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Holter Supplies

Ambulatory Blood Pressure Monitor

User manual

WBP-02-A

VER：A/1

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).

Manufacturer:

Monitor :

Shenzhen Hingmed Medical Instrument Co., Ltd.

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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 efficacy, 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-03D Hospital ABPM

Blood Pressure Monitor with Body Position Information

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.

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-03D Hospital 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 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. The Quick BP PC software can be downloaded from Holter Supplies website.

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 UUSB 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 Holter Supplies, otherwise it may cause measurement errors.
- Maintenance should be conducted only by trained personnel or personnel authorized by Holter Supplies.
- 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 customer service for help.

Basic Kit :

Name	Qty
ABPM monitor	1
Storage bag for monitor	1
USB cable	1
Large Adult cuff (26-36 cm) or medium (22-32cm)	1
User manual with a link to download the software.	1
Battery Quick charger	1

Optional accessories

Référence	Nom
WP-B-18	Small Adult cuff (18-26cm)
WP-B-22	Medium Adult cuff (22-32cm)
WP-B-26	Large Adult cuff (26-36cm)
WP-B-30	Extra Large Adult cuff (30-43cm)
WP-C-01	Battery Quick charger

3.2 Name and Function of Each Component

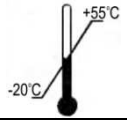
3.2.1 Monitor Introduction :

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 Display

MEM	Quantities of historical memory, it flashes means full of memory
AUTO	Automatic measurement
00:00	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

Symbol	Description	Symbol	Description
	CF type applied part	SN	Serial number
	Manufacturer		Attention, refer to accompanying documents
	Keep away from rain		This way up
	Fragile		Complying with WEEE standard
	Stacking limit by number		Temperature limits
	Refer to user manual	IP22	It means the device is safe against solid foreign objects of 12.5mm and greater, and against vertical falling water drop 15°

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-03D Hospital ABPM on your arm. Press the middle button for about 5 seconds to power on/off the monitor.

4.2.1 Wear cuff correctly

a) Select right size cuff and wrap it on the upper arm. The arrow sign "Index" should between the "Max" and "Min" of "Range", if not, change to a bigger or smaller cuff.

b) To wear cuff correctly, the cuff down side should be 2-3 cm away from the elbow. Make sure the artery sign is above the arm artery, cuff tube should be upwards. See the picture right:

Note: 1 Inappropriate size of cuff will lead to error of measurement.

2 Do not wrap the cuff on the diseased skin directly; wrap it on a partition like cloth to avoid cross-infection.

4.2.2 Start for single measurement

Press "►/■" 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 Start ABPM:

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 "►/■" 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.
- To stop recording temporarily or permanently, the monitor must display either the measurement results or the time. If it is in standby mode (symbol "♦"), press the "► / ■" button to see the time, then press and hold the "► / ■" button until 4 beeps And then release the button: the recorder screen turns off completely.
  To resume the automatic measurement cycles, press the "► / ■" button until you hear 2 beeps.
  When the monitor is supported with a USB cable, the measurements are automatically interrupted.

4.3 Quick BP software

4.3.1 Hardware

PC Windows XP, 7, 8, 10 or more, display minimum 1024*768, 1 USB port.

4.3.2 Software:

Donwload the Setup of QuickBP on the website of Holter Supplies with this link:

www.holtersuppliessas.com/telechargements

4.3.3 Software Installation:

Double click on the SetUpQuickBP file to start the installation automatically on your computer. Just answer the questions. The setup installs the program and places an icon on the desktop.
The program includes access to the complete user manual ("?" Icon). The paragraphs below summarize the main points.

Note: *the* USB cable must be disconnected after installation.

4.4 Perform ambulatory blood pressure measurements

4.4.1 Communication with the monitor

After installing the program on the PC, the PC must be able to communicate with the monitor for programming and reading the recorded data.

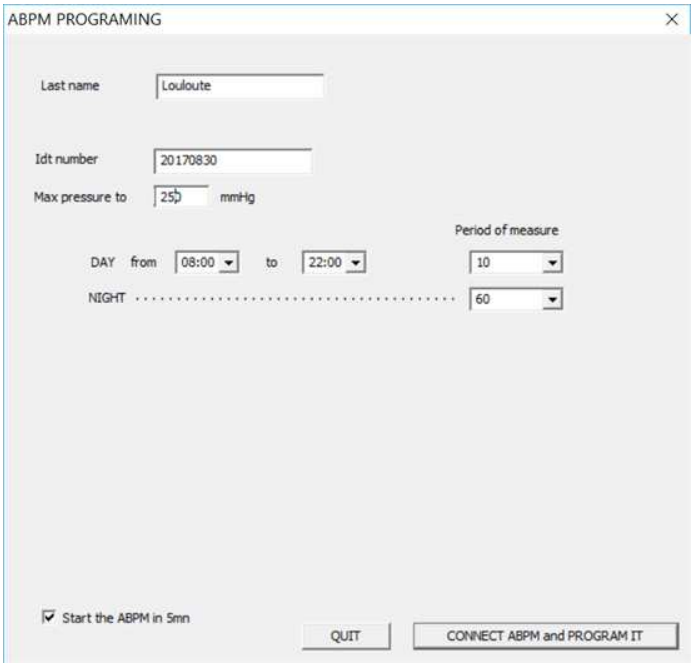
4.4.2 Connect the monitor to the PC:

a) Connect the Micro USB plug of the cable to the USB port of the monitor.

b) Connect the USB plug of the cable to the USB port of your PC.

