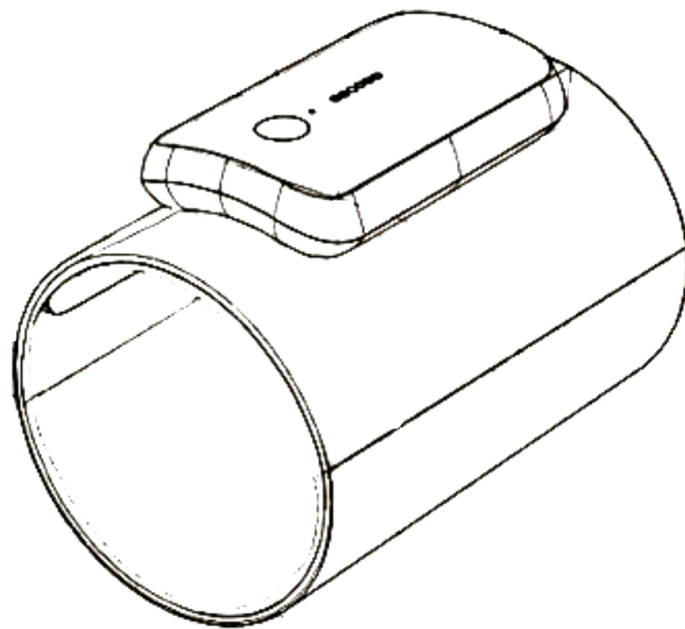

Hingmed
Upper Arm Blood Pressure Monitor

User Manual

This manual applies to model: V03



V03 User Manual

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About this manual

The manual mainly introduces the installation and application method of digital home blood pressure monitor. Users should read carefully before application (include warnings, contraindications, and notes). Please read the measurement items related to this product carefully, and then use the product correctly.

Production information

Model: V03

Product name: Upper Arm Blood Pressure Monitor

Date of manufacture: See the fuselage for details

Service life: Five years

Manufacturer:

Shenzhen Hingmed Medical Instrument Co., Ltd.

Manufacturer address: 4th Floor, Zhong Hang Flying Industrial Building, #371, Guangshen Road, Xixiang, Bao'an District, Shenzhen, China.

Tel: +86755-23720600

Post code: 518102

Service:

Company: Shenzhen Hingmed Medical Instrument Co., Ltd.

Adress: 4th Floor, Zhong Hang Flying Industrial Building, #371, Guangshen Road, Xixiang, Bao'an District, Shenzhen, China.

Tel: +86755-23720600

Post code: 518102

Version Information

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

Embedded software release version: V1

Mobile terminal software release version: V1

■ Version: A/1

■ Reversion time: June, 2023

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I Introduction

1.1 Introduction to Upper Arm Blood Pressure Monitor

Scope of Application

Diastolic blood pressure, systolic blood pressure and pulse rate were measured by oscillometric method, and the values were used for diagnosis.

Note: Please read the instructions in detail before use. If you have any questions, ask the purchase salesman or ask your doctor.

* This product is suitable for people aged 12 years old and above.

1.2 Contraindication

- No use near x-ray tomography units.
- Do not use it in places where flammable anesthetics exist, which may cause an explosion.
- The cuff is not worn on the limb used for IV injection as inflation of the cuff may block the injection and injure the patient.
- Do not immerse the sphygmomanometer in any liquid or wash with any liquid detergent, which will cause electrical damage.

1.3 Warnings

- The cuff should not be worn over the wound as the inflation pressure may cause further injury.
- People under 12 and those who cannot express their ideas cannot use this instrument.
- This instrument must not be used simultaneously with the defibrillation device.
- Use of components not included in the supply list may result in a measurement error.
- Ensure that the pressure is appropriate for all patients. If any abnormality occurs in the monitoring, immediately stop the measurement and disconnect the cuff from the patient or short-press the key. If the cuff is faulty, the patient shall be instructed to remove it properly and safely.
- If the equipment is accidentally damp, please put it in a cool place to dry naturally before use.
- When the patient has common arrhythmias (such as early atrial, early chamber, atrial fibrillation, etc.), the measurement results of the device may be affected.
- Charge the device and use an adapter that meets the IEC60601-1 standards (output: 5V $\overline{=}$ 2A).
- Persistent overinflation may cause blood obstruction and make the patient feel uncomfortable.
- Only a professional physician can interpret the measured blood pressure values.

