

Instruction for Use

(File No.: IFU-MBPT)

Version: 01

Mobile Blood Pressure Terminal

Zhejiang Medzone Medical Equipment Co.,Ltd

1 Preface

Dear Customers, thank you for purchasing the Mobile Blood Pressure Terminal.

This instruction for use describes the characteristics and technical requirements of the device, main structure, performance, specifications, transportation, usage, operation, maintenance and storage methods, safety measures are also included, please see specific chapters.

Please read this instruction for use carefully before you using this device, and follows this instruction. This instruction will tell you how to use the device, operations which may cause to abnormal conditions, risks to causes damages to the device and human body. Any abnormal condition or damages to the device and human body which caused by without following this instruction for use, the company will not assume responsibility for safety, reliability and performance, and will not be free of charge for such failure.

This product is a medical device that can be reused.

Please keep the instruction for use well, and refer it at any time.

2 Safety

2.1 Safety information

Warning	To remind potential dangers or unsafe operations, if not avoided, may result in death or serious personal injury or property damage.
Caution	To remind potential dangers or unsafe operations, if not avoided, will lead to minor personal injury, product failure, damage or loss of property.
Attention	To emphasize important attentions, provide a description or explanation to better use this device.

2.1.1 Warning

- ◆ For patients, it is danger to self-judge and self-treat according to measured results, please follow doctors guidance, self-judge may cause disease deterioration.
- ◆ Patients who has blood circulation disorder, blood disease, please use under the guidance of doctors. During measurement, the shoulder will be extruded, it may cause acute internal bleeding.
- ◆ When common arrhythmia (for example, atrial premature, premature ventricular and atrial fibrillation), the measured values may not be accurate or blood pressure cannot be measured.
- ◆ People who suffers from diabetes, renal failure, during measure, its blood pressure may fluctuate.
- ◆ The product is not suitable for arrhythmia.

2.1.2 Caution

- ◆ Not to inflate the wristband which was not well fixed in the wrist, or lastingly inflate the wristband, it may cause rupture of the wristband.
- ◆ When lastingly inflate the wristband, the user's wrist may be pressed excessively, in this case, immediately open the wristband manually.

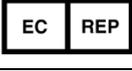
2.1.3 Attention

- ◆ If the product is stored, transported and used at environment outside the temperature and humidity range specified by the manufacturer, the measure

results may not be able to achieve the expected performance.

- ◆ The measured value shall be interpreted by professional person.
- ◆ The error between measured value by this product and measured value by the stethoscopy shall comply with EN ISO 81060-1:2012 requirements.
- ◆ If the measured value is always abnormal, please contact the doctor, it is prohibited to self-measure without consultation of the doctor.
- ◆ The product is only used to measure blood pressure.
- ◆ The product is only used for people who are more than 12 years old.
- ◆ The infant and people who can not express himself can not use this product.
- ◆ The maintenance and repair of the product can only conducted by the company authorized personnel. Do not disassemble or repair, reconstruction the blood pressure and wristband, otherwise the device can not measure correctly. If need to maintenance or repair, please contact the company sales repair office or contact the customer service number of the company 86-400-613-6601.
- ◆ If you use this product near the microwave oven, TV, X-ray equipment or other strong electromagnetic field, the measuring results may make mistakes; in order to avoid electromagnetic field effect, please stay away from the electrical measurement facilities, or to switch off the appliance before use.
- ◆ Non the company's replace parts are used to change parts, wrong measure result may happen.
- ◆ The products and its accessories and packaging (battery, plastic film, plastic boxes and cartons, etc.) shall be disposed according to local laws and regulations.
- ◆ Please get out the battery when not use the device in long time (more than 3 months)
- ◆ Please pay attention to the polarity of the battery, they shall be installed correctly, otherwise it may cause damage to the product.
- ◆ The product shelf life is 5 years, overdue use will cause inaccurate results.