4.4.3 Program automatic measurements

Click on the icon 



- Enter the name of the patient. Programming is only possible if the name has a minimum of 3 characters.
- Possibly change the identification number. By default, it displays a number corresponding to the date: year month and day. Programming is only possible if the number has at least 1 number. Non-numeric characters are not allowed.
- Choose the Periodicity of measurements during the day and during the night, between 5mn and 120mn. For the day, we usually choose 15 or 30mn, and for the night, 60mn.
- The beginning and end of the day period should also be specified according to the patient's habits.
- The night corresponds to the time not selected in the period of the day.
- Set the maximum permissible pressure for the measurement
- Check the "Start the ABPM in 5 minutes" checkbox if you want to see the ABPM start the first

measurement 5mn after disconnecting the PC. If the box is not checked, it waits until the "►/■" button on the monitor is pressed to start the first measurement.

Starting a new program deletes old data from the monitor.

4.4.4 Start monitoring

Check that the monitor is working properly before placing it on the patient.

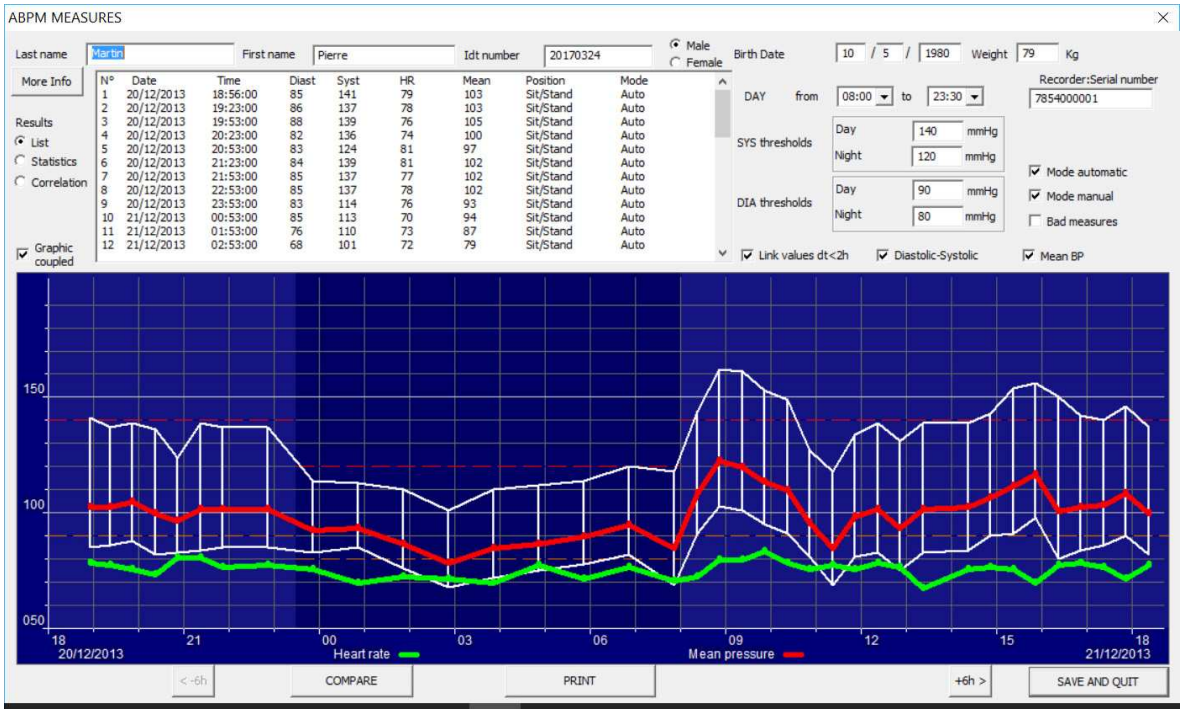
- Make sure that the monitor displays the time.
- Press the "start / stop" button or wait 5 minutes (if you have checked the "Start in 5mn" command to check that the first measurement is correct and without problems before leaving the patient.

4.4.5 Complete measurements

When the measurements are complete, remove the monitor from the patient and stop the monitor by holding down the "► / ■" button at least 5s until the screen is turned off.