1.4 Note

1.4.1 Battery

- The upper arm blood pressure monitor uses a built-in lithium battery; it is forbidden to replace the battery without authorization; please charge in time with low power; and the maximum ambient temperature of the sphygmomanometer should not exceed 60 degrees Celsius.
- When placing the upper arm blood pressure monitor, we must choose a place far away from the high temperature, but also to avoid the direct sunlight in summer.
- Found that the upper arm blood pressure monitor battery cannot be charged or the battery discharge speed is very fast, for the sake of safety, we should consult the after-sales technical support personnel as soon as possible.
- The upper arm blood pressure monitor should be charged at least once every three months, otherwise, the battery life may be affected.

1.4.2 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 measurement, especially do not move the cuffed arms, and try to avoid talking.
- 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.

1.4.3 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 the cuff fails to inflate in two and a half minutes, the patient is instructed to manually remove the cuff. Long overinflation may cause the patient's blood obstruction and make the patient feel uncomfortable.

1.4.4 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.

1.4.5 Maintenance

- Please use the accessories provided by Hingmed, otherwise it may cause measurement errors.
- Repairs should only be performed by trained or Hingmed authorized personnel.
- Fault display method: when the blood pressure monitor fails, the corresponding code number will appear on the display screen, see "Four Common Failures" for details.

1.4.6 Bluetooth connection

The Bluetooth connection distance of the device is about 10m in the open distance, if beyond the range may affect the quality of Bluetooth connection.

1.4.7 Cuff

The cuff is a consumable product and the cuff life test is 10,000 times. (Adopting our company's test conditions)

Declaration

The blood pressure value measured by the equipment is equivalent to the measured value of the auscultation method, and the error meets the requirements of YY0667-2008.

II Product list and specification

2.1 Product list

Hingmed packing list

Accessories items name	Qty
Hingmed Upper Arm Blood Pressure Monitor (arm end)	1
USB cable	1
Cuff (cuff circumferences: 22-42 cm)	1
Quality certification	1
APP quick user guide	1
User manual (including warranty card)	1

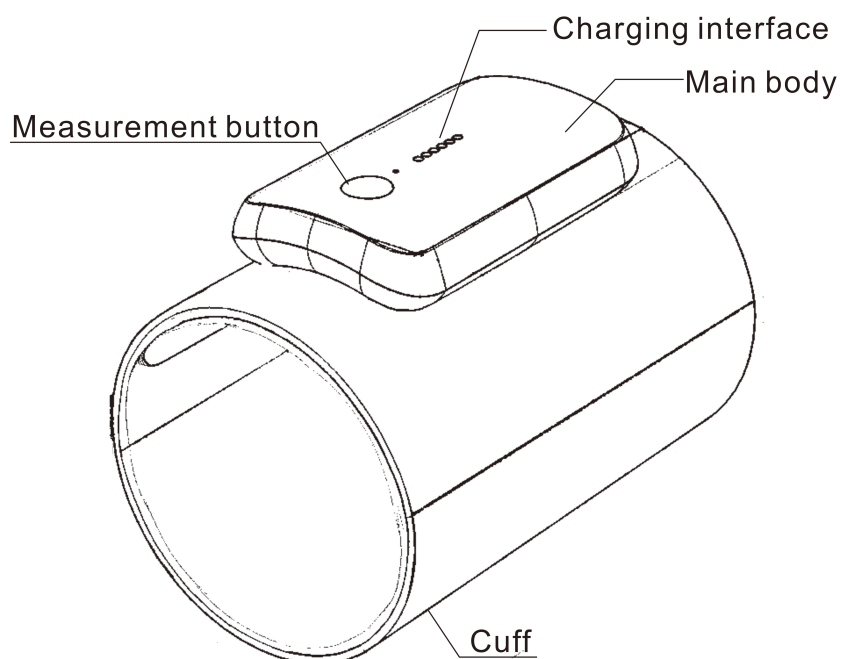
- The product packaging should include all of the above items. If there is any shortage, please contact Hingmed or distributor immediately.

