

Wrist Electronic Blood Pressure Monitor

Herz P1 Smart BPM

Model No.: FC-BP201



Manual Ver.: 1.1

Software Ver.: FC-BP201-V1.0

Issuing Date: Feb 1, 2026



- Read this manual carefully before use.
- Keep this manual for future reference.
- The patient is the intended operator.

Contents

1. Before Using the Unit	1
1.1 Introduction	1
1.2 Important safety notices	3
1.3 Warning and safety notices	4
2. Operating Instruction	6
2.1 Know your unit	6
2.2 Battery Installation / Replacement	8
2.3 Settings	9
2.4 Proper Use of the wrist Cuff	12
2.5 Take a Measurement	14
2.6 Use the Memory function	15
2.7 About Blood Pressure	17
3. Care and Maintenance	20
3.1 Cleaning/Disinfecting and Maintenance	20
3.2 Calibration and Service	21
3.3 Error Indicators	22
3.4 Troubleshooting	24
3.5 Technical Data	25
3.6 Warranty Information	34
3.7 Indication for Use	35
Considerations for measuring	36

1. Before Using the Unit

1.1 Introduction





■ Thank you for purchasing Herz P1 Smart BPM.















■ The unit uses the oscillometric method of blood pressure measurement. It means the unit detects the movement of your blood through your brachial artery, and converts your blood pressure into a digital reading. The unit is simple to use because a stethoscope is not needed while using an oscillometric monitor.


■ The unit stores automatically 2*120 sets of measurement values. You can read the stored data conveniently by pressing the memory button.

■ The unit comes with the following components:

- Main Unit
- Cuff
- Instruction Manual printed in English

SYMBOLS USED IN THIS INSTRUCTION MANUAL	
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.
	Keep dry
	CE mark

	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	Refer to instruction manual/booklet
	Manufacturer
	Serial number
	Type BF applied part
IP22	Ingress protection
	The marking of electrical and electronic devices according to Directive 2012/19/EC. The device accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal
	Device used within the Magnetic Resonance (MR) environment is prohibited.
	Date of manufacture
	Model number
	Medical device
	Made in China
	Importer
	Keep away from sunlight
	Fragile, handle with care

SYS	Systolic blood pressure–High blood pressure value
DIA	Diastolic blood pressure–Low blood pressure value
PUL/min	Pulse rate
	Unique device identifier

1.2 Important safety notices

To assure the correct use of the product basic safety measures should always be followed including the precautions listed as below:

- Please read all information in the instruction manual and any other literature included in the box before using the unit.
- Please contact your physician for specific information about your blood pressure.

Self-diagnosis and treatment by measure results may be dangerous. Follow the instructions of your health care provider.

- Operate the unit only as intended. Don't use for any other purpose. The unit is intended to use in measuring blood pressure and pulse rate for adult only, not recommended using for neonatal baby at home or medical centre.

- Please avoid using the device in areas with strong electromagnetic or radiant interference to ensure accurate measurement results.

- Do not disassemble or attempt to repair the unit or components. Do not use the equipment in places where there are flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) .

- 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.

■ Please note that too frequent measurements may cause injury to the patient due to obstruction of blood flow.

■ Please remove the batteries if the unit will not be used for Three months or More.

■ Please do not put CUFF over a wound, as this can cause further injury;

■ Please ensure the tubing is not tangled, as restricted blood flow and prolonged cuff pressure may cause discomfort or potential injury to the patient.

■ Please install the battery properly.

■ When the battery power is off, please replace two new batteries.

■ Intended Use: Herz PI Smart BPM is intended for use by adults to measure systolic and diastolic blood pressure and pulse rate using a non-invasive method with an inflatable cuff worn on the wrist.

■ Intended users: Professional medical medical staff, lay persons.

■ Patient population: Adults.

Clinical Benefits: Measures blood pressure to help assess and monitor overall cardiovascular health.