2. Symbols instruction

	BF type application part		Serial number
	Recycling according to local laws		Date of manufacture
	See the Instruction		Manufacturer
	Cautions		European union representative
	Standby	IPX0	IP degree
	Temperature range		Avoid sunlight

	Humidity range		Up toward
	Keep dry		

3 Product brief

3.1 Product characteristics

The Mobile Blood Pressure Terminal has a small size, low power consumption, easy to use and carry.

3.2 Intended use

The mobile blood pressure terminal is applicable to measure blood pressure and check pulse number in medical institute or homehold, and show, analyze, store and transmit the measured blood pressure data by the blood pressure management software.

3.3 Contraindication

The product can not be used for patients with arrhythmia.

This product can not be used for infants and neonates.

The product is only used for people who are more than 12 years old.

The infant and people who can not express himself can not use this product.

4 Prepare before use

4.1 Structure of the product

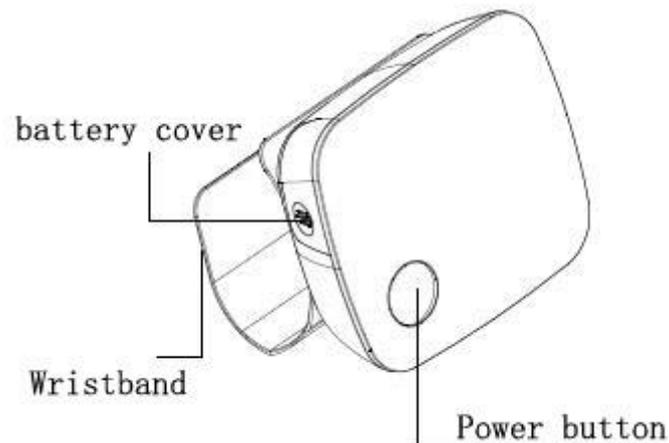


Diagram 1. Measurement hardware structure

4.2 How to install and change the battery

4.2.1 To press the battery cover groove, slip outward and open the battery cover;

4.2.2 To refer the battery cover reed polarity direction, insert into two No.7 alkaline battery;

4.2.3 Close the battery cover.

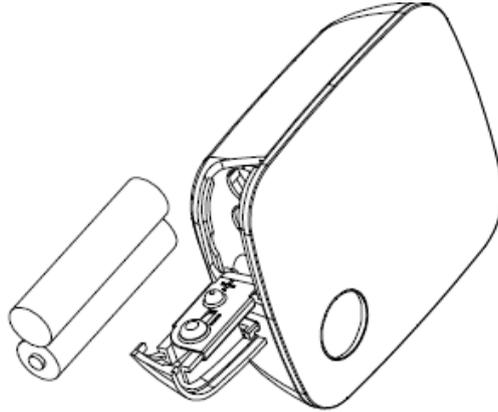


Diagram 2. How to install and change the battery

Warnings: When the device appears low voltage, please change the battery in time. If it is not used for a long time, remove the battery, so as to avoid battery leakage.

4.3 Installation and use of the Mobile Blood Pressure Terminal management software, see “Rapid use manual of Mobile Blood Pressure Terminal”

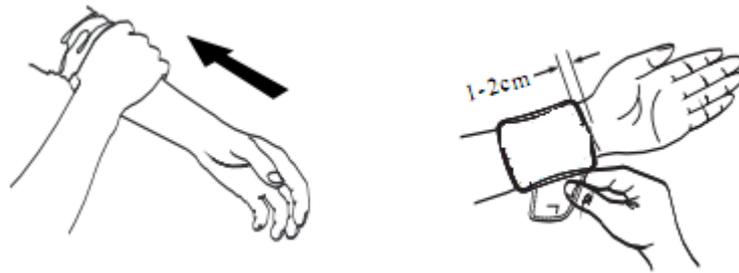
5 Method of use

5.1 Use cautions

- 5.1.1 Product intended use: mainly used to measure human blood pressure.
- 5.1.2 Don't measure during meal or sports.
- 5.1.3 Don't measure in transport tools and in cold environment.
- 5.1.4 The left and right hand all can be measured, but the measure value of the left and right may show different for different people, only the measure value which conducted in the same day, the same time, same wrist, and same gesture has comparability.
- 5.1.5 Please keep at least 5 minutes quiet time for relax before measurement.
- 5.1.6 Please empty urine before measurement.
- 5.1.7 Deeply breathe 2-3 times to relax the body before measurement.
- 5.1.8 The measurement interval of continuous two times shall not be less than 3 minutes.
- 5.1.9 During measurement, don't twist the wrist and body, keep quiet.
- 5.1.10 Don't stand to measure.
- 5.1.11 During measurement, try to avoid strong electromagnetic interference such as X ray equipment.