Please confirm whether the accessories are complete and whether there is damage to the main machine and the accessories before use. If the accessory is insufficient or damage is found, please contact the

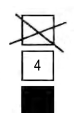
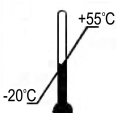
dealer who purchased the instrument or call the customer service hotline for consultation.

2.2 Product introduction

Structure: It consists of main body, cuff, USB cable and mobile terminal software.



2.3 Symbols

Symbol	Description	Symbol	Description
	CF type applied part	SN	Series number
IP22	It means the device is safe against solid foreign objects of 12.5mm and greater, and against vertical falling water drop up 15°		Medical instrument
	Keep away from rain		This way up
	Fragile		Complying with WEEE standard
	Stacking limit by number		Temperature limits
	Non-ionizing radiation		Pulse rate unit: second / minute
	Refer to user manual		

III Measurement Operation

3.1 Powering on

Press the measurement button to the power, and then press it again to start measurement.

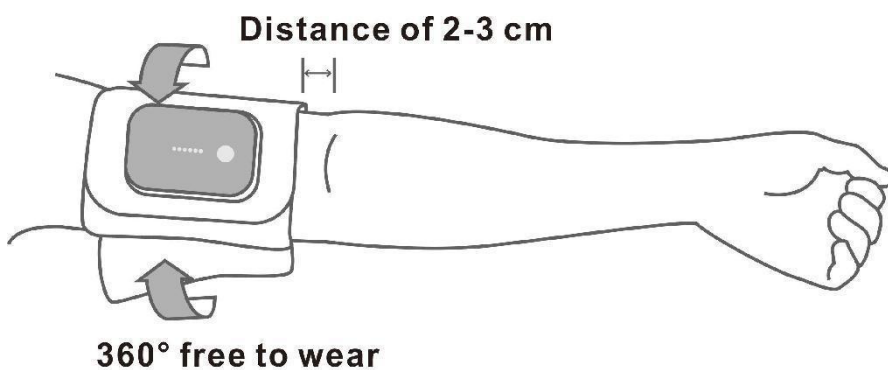
3.2 Charging method

Use the magnetic data cable to align the magnetic connector with the charging contact point of the main machine on the arm. When the indicator light turns red, it means it is charging, and if it turns green, it means it is fully charged.

*Note: The device does not work when charging!

3.3 Wear your cuff correctly

Wear the blood pressure cuff on your bare left upper arm so that the lower edge of the cuff is 2-3 cm away from the elbow joint.