1.3 Warning and safety notices

■ Please note that the Application and pressure of a CUFF to any limb with vascular access or treatment or an arteriole-venous (A-V) shunt may temporarily cut off blood flow and result in injury to the PATIENT.

■ Please note that the CUFF application and pressure on the arm may adjacent to mastectomy which is harmful for user.

■ Pressurization of the CUFF can temporarily cause loss of function simultaneously used monitoring ME EQUIPMENT on the same limb;

- Please note that the need to verify that the automatic blood pressure monitor is not triggered (for example, by observing the relevant organs).
- When the arm is oppressed by air pressure, please loosen CUFF or remove batteries.
- Please do not touch the patient and battery output simultaneously when measuring.
- Warning: Do not allow to use the lure connectors. If lure lock connectors be used in the construction of tubing, there is a risk that they might be inadvertently connected to vascular fluid systems and allowing air to be pumped into a blood vessel.
- Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Blood Pressure Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: Keep BPM out of reach of children and animals.

Warning: The risk of accidental ingestion due to the small parts that can be disassembled (such as batteries, etc.) after being touched by a child;

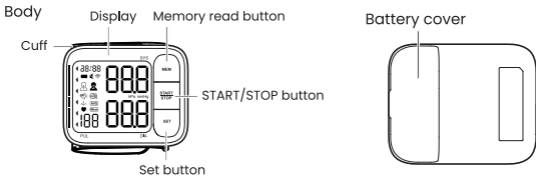
Place the product out of the reach of children, etc.; use it under the supervision of an adult, etc.;

- The cuff cannot be replaced by the user.
- Any part of the device shall not be serviced or maintained while in use with a PATIENT.

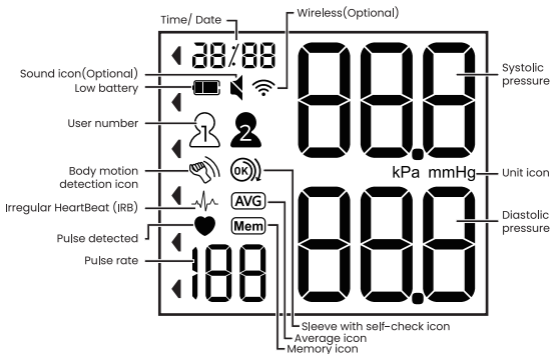
- Do not use the device if you notice any deviations or changes in its performance.
- The surface materials of the device was tested qualified for in vitro Cytotoxicity, Skin sensitization and Skin irritation, but it still may cause potential allergic reactions.
- Do not use any accessories or materials not included in the package, as this may cause inaccurate measurements or device malfunction.
- Failure to follow all warnings and safety instructions may result in inaccurate measurement results.
- The applied part may reach 41–48°C (105.8–118.4°F), so contact should be limited to under 1 minute, avoid touching the tubing, and discontinue use immediately if any skin discomfort occurs.
- Please keep away from children, pets. Avoid dust and light (including sunlight), etc.;

2. Operating Instruction

2.1 Know your unit

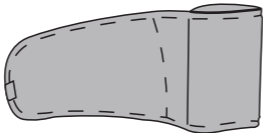


Display



Cuff

Fit for 5.3-8.4 inches (13.5-21.5cm) range of wrist perimeter.



Power

2 AAA Alkaline Batteries

- Please keep the instruction manual well after using.



⚠ Do not use rechargeable batteries.

2.2 Battery Installation / Replacement

2.2.1 Remove the battery covers from the battery compartment.

2.2.2 Install 2 “AAA” size batteries to match the + (positive) and - (negative) polarities with the polarities of the battery compartment as indicated.

2.2.3 Replace the battery cover



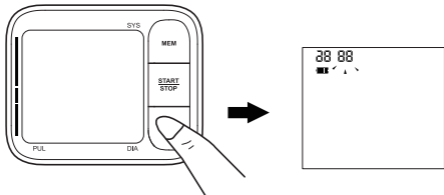
⚠ Caution!