5.2 Method of use

- 5.2.1 To wear the hardware
 - a) To loose the cuffs and bare the wrist, ensure the wron clothes does not stretch the arms, the wristband face to the wrist inside and strap the wristband on the bare wrist.
 - b) To moderately tension wristband so as to stick the wristband in the wrist, the distance between the wristband edge and wrist joints is about 1-2cm.



(Remove the cloth, and bare the wrist) (wear the wristband correctly)

Diagram 3. How to wear the product

- c) To measure with a relaxed position in quiet place, use the right hand gently hold the left elbow and make the wristband and the heart in the same level, then push the begin button to conduct measurement.

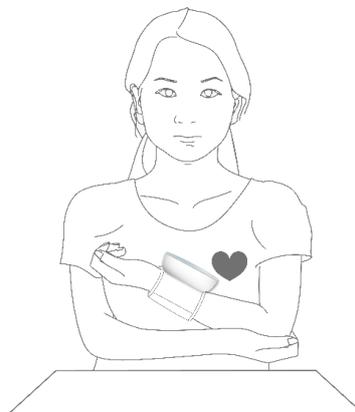


Diagram 4. Right gesture

5.2.2 Blood pressure measurement

1) Starting link

Press the power button to start the device, the blue indicator flashes, open the management software in mobile phone and connect the blood pressure measurement hardware, when successfully connected, the blue indicator will keep light continuously.

2) Pressure measurement

Click on the detection start command, the blood pressure terminal will exert pressure normally to 190mmHg, if the patients blood pressure is too high, the blood pressure terminal will adjust present pressure gear and then start air pump to exert pressure again. (pressure gear: 190mmHg, 220mmHg, 250mmHg, 280mmHg)

If the wristband is not connected successfully or the connection joint softened, and cause the wristband pressure increasing abnormally, the blood pressure terminal will stop air pump after a period of time from starting the air pump. In this time, please check the wristband air circuit connection status.

When the inflation pressure reaches the present pressure gear, and begin to enter decreasing pressure measurement state, the blood pressure terminal will automatically exhaust, the wristband pressure will decreases gradually. After measurement of blood pressure, exhaust the blood pressure terminal and transfer the measure results to the host mobile by bluetooth module.

Cautions: this blood pressure terminal does not provide irregular heartbeat detection function. During measuring blood pressure, when there are more than two times in which heart rate interval exceed average heart rate interval about 25%, and also this measure was not effected by irregular heartbeat, the irregular heartbeat parameters will transmitted to the management software with the blood pressure measure results. If you often have irregular heartbeat, please tell your doctor for advice. It is danger to self-diagnose and self-treat according to the measured value, the measured blood pressure value shall be interpreted by professional personnel.

3) Low voltage test

when there is a low power supply, the orange indicator of the blood pressure terminal will turn on lastingly, in this case, please change the battery in time.

6 Maintenance and repair

6.1 Don't fall or strongly collide the device.

6.2 Avoid high temperature or exposure to the sun!

6.3 When clean the shell or rubber pad, firstly turn off the power, use soft cotton fabric dipped in a little neutral detergent gently wipe the surface, and dry naturally, it is prohibited high temperature baking! It is recommended to clean monthly.

6.4 This product is strictly forbidden water!

6.5 Please take out the battery if long term not to use, so as to avoid battery leakage!

6.6 Do not disassemble the product body!

6.7 It is forbidden to use this product for other purposes!

6.8 The mobile blood pressure terminal precise has been strictly tested and calibrated, it is recommended to conduct a calibration every 2 years..