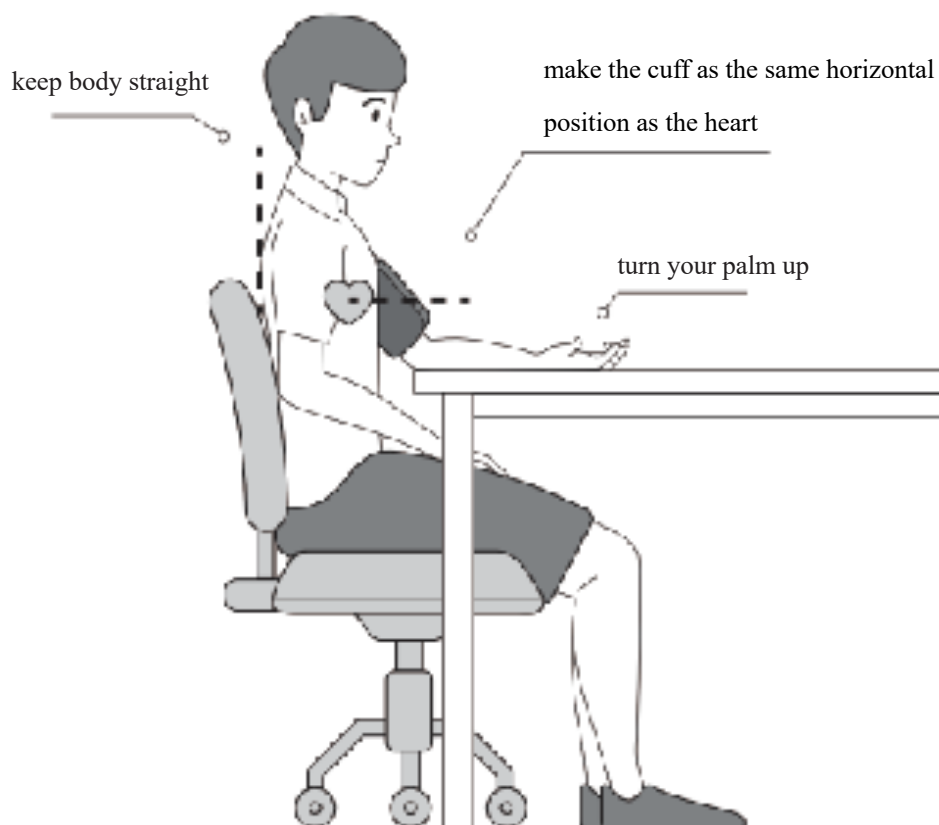


*Friendly reminder:

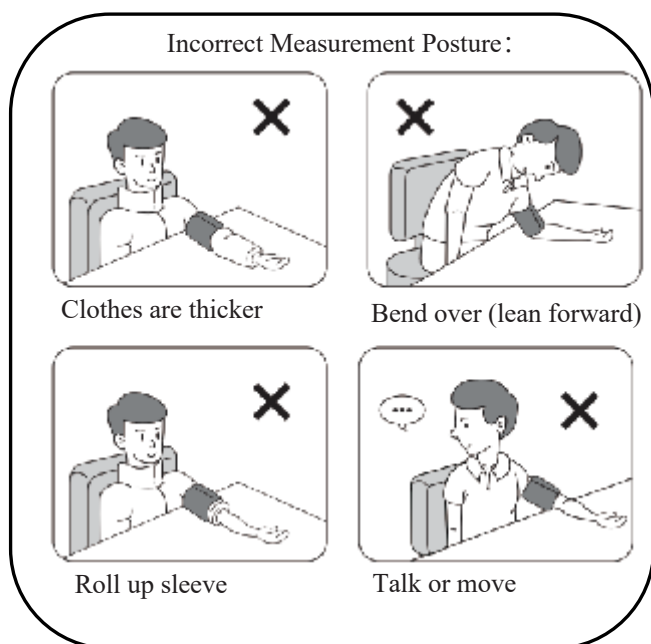
The cuff should be comfortably wrapped around the upper arm to prevent too tight or excessive loosening.

3.4 Correct measurement posture

Place your left arm on the table, turn your palm up, and maintain your quiet balance.



- If the cuff is below the heart, place the cushion or towel below.



3.5 Bluetooth connection

Way to connect to the Bluetooth:

- ① Turn on the phone's Bluetooth and location first. (*Mobile phone positioning should allow the software to obtain location information.)
- ② Open the "Hingmed BP" App page —— click the " three horizontal lines"  on the upper left corner.
- ③ Click "Devices" —— click "scan" to search for Bluetooth devices —— select V03——Connect.