- Replace batteries if the symbol of low battery appears on the display.
- Never leave any low battery in the battery compartment since they may leak and cause damage to the unit.

2.3 Settings

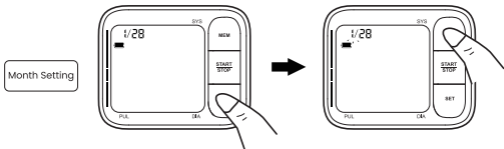
2.3.1 To set year

Long press the "SET" button when power off, you can see the year icon appears and flashes, then press the "MEM" to increase one year, long press the "MEM" button and the value quickly changes.

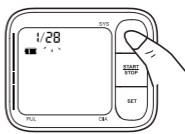
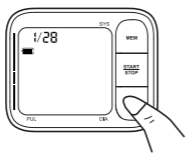


2.3.2 To set Time/Date

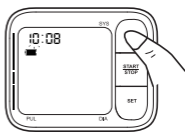
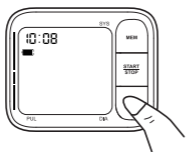
Based on first step and press the "SET" button again, it will change from year mode to date mode, press "MEM" button to change month, long press the "MEM" button and the value quickly changes. Use the same way to set day, hour and minute mode.



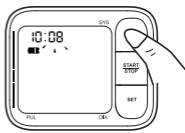
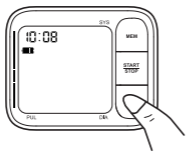
Day Setting






Hour Setting



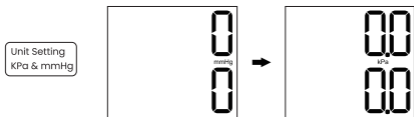
Minute Setting



2.3.3 To set unit

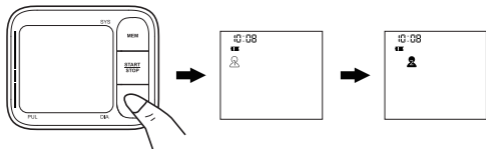
Based on the second step and press the “” button to change the previous unit(kPa or mmHg), the mark “” appears and flashes, now the BPM is in mmHg status, and then press the “MEM” button, to change it into “”, now the BPM is in kPa status.


Press the “START/STOP” button to confirm the current setting.



2.3.5 To set user

Press the "SET" button when power off, and then press the "SET" button again to switch User 1 or user 2.



 The operation of setting can be stopped at any time by pressing “START/STOP” button.

2.4 Proper Use of the wrist Cuff

2.4.1. Unpacking: Open the packaging color box and take out everything in the packaging.

2.4.2. Inspection before use: First check whether the items in the package are consistent with the accessories list:

- 1) Blood pressure monitor machine inspection: Check whether the appearance is intact;
- 2) Cuff inspection: whether the cuff is intact;
- 3) Function check: Press the [Start/Stop] button to see if it can start up normally.

2.4.3. How to use cuff

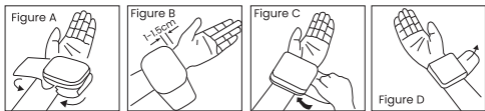
1) Take off the jewelry on your wrist, roll up your sleeves, and tie the wristband of the blood pressure monitor to your uncovered left wrist. Palm facing up, as shown in Figure A.

2) As shown in Figure B, keep the edge of the wristband 1–1.5 cm (0.39–0.59 inches) away from your palm

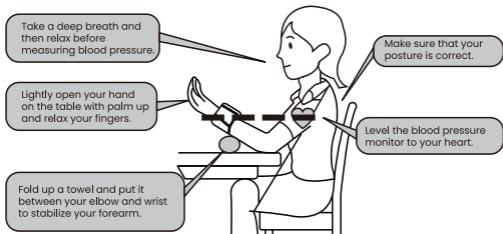
3) In order to ensure accurate measurement, please tighten the wrist strap, as shown in Figure C

4) If the wrist strap is not fastened tightly, the measurement results will have errors.