4.4.6 Recover data

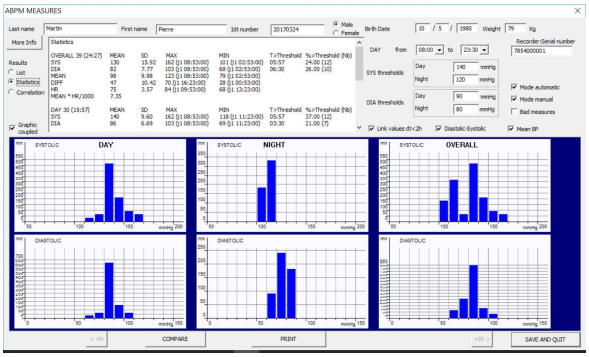
1. Connect the monitor to the computer via a USB port;
2. Launch the QuickBP software from Holter Supplies;
3. Click on the icon  : the data is transferred and the results are displayed:

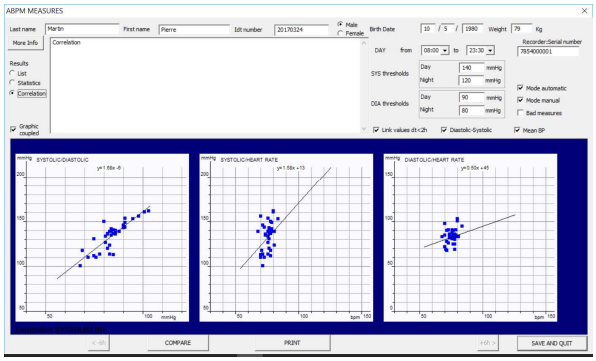


•4.4.7 Analysis and editing of the report.

Complete information about the patient (first name, date of birth ...), adjust the systolic and diastolic day-night thresholds and the hours defining the day and night.

You can view the trend line on 24h and the measurement list. On the curves, the night is represented in very dark blue. By selecting Statistics and Correlation, you access the data displayed on histograms and correlation clouds with regression lines.





You access to the print commands of the report by clicking on the "PRINT" button.

Note:

1. **The complete software manual can be accessed by clicking on the "?" Icon..**
2. **Record the data with a click on “SAVE AND QUIT”.**
3. **The monitor could store maximum 300 readings. When storage is full, the monitor can’t save data normally until next programming;**

Chapter 5 Troubleshooting and Maintenance

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.

* If the errors cannot be fixed by yourself, please call After Sales services.

5.2 Maintenance and repairing

5.2.1 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.

5.2.2 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.

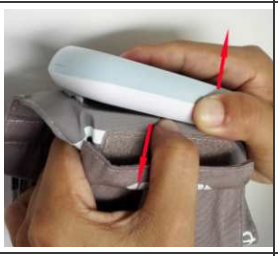
● DO not disinfect, immerse the monitor in any fluid, or attempt to clean with any liquid detergents, cleaning agents, or solvents. You may use a soft, damp cloth to remove dirt and dust from the monitor. If the unit does become immersed in water, do not use it and contact the distributor or our service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

a) Separation from cuff

Step	Picture	Description	Step.	Picture	Description
1		Hold the top corner position as shown in the picture, and lever the monitor from the cuff by following the marked direction.	2		Pull it out from the top two fixing clips
3		Then move down along the enclosure to take the monitor off from the cuff	4		Pull out the middle two fixing clips
5		Hold the same positions in step 3, and give force by following the red arrow.	6		Then the main unit and the cuff are detached.

b) Assemble

NO.	Picture	Description	NO.	Picture	Description
1		Put the bottom clip and air nipple into the monitor unit, and push the unit following the red arrow direction	2		The two bottom clips are put into monitor.

3		Hold the positions shown in the picture, and press simultaneously, then press around the edges of main unit	4		The monitor is installed on cuff well

Chapitre 6 Product specifications

Name	**Wearable Ambulatory Blood Pressure Monitor**
Model	WBP-03D Hospital
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
Data transmitted by	USB cable
Protection against harmful ingress of water	IP22
Software version	Embedded software: 1.0

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.

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** $d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in 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	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
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

Model and serial number： . . . . . .

Date of purchase：. . . . . .

Name：. . . . . .
Address: . . . . . .
City: . . . . . .
Postal code：. . . . . .
Tel：. . . . . .

Distributor’s stamp :

The limited liability of guarantee:

Holter Supplies provides the original purchaser the following limited warranty from the date of invoicing:

Ambulatory blood pressure monitor..... 24 months

Accessories except cuff……90 days

Cuff..……..……6 months

Holter Supplies 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). Holter Supplies 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 Holter Supplies of the suspected defect; the monitor should be carefully packaged and be prepaid shipped to:

Holter Supplies SAV
Centre d’Affaires Poincaré
78 Avenue Raymond Poincaré
75116 PARIS FRANCE

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 not authorized person.