3.6 Blood pressure measurement

To obtain accurate measurements, note the following before measuring:

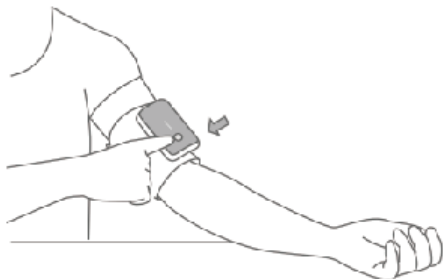
- ① Sit still for 5-15 minutes before measurement.
- ② Try to measure blood pressure every day during a fixed period (when waking up and before bedtime)
- ③ Measure it within 1 hour after getting up, or after going to the toilet, before breakfast, or before taking medicine. Please rest in your seat for 5 to 15 minutes before starting the measurement.
- ④ Too cold or overheated environment can lead to temporary fluctuations in blood pressure. Please measure in a comfortable environment.
- ⑤ Please do not eat, drink, drink tea, exercise, bathe, or any form of activity before the measurement. Please relax in a quiet environment, and then measure after the mood is calm.

-
- ⑥ If the same person measures again, the arm should rest for at least 5~15 minutes, and then the arm is fully restored to blood circulation.

Measurement method

- ① Press the “measurement button” to measure directly.
- ② Click "Start measurement" on the main interface of the app to measure blood pressure.

* See App Quick Use Guide for app software operation.



3.7 View the results

View the history records through the app mobile terminal software * See App Quick Use Guide for app software operation.

- *Note: If you cannot view the history, please click the three lines in the upper left corner of the app page-setting-NB management, delete the device number, and click the number to the left to see the record.

Blood pressure reading:

Blood pressure category	Systolic pressure (mmHg)		Diastolic pressure (mmHg)
Normal	Less than 120	and	Less than 80
Elevated	120-139	and	Less than 80
High blood pressure(stage1)	130~139	or	80~89
High blood pressure(stage2)	140 or higher	or	90 or higher
Hypertensive crisis (consult your doctor immediately)	Higher than 180	and/or	Higher than 120

- *Reminder: Due to the fluctuation of blood pressure, the results of each measurement will be different. If the user's blood pressure fluctuates greatly, it is best to average the three measurement results on different days at the same time as the blood pressure measurement value, which is more referent.

3.8 Network security-related instructions

User access control mechanism: account password login

Electronic interface: network electronic interface (Bluetooth, WIFI)

Data type: Non-sensitive medical data (measured values)

Technical characteristics:

Network form: wireless

Network type: the WAN

Interface form: electrical port

Data interface: private protocol

Remote access and control mode: real-time

Performance indicator: Bluetooth transmission rate 115200 bps

WIFI transport rate: 150Mbps

Network security feature configuration: no

Running environment:

Hardware conditions: a mobile phone with Bluetooth function or mobile phone card communication function

The iPhone must be iPhone 6 or above, and the minimum resolution of the display device is 480x800

Software conditions:

Apple phone: Apple iOS version 9.0 or above

Android phone: Android 6.0 and above

*The user can automatically clear the local data after logging in * It has the running environment boot self-check function.

3.9 Power off

If you want to shut down, please press the [measurement button] for 6 seconds to let go, and the red light flashes for about 5 seconds.

IV Troubleshooting and maintenance

Troubleshooting

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	Check the cuff. If leakage is not still resolved, contact agent or dealer
EC04	Weak signal, maybe weak 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 measurement range	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 measuring and do not move the arm with cuff
EC07	Overpressure, cuff pressure beyond	Press “start/stop” button to measure again