5) If the doctor diagnoses that the blood circulation in your left wrist is poor, wrap the wristband around your right wrist as shown in Figure D.



The wristband is suitable for limb circumference: 13.5–21.5cm (5.3–8.4 inch)



1. The device has the WHO warning strip “■” symbol display function, with the blood pressure value change, the higher blood pressure value “■” symbol will appear relatively in the higher position (refer to WHO definition of high blood pressure levels-reference table).
2. The device has the average of the last three display function (press the memory key for the first time to display the value that is the average of the last three measurements).
3. The device has a large screen display and digital reading.
4. The device has kPa and mmHg display switching and measurement functions.
5. The device has double memory lookup function and can store 120 set of measurements for each person to remember the normal status of your blood pressure.
6. Clock function: year, month, day, hour, minute setting.
7. Low power detection: detecting low power under any working state, LCD displays “■” symbol indicates low power.
8. Overpressure Protection: If the pressure exceeds 300 mmHg, the device will automatically release air to prevent overpressure.

9. Automatic shutdown function: no operation for 2 minutes the device will shut down automatically.

Operation time: 3 minutes

10. Heartbeat prompting voice.

11. Measurement completed prompting voice.

12. Incorrect prompting function.

RATED ranges of the DETERMINATION:

Cuff pressure: 0-299 mmHg

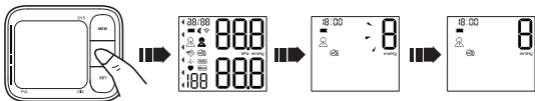
SYS: 44-230 mmHg

DIA: 19-160 mmHg

2.5 Take a Measurement

2.5.1 Press the "START/STOP" button.

All display symbols appear on the screen. The cuff starts to inflate automatically.

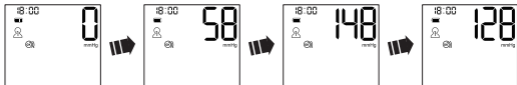


2.5.2 Measurement start.

When pressurized to stop blood flow, the Blood Pressure Monitor stops pressure before automatically leaking air and automatically measuring blood pressure.

The heartbeat symbol flashes once a pulse is detected.

When the heart beat symbol appears and flashes, the Blood Pressure Monitor detects the pulse and begins to calculate the pulse automatically.



2.5.3 The blood pressure and pulse rate are displayed when the measurement completed.

The cuff is deflated automatically, and all of the measurement results be stored in the memory with date and time.

The “” symbol will be displayed if irregular heartbeat is detected.



2.5.4 Press the “START/STOP” button to turn off the unit.

The unit will automatically turn off after two minutes if no more operation.

NOTE: The inflation or measurement can be stopped by pressing the “START/STOP” button at any time.

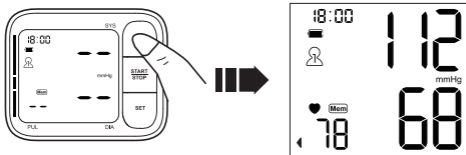
2.6 Use the Memory function

The unit stores the blood pressure and pulse rate in the memory after completing a measurement each time. 2x120 sets of measurement values can be stored automatically.

The earliest record will be deleted automatically to save the latest measurement value when more than 2x120 sets.

The unit also calculates an average reading based on the values of the latest 3 times measurement .

2.6.1 To enter the memory mode & to read the average value
 Press the “MEM” button while power off, the unit enters the memory mode and the average value of the latest 3 times measurement values of the current user will be displayed.



2.6.2 To read the measurement value

Press the “MEM” button when power off, the latest measurement values with the measuring month, date and time will be displayed.
 Press the “MEM” button once more, the measurement values before the latest will be displayed, and so on.

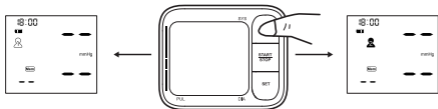


2.6.3 To delete the memory value

■ In the memory mode, long press the “MEM” button, the unit displays the following symbol to cancel all the memory records of the current user.

