for easier insertion.
5		Check that the screen lights up to confirm the terminal is fully connected.	6		Organize the wires as shown in the following figure, then close the battery cover.

Chapter 6 Product Specifications

Name	**Wearable Ambulatory Blood Pressure Monitor**
Model	WBP-02A
Measurement technology	Oscillometric
Systolic blood pressure measurement range	40-260 mmHg
Diastolic blood pressure measurement range	20-210 mmHg
Pulse rate measurement range	40-200 bpm
Resolution	Blood pressure: 1mmHg or 0.1Kpa; pulse rate: 1BPM
Repeatability	The difference of repeated readings of each point is within 4mmHg in the statically continuous low-pressure mode
Accuracy	Static Accuracy: ±3 mmHg; Pulse rate: ±3BPM
Pressure Sensor	American Freescale pressure sensor
Power supply	3.7 v Li battery
Data memory	Flash memory stores up to 300 readings
Calibration frequency	At least one time every two years
Security system	Cuff pressure range: 0~290mmHg
Intervals	Multiple independent programming intervals (5,10,15,20,30,45,60,90,120 minutes)
Size	About 119×52×21mm
Net weight	About 105g，including battery
Working condition	T: 5℃-40℃; HR: 10%-95%; gas pressure: 70KPa-106KPa
Storage Condition	Stored under the condition of temperature (-20℃-+55℃), HR (no more than 95%) and atmospheric pressure (70KPa-106Kpa), no corrosive gases and well-ventilated.
Data transmitted by	USB cable
Protection against harmful ingress of water or particulate matter	IP22
Software version	Embedded software: 1.0 PC software: 3.1

* There is not further notice if product specification changes.

Chapter 7 EMC Information

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.

Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.

Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

Caution: this machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacture's declaration – electromagnetic emission		
The WBP-02A is intended for use in the electromagnetic environment specified below. The customer of the user of the WBP-02A should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The WBP-02A use 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 WBP-02A is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity

The WBP-02A is intended for use in the electromagnetic environment specified below. The customer or the user of WBP-02A should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
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 sec	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the WBP-02A requires continued operation during power mains interruptions, it is recommended that the WBP-02A be powered from an uninterruptible power supply or a battery.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

The WBP-02A is intended for use in the electromagnetic environment specified below. The customer or the user of the WBP-02A should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the WBP-02A, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz~800MHZ
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 2.3\sqrt{P}$ 800MHz~2.5GHZ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the WBP-02A is used exceeds the applicable RF compliance level above, the WBP-02A should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the WBP-02A.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the WBP-02A .

The WBP-02A is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the WBP-02A can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the WBP-02A 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	12	23

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

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

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

Chapter 8 Warranty Card

Warranty Card

Product model and SN number：	Name：
Purchase Date：	Address：
Dealer：	Tel：
Postal Code：	Dealer stamp：

The limited liability of guarantee

Hingmed provides the original purchaser the following limited warranty from the date of invoicing.

Hingmed Wearable ambulatory blood pressure monitor…… 24 months

Accessories except cuff……90 days

Cuff..……..……6 months

Hingmed warrants each monitor to be free from defects in material and workmanship. Liability under this warranty covers servicing of the returning monitor from customer prepaying to the prospective factory (depending on location). Hingmed will repair any defective component(s) or part(s) during the period of this limited warranty.

Should a defect become apparent, the original purchaser should notify Hingmed of the suspected defect; the monitor should be carefully packaged and be prepaid shipped to:

Shenzhen Hingmed Medical Instrument Co., Ltd.

Address: West block, 4th Floor, Zhonghang Flying Building, #371, Guangshen Road, Xixiang, Bao'an District, Shenzhen, China

Tel: +86 755 23720600

Postal code: 518102

Email: service@Hingmed.com

The monitor will be repaired as soon as possible, and be returned by the same shipping method as received by the factory if it is prepaid.

This limited warranty is invalid if the monitor has been damaged due to accidents, misuse, negligence, or maintained by any person not authorized by Hingmed.

This limited warranty contains the entire obligations of Hingmed exclude other expressed, implied or regulated warranties. There is no any authorization from Hingmed to representatives or employees to take any further liability or grant any further warranties except as set herein.