	290mmHg	
EC08	Signal saturation, making the signal amplitude too large due to movement or other reasons	Keep still. Press “start/stop” button to measure again
EC09	Overtime : one time measurement takes more than 120s	Keep still. Press “start/stop” button to measure again
EC10	Manual stop	Keep still. Press “start/stop” button to measure again
EC11	Low power	Please charge
EC12	Calibration information reading error	Please contact customer service
EC13	No signal	Press “start/stop” button to measure again
EC15	Charging stops measurement	Measurement is only done after charging
EC16	Overpressure protection. Cuff pressure beyond the max pressure setting (290)	Keep still. Press “start/stop” button to measure again
EC17	The measurement result is wrong	Press “start/stop” button to measure again
EC18	RTC clock error	Please contact customer service
EC19	Storage error	Please contact customer service
EC32	Handshake communication failed	Press “start/stop” button to measure again
EC35	No response from monitor when press the start/stop button	Press “start/stop” button to measure again
EC36	No measurement results, measurements cannot be obtained	Press “start/stop” button to measure again
EC37	Overtime (beyond 180s)	Press “start/stop” button to measure again
EC50	Measurement interruption	Press “start/stop” button to measure again
EC53	Continuous frequent measurement	Please measure it again after 5 seconds

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

V Frequent asked questions (FAQ)

- ❶ Q:** Why do you need to ensure that you are in a comfortable and relaxed state before the measurement?
- A:** This is because if the measurement is performed under strong support or mental stress, it may cause blood pressure to rise.
- ❷ Q:** Why is the measurement position as high as the heart?
- A:** If the measurement position is above or below the heart, sometimes incorrect measurement results will also be obtained.
- ❸ Q:** When measuring, I always feel nervous and hold my breath. Does it have an impact on the measurement results?
- A:** This has an impact on the measurement results! Holding your breath may raise blood pressure, please keep calm, nervousness, speech or activity; try to adjust or rest for 5-15 minutes before measurement.
- ❹ Q:** When measuring, the blood pressure value is sometimes high and sometimes low, what is the case?
- A:** Medical experiments have proven that human blood pressure fluctuates throughout the day. Blood pressure is low during sleep and high between 8 a.m. and 10 a.m. The value measured by the digital blood pressure monitor reflects the blood pressure value at the time when the human body was measured. Two or more The possibility of obtaining the same blood pressure value from multiple measurements is relatively low. It is recommended to test blood pressure at the same time and in the same posture every day to obtain comparable blood pressure values.
- ❺ Q:** Multiple repeated, continuous, rapid measurements, why are the results different?
- A:** Repeated and continuous measurement will make the arm compression lead to poor blood flow, easy to cause changes in blood pressure. It is recommended to rest for 5-15 minutes in the second measurement.
- ❻ Q:** Why the home measurement is different from the hospital results? Why the measurements are low?
- A:** Changes in the environment will cause fluctuations in the human body's mood to a certain extent. If the mood is stable and the environment is suitable when measured at home, the value will generally be 20-30mmHg lower than the value measured in the hospital. It is important to understand the average blood pressure when the blood pressure is calm at home.

VI Maintenance and repairing

6.1 Maintenance, inspection & safety management

Use the naked eye to check whether the blood pressure monitor shell is cracked or damaged and whether the blood pressure monitor and cuff are tightly connected. Do not use the blood pressure monitor if it shows any signs of damage. Please contact the maintenance service department.

6.2 Cleaning and disinfection

The blood pressure monitor and accessories do not need to be sterilized, but they should be kept clean. If there is contamination, it should be cleaned first and then disinfected.

*When cleaning and disinfecting, do not immerse the product and accessories in liquids. Do not let the liquid flow into the connection socket or case of the blood pressure monitor to prevent damage to the blood pressure monitor.

Cleaning

- (1) Turn off the main machine before cleaning the blood pressure monitor;
- (2) Wet a soft, clean, fluffy cloth with mild soapy water or non-corrosive diluted detergent.
- (3) Wipe machine and the place patient contact surfaces
- (4) Dry with a clean, dry, soft cloth

Disinfection

It is recommended that users soak a piece of clean dry gauze with 70%~80% (volume ratio) ethanol disinfectant, and then wipe the surface of the object to be disinfected with the gauze twice for 3 minutes. Let it air dry naturally or wipe away the residual disinfectant with a clean, dry cloth.