■ Please operate the delete memory function cautiously.

■ Press the “START/STOP” to cancel the memory records of the current user if you are sure all the data of corresponding user can be deleted, the unit will turn off after deleting.




2.7 About Blood Pressure

2.7.1 Irregular Heartbeat Symbol IRB

When the unit detects an irregular rhythm two or more times during the measurement, the irregular heartbeat Symbol will appear on the display with the measurement values.

An irregular heartbeat rhythm is defined as a rhythm that is more than 25% slower or 25% faster from the average rhythm which detected while the monitor is measuring the systolic blood pressure and the diastolic blood pressure.

If the Irregular Heartbeat Symbol () displays with your measurement results, we recommend you consult your physician, and follow the doctor's directions.



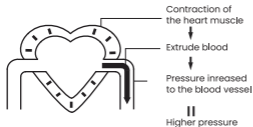
2.7.2 Blood Circulation

The blood circulation is responsible for supplying the body with oxygen. Blood pressure is the pressure exerted on the arteries.

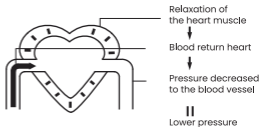
The systolic blood pressure value (higher pressure or top value) represents the blood pressure produced by contraction of the heart muscle.

The diastolic blood pressure value (lower pressure or lower value) represents the blood pressure produced by relaxation of the heart muscle.

Systolic Blood Pressure

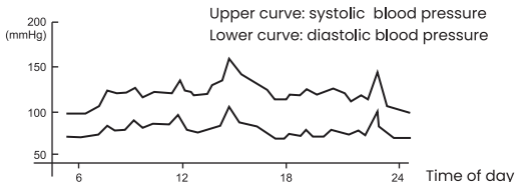


Diastolic Blood Pressure



2.7.3 Health and Blood Pressure

The incidence of hypertension increases with age. In addition, if lack of exercise, excess body fat and high levels of cholesterol (LDL), would sticks to the inside of blood vessels, which reduces elasticity of these vessels. Hypertension accelerated arteriosclerosis which can lead to serious conditions such as stroke and myocardial infarction. For these reasons it is very important to know whether the blood pressure is within a healthy range. Blood pressure fluctuates from minute to minute, throughout the day. Therefore it is essential to take regular measurements to help you identify an average blood pressure.



2.7.4 Classification of Blood Pressure

After each measurement, the LCD display will show the systolic and diastolic blood pressure values in mmHg.

Please consult your healthcare provider for interpretation of your blood pressure results and for appropriate medical advice.

2.7.5 Symptoms of High Blood Pressure

High blood pressure can go unnoticed for a long time, since it doesn't cause noticeable symptoms. The following are possible causes of abnormally high blood pressure:

- Overweight;
- High cholesterol level;
- Smoking;
- Excessive alcohol consumption;
- Stress and emotional upset;
- Excessive consumption of salt;
- Lack of physical exercise;
- Genetic / hereditary predisposition;
- Underlying illnesses, such as kidney disorders or endocrine disturbance.

2.7.6 Treatment of High Blood Pressure

If your blood pressure reaches upper values of 140~160 mmHg and lower values of 90~95 mmHg in repeated measurements over several days, you should consult doctor for detailed medical examination.

You can assist the treatment prescribed by your doctor in the following ways:

- Lose weight and lower your cholesterol level;
- Reduce the consumption of alcohol;
- Reduce the intake of salt;
- Stop smoking;
- Take regular exercise;
- Monitor your blood pressure.

3. Care and Maintenance

3.1 Cleaning/Disinfecting and Maintenance

To keep your blood pressure monitor in the best condition and protect the unit from damage, please follow the directions listed below:

3.1.1 Clean the blood pressure monitor frequently after use.

Do not use any abrasive or volatile cleaners. Never immerse the unit or any components in water.