7 Troubleshooting

Abnormal phenomenon	Reason of analysis	Troubleshooting
Measured blood pressure abnormal (higher or lower)	the wristband tightened too tight or soft, or the tightened position is wrong	Correctly tightened the wristband
	Talking or moving during measurement	Keep quiet and wrist stable, don't move the product
	Wrong measure gesture	Adjust the gesture
	Rolled clothes express the arm	Take off the clothes
Don't exert pressure during measure	Wristband exhaust	Change a new wristband
	Wristband incorrectly connected	Correct connection
The management software can not	Power orange lamp flashers, low battery voltage	Change the battery

connect the hardware	The blood pressure hardware possibly enter standby/ automatic power off	Push the button, blue light flashes, open the software connection
	Mobile bluetooth function does not open	Open the bluetooth function of the mobile
No display after pressing power button	Battery energy exhausted, or no battery	Change the battery
Orange indicator flashes after pressing power button	Two low power voltage	Change the battery

8 Blood pressure basic knowledge

Referring to 2010 "Chinese hypertension prevention guide", blood pressure level classification and definition:

Classification	Systolic pressure (mmHg)		Diastolic blood pressure (mmHg)
Normal blood pressure	<120	and	<80
Normal high value	120-139	and/or	80-89
Hypertension:	≥140	and/or	≥90
Class 1 (Slight)	140-159	and/or	90-99
Class 2 (Moderate)	160-179	and/or	100-109
Class 3 (Serious)	≥180	and/or	≥110
Isolated systolic hypertension	≥140	and	<90

When the Systolic pressure and Diastolic blood pressure belongs to different class, will adopt the higher class.

9 Specification

Unit:	mmHg / kPa	
Measure method	Oscillography	
Measure range:	Pressure	(0~260) mmHg
	Pulse	30~170bpm
Precise:	Pressure	±3mmHg
	Pulse	±5%
Exerting pressure	Automatically exerting pressure	

type		
Function	Irregular heartbeat	
	Low voltage test	
	Automatic power off after 2 minutes	
Power:	2 AAA (No.7) battery, DC 3V	
Weight	About 96 gram (not including battery)	
Dimension	7.6cm×6.6cm×2.6cm	
Wrist circumference	13.5cm~21.5cm	
Operation Environment	Temperature	5°C~40°C
	Relative Humidity	15%~80%
	Air pressure	80kPa~105kPa
	Power	Internal d.c. 3±10% V
Transport/storage Environment	Temperature	-20°C~55°C
	Relative Humidity	15%~90%RH
Equipment information	Classification of electric shock type: internal power supply equipment Classification of electric shock degree: BF type Protection against liquid: IPX0 Running mode: continuous operation Safety classification of using with flammable anesthetic gas or flammable anesthetic gas mixed with oxygen or nitrous oxide: Non AP/APG	

10 Components list

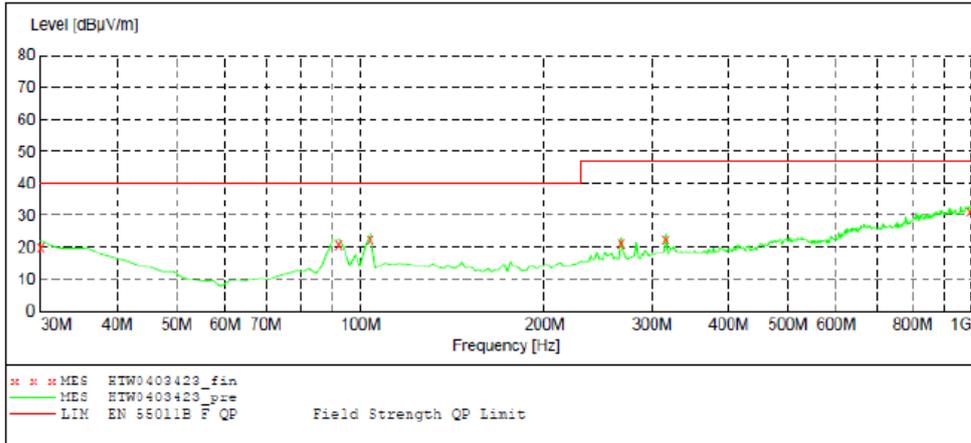
Component	Specification	Qty.
Wristband	(13.5~21.5cm,CH,A)	1