Clean before disinfection. Ethanol is flammable. Please stay away from fire sources during the disinfection process. People who are allergic to alcohol should use ethanol disinfectant with caution.

6.3 Blood pressure calibration

- The pressure sensor of this device needs to be calibrated regularly. It is recommended to calibrate it every two years. Please contact the dealer or manufacturer for calibration.
- To enter static pressure mode, please contact the manufacturer to obtain dedicated calibration software.

VII Product features and technical parameters

7.1 Product features

Integrated design	Lithium battery charging
Portable	Pulse rate detection
One-button measurement	Sleeve self-inspection
Small, light	Bluetooth transmission

7.2 Technical parameters

Model	V03
Measurement technology	Oscillometric
Range	0-289mmHg
Pulse rate measurement range	40-200 bpm
Resolution	Blood pressure: 1mmHg; pulse rate: 1bpm
Repeatability	The difference of repeated readings of each point is within 3mmHg in the statically continuous low-pressure mode
Accuracy	±3 mmHg
Power supply	3.7V Li battery
Power life	After the lithium battery is fully charged, it can be measured about 60 times (at room temperature of 25 degrees, each time pressurized to 140 mmHg) * Note: In the test environment and instrument, different measurement environments and conditions using different measurement tools may cause errors.
Size	Arm end about 82×49×13.5mm (not including cuff)
Net weight	About140g (including cuff)
Working condition	T: 5°C~40°C; HR: 10%~95%
Storage condition	Stored under the condition of temperature:-20°C-+55°C; HR no more than 95%; Atmospheric pressure: 70kPa~106kPa, no corrosive gases and well-ventilated.

*There is not further notice if product specification changes.

Appendix I: Guidance and manufacturer's declaration

Guidance and manufacturer's declaration-electromagnetic emission		
The V03 is intended for use in the electromagnetic specified below. The customer of the user of the V03 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions GB4824	Group 1	The V03 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 emissions GB4824	Class B	
Harmonic emissions GB17625.1	Not applicable	
Voltage fluctuations/flicker emissions GB17625.2	Not applicable	

Guidance and manufacturer's declaration-electromagnetic immunity			
The V03 is intended for use in the electromagnetic specified below. The customer of the user of the V03 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge GB/T 17626.2	±6kV contact ±8kV air	±6kVcontact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst GB/T17626.4	±2kV for power supply lines ±1kV for input/output lines	Not applicable	Not applicable
Surge GB/T 17626.5	±1kV line(s) to line(s) ±2kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and	<5% U_T , (>95% dip in U_T) for 0.5 cycle	Not applicable	Not applicable

voltage variations on power supply input lines GB/T 17626.11	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		
Power frequency magnetic field (50Hz/60Hz)GB/T 17626.8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration-electromagnetic immunity			
The V03 is intended for use in the electromagnetic specified below. The customer of the user of the V03 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF GB/T 17626.6	3Vrms 150kHz~80MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the V03, 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 $d = 2.3\sqrt{P}$ 800MHz~2.5GHZ
Radiated RF GB/T 17626.3	3V/m 80MHz~2.5GHz	3V/m	

			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
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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 24 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 V03 is used exceeds the applicable RF compliance level above, the V03 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the V03.

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 V03

The V03 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the V03 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the V03 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)		
	150kHz~80MHz $d = 1.2\sqrt{P}$	80MHz~800MHz $d = 1.2\sqrt{P}$	800MHz~2.5GHz $d = 2.3\sqrt{P}$
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.			

Warranty Card

Warranty Card

Product model and SN number:

Name:

Purchase date:

Address:

Dealer:

Tell:

Address:

Dealer stamp:

Postal code:

The limited liability of guarantee

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

Hingmed upper arm blood pressure monitor.....12months

Accessories except cuff..... 3 months

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, Zhong Hang Flying Industrial Building, #371, Guangshen Road, Xixiang, Bao'an District, Shenzhen, China.

Tell: +86755-237320600

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.

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

The 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 or any further warranties except as set herein.