If the user is to be changed, it is necessary to disinfect the ME EQUIPMENT and the accessories once more to avoid cross-contamination.

3.1.2 Use a soft dry cloth towel to clean this blood pressure monitor, if it is very filthy you can wet the towel with water or neutral detergent, wring out it and wipe the monitor.

3.1.3 Disinfect the cuff using a cotton pad moistened with 75% alcohol.

3.1.4 Store the unit in a safe and dry location. Do not fold the cuff too tight. Do not subject the unit to extreme hot or cold temperatures/ humidity and do not subject the unit under the direct sunlight.

3.1.5 Avoid subjecting the unit to strong shocks, such as dropping the unit on the floor.

3.1.6 Remove the batteries if the unit will not be used for three months or longer. Always replace all the batteries with new ones at the same time.

3.1.7 Use the unit consistent with the instruction provided in this manual. Use only authorized parts and accessories.

3.1.8 Do not carry out repairs of any kind yourself. If a defect occurs, Please contact the local distributor.

3.1.9 We will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist service personnel who is trained by the manufacturer and has got the relevant qualification certificate.





3.1.10 Wristband components Equipment parts: wrist straps that shall not be serviced or maintained while in use with a PATIENT




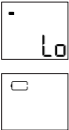
3.2 Calibration and Service

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult local authorized distributor or dealer.

3.3 Error Indicators

The following symbols will appear on the display when measuring abnormally.

Symbol	Cause	Correction
	An error occurred during inflating	Wrap the cuff correctly and tightly Inflate over again after ensuring
	When measurement fails	Do not move your arm and body
		Repeat the measurement following the correct procedure.
		Abnormal sensor vibration
	Can't detect enough heartbeats or count blood pressure	Repeat the measurement following the correct procedure.
	Abnormal measurement results	Repeat the measurement following the correct procedure.

	<p>The wristband is too loose or leaking (pressurized less than 30mmHg within 10 seconds)</p> <p>When the measurement is normal, the indicator light is green.</p> <p>When the blood pressure is high and measurement Error ,the indicator light is white.</p>	<p>Wrap the cuff correctly and tightly</p> <p>Repeat the measurement following the correct procedure.</p>
	<p>Large pressure fluctuations during measurement</p>	<p>Repeat the measurement following the correct procedure.</p>
	<p>Out of range diastolic/ systolic ambulatory blood pressure appears error</p>	<p>Normal blood pressure range</p> <p>Repeat the measurement following the correct procedure.</p>
	<p>When the batteries power is too low</p>	<p>Replace all of the worn batteries with new ones</p>

3.4 Troubleshooting

Problem	Causes and Solutions
No power	Is the battery low?
	Replace all of the worn batteries with new ones
No display appears on the display screen	Are the positive and negative terminals of the battery connected backwards?
	Check the battery installation for proper placement of the batteries polarities
Measurement values appear too high or too low	Incorrect blood pressure measurement? Is the cuff in the correct position? Are measurements taken immediately after exercise or alcohol consumption?
	Blood pressure varies constantly. Many factors may effect your blood pressure, including stress, time of day, how you wrap the cuff. Review the sections "Proper Way of Measurement" and "Take a Measurement"

3.5 Technical Data

3.5.1 Specifications

1	Model	Herz PI Smart BPM
2	Measurement Method	Oscillographic measurement method
3	Display	LCD Digital Display
4	Measurement Range	Blood Pressure range: 0~299mmHg (0 kPa - 39.9 kPa) Pulse: 40 to 180 beats/min
5	Accuracy	Static Pressure: $\pm 3\text{mmHg}(\pm 0.4\text{ kPa})$ Pulse rate: Within $\pm 5\%$ of reading
6	Inflation	Automatic inflation by pump
7	Deflation	Automatic rapid deflation
8	Pressure Detection	Semiconductor pressure sensor
9	Memory	2 Users*120 memories
10	Power supply	2 AAA alkaline batteries (not included), DC3V
11	Battery life	Approximately 300 measurements when using alkaline batteries at the room temperature of 22°C (71.6°F) and by using three times a day and inflating to 170 mmHg
12	Storage Temperature	-4°F to 131°F (-20°C to 55°C), and Humidity: 0 to 95% RH Atmospheric pressure: 70 - 106kPa