11. Guidance and manufacturer's declaration-electromagnetic emissions

11.1 Emission

Band width: 120kHz; Frequency range: 30MHz to 1000MHz

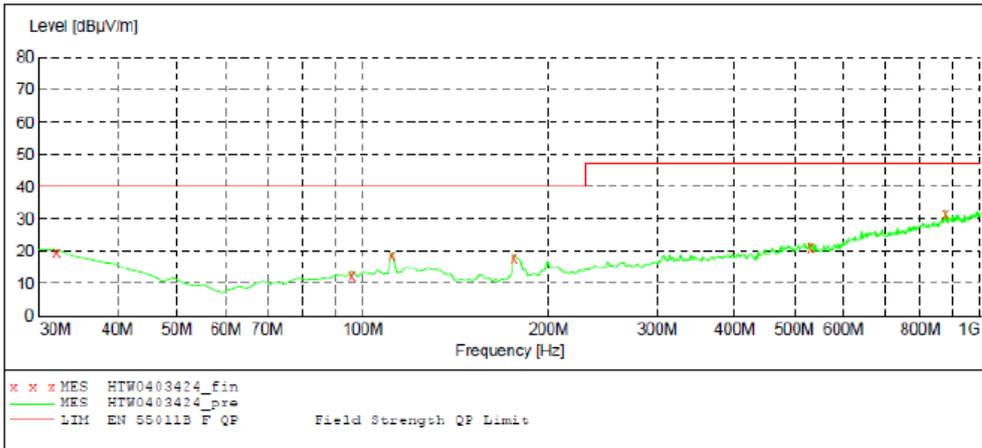
Result: Fulfilled



MEASUREMENT RESULT: "HTW0403423_fin"

4/3/2015 4:47PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
30.000000	19.90	-10.0	40.0	20.1	QP	100.0	225.00	HORIZONTAL
92.210000	20.70	-18.7	40.0	19.3	QP	300.0	163.00	HORIZONTAL
103.810000	22.50	-18.3	40.0	17.5	QP	300.0	14.00	HORIZONTAL
267.120000	21.20	-16.4	47.0	25.8	QP	100.0	297.00	HORIZONTAL
315.750000	22.30	-14.6	47.0	24.7	QP	100.0	209.00	HORIZONTAL
996.110000	31.10	-3.0	47.0	15.9	QP	100.0	158.00	HORIZONTAL



MEASUREMENT RESULT: "HTW0403424_fin"

4/3/2015 4:59PM

Frequency MHz	Level dBµV/m	Transd dB	Limit dBµV/m	Margin dB	Det.	Height cm	Azimuth deg	Polarization
31.940000	19.40	-11.1	40.0	20.6	QP	100.0	96.00	VERTICAL
96.090000	12.50	-18.5	40.0	27.5	QP	100.0	303.00	VERTICAL
111.640000	18.60	-18.1	40.0	21.4	QP	100.0	56.00	VERTICAL
175.790000	17.70	-21.0	40.0	22.3	QP	100.0	35.00	VERTICAL
531.520000	21.20	-11.1	47.0	25.8	QP	100.0	323.00	VERTICAL
879.470000	31.80	-4.4	47.0	15.2	QP	100.0	354.00	VERTICAL

11.2 Immunity

Test frequency: 50Hz, 60Hz; Continuous field: 3 A/m; Test duration: 5m; Antenna factor: 0.917A/m; Axis: X, Y, Z.

Test results: No degradation of function, comply with EN 60601-1-2:2007+AC:2010, ISO

80601-2-61:2011 Clause 202, EN 60601-1-11:2010 Clause 12.