13	Operating Temperature	50°F to 104°F (10°C to 40°C), and Humidity: 15 to 85% RH Atmospheric pressure: 70kPa – 106kPa
14	Automatic Power-OFF	Within 2 Minutes
15	Weight of Main Unit	133 g (4.69 oz) (Not including batteries)
16	External Dimensions	80.5 × 65.5 × 25 mm (3.17 × 2.58 × 0.98 inches)
17	Cuff	13.5–21.5cm (5.3–8.4 inch)
18	Electric Shock Protection	Internal power supply appliance type BF
19	Accessorial Components	Cuff, Instruction Manual, Storage Box
20	Device Life	5 Years

To improve performance, these specifications are subject to change without notice.

The device, accessories and the packaging have to be disposed of correctly after the end of the usage, so that the risk of patient or user can be lowered to an acceptable level.

3.5.2 Statement

- The unit is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the arm by using the oscillometric method.
- The unit is intended for use in only the adult population, not applied to other populations such as neonatal babies.
- Do not use the device on a wrist or arm with open wounds or bleeding, as pressure may cause blood flow from the injury.

•The device's accessories and batteries have to be disposed of waste correctly at the end of the usage, please follow Local Ordinances or Regulations for disposal.

•Applied part: CUFF.

Protection Class: Internally powered equipment.

•Applied Part Type: Type BF.

Moisture Protection: IP22, continue operation.

Altitude<2000m;

Overvoltage:II;

Pollution degree:2

•The risk of patient and user can be lowered to acceptable level.

•The unit might not meet its performance specification if stored or used outside the following specified temperature , humidity and altitude ranges.

•The unit satisfies the requirements of IEC60601-1 Medical electrical equipment,

IEC 60601-1-2: Electromagnetic compatibility –Requirements and tests

IEC 80601-2-30: Non-invasive sphygmomanometers – Part 1:

Requirements and test methods for non-automated measurement

type EN1060-3: Non-invasive sphygmomanometers – Part 3:

Supplementary requirements for electro-mechanical blood pressure measuring systems.

The time required for the ME EQUIPMENT to warm from the minimum storage temperature between uses until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C (68 °F):
30 minutes

The time required for the ME EQUIPMENT to cool from the maximum storage temperature between uses until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C (68 °F):
30 minutes

3.5.3 IEC 60601-1-2:2014/AMD1:2020 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Wrist Electronic Blood Pressure Monitor (FC-BP201), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY).

ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term “ESSENTIAL PERFORMANCE” need not be used).

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.

2. Guidance and manufacturer’s declaration–electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer’s declaration–electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000–3–2	Class A
Voltage fluctuations/ flicker emissions IEC 61000–3–3	Compliance

Table 2

Guidance and manufacturer's declaration–electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Compliance level
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines: ±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ±1 kV.	line(s) to line(s): ±1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz

Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	10V/m 80MHz – 2,7 GHz 80% AM at 1 kHz	10V/m 80MHz – 2,7GHz 80% AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration-electromagnetic Immunity								
Radiated RF IEC 61000- 4-3 (Test specific- ations	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power(W)	Distance (m)	IEC 60601- 1-2 Test level (v/m)	Complia- nce level (v/m)
	385	380- 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430- 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
	710	704- 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
780								

Guidance and manufacturer's declaration—electromagnetic Immunity

Radiated RF IEC 61000- 4-3 (Test specific- ations	810	800- 960	GSM 800 900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1 700- 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2 400- 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5 100- 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

Table 4

Guidance and manufacturer's declaration – electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation ^a 2,1 kHz	65 ^b
13,56 MHz	Pulse modulation ^a 50 kHz	7,5 ^b
<p>a) The carrier shall be modulated using a 50% duty cycle square wave signal.</p> <p>b) r.m.s., before modulation is applied.</p>		

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment of and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

MODIFICATION: Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

RF exposure information:

This device complies with FCC radiation exposure limits set forth for an uncontrolled environment.

3.6 Warranty Information

■ The unit, excluding the unit cuff, is guaranteed to be free of defects in workmanship and materials for a period of two years from the date listed on the purchase record, when used in accordance with the instructions provided with the unit. The unit cuff is warranted to be free from defects in materials and workmanship appearing within one year from the date listed on the purchase record when the unit is used in accordance with the instructions provided with the unit.

■ This guarantee does not cover damage incurred by using without following in accordance with the instructions, accidental damage, or being tampered/serviced by unauthorized service agents.

■ For repair under this warranty. Our authorized service agent must be advised of the fault within the period of the warranty. This warranty covers parts and labor only under normal operations.

A transportation fee or freight fee that may be incurred will be the owner's responsibility.

Any defect resulting from natural causes, e.g., flood, hurricane etc., is not within this guarantee.

■ Unit subjected to misuse, abuse, and neglect of these manual contents, non-instructional purposes, and unauthorized repair or modifications will be excluded from this warranty.

This guarantee specifically excludes expendables and consumables, for example batteries.

All warranty claims must be directed to the distributor responsible for the sale of the device.

The content of this warranty is subject to change without further notice.

■ **WARNING:** No modification of this equipment is allowed.

3.7 Indication for Use

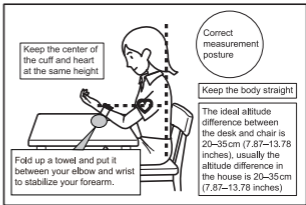
Wrist Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist arm.

The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.

Considerations for measuring

1. The correct using method

- (1) Elbow on the table; comfortably seated; legs uncrossed; back and arm supported;
- (2) Keep the center of the cuff and the heart or nipples at the same height.
- (3) Do not put the clothes into the cuff.



- (4) Palms up, body keep relaxed.
- (5) Sitting in a chair keep your foot flat on the ground.

A recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE; a recommendation that 5 min elapses before the first reading is taken; need to avoid compression or restriction of the connection tubing.

2. Ideal environment for measuring blood pressure.

- (1) Get up in the morning, when the mood is relaxed.
- (2) No consciousness to the toilet
- (3) Room temperature is about 20 °C (68 °F)
- (4) Quiet place and there was no noise around.

3. Measure blood pressure at the same time each day: Blood pressure naturally fluctuates, so a single measurement cannot accurately reflect your overall condition. For more reliable results, take measurements consistently over a period of time. It's recommended to measure at the same time each day, ideally early in the morning after waking, when your body is in a stable state.

Ideal method is to measure as far as possible at the same time every day.

Note: be sure to have more than 2-3-minute interval between two measurements.

Depending on your individual physiological characteristics, between the two measurements may need to rest for a longer time.

Please keep the wristband around the wrist before you start measuring.

U.S. Agent

CTI U.S. Inc.

Suite 230,1455 CTI U.S. Inc.

Lincoln Parkway, Atlanta, Ga, 30346

EU REP RIOMAVIX S.L.

Calle de Almansa 55, 1D, Madrid, 28039 Spain

SRN: ES-AR-000001202

Manufacturer:

Shenzhen Finicare Co., Ltd

201, No.50, the 3rd Industrial Park, Houting Community,

Shajing Street, Bao'an District, Shenzhen 518104 China

Distributed with Love from Ohio, USA by:

Herz P1, LLC

Email: support@herzpl.com

Phone: (877) 309-3614

EU Distributor: TIB B.V., Postbus 56907, 1040 AX Amsterdam, The Netherlands

For Support Inquiries please visit www.herzpl.com

Made in China