

BMP-2244BT

# Blood Pressure Monitor

## Instruction Manual



CE 0123



Manual Ver.: 1.0

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Proven





Thank you for selecting iProven arm type Blood Pressure Monitor BPM-2244BT. The device features blood pressure measurement, pulse rate measurement and the memory function of the measurement results for two users. The device is also equipped with Bluetooth. The iProven Health app will help you get even more insight in your measurement results.

Readings taken by the BMP 2244 BT are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product. Read the manual thoroughly before using the product.

It is our passion to develop high quality products for home use. Our products are manufactured at the highest technical standards of professional quality, durability, and consistency. They are also designed with elegant simplicity in mind, making them easy to use at home.

To help you get the most from our products, we provide clear instructions with each device. The manual also includes helpful information that contributes to your overall health awareness. In order to make sure that our products are tailored to your needs, we welcome your feedback. If you have any issues, questions or recommendations, please share your thoughts with us at **[www.iproven.com](http://www.iproven.com)**

## **iProven - Professional Care Brought Home**

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## Indications for Use

1. The iProven Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 8¾" to 16½" (22 cm to 42 cm)
2. The monitor detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
3. It is intended for adult use in the home/domestic setting only.

## Contraindications












1. The device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument such as a pacemaker or defibrillator.
2. The device is not intended to be a diagnostic device. Contract your physician if hypertensive values are indicated.

## Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. It then starts to inflate the arm cuff, while the unit detects pressure oscillations generated by beat-to-beat pulsations, which are used to determine the systolic and diastolic pressure as well as pulse rate. The device also compares the longest and shortest time intervals of detected pulse waves to the mean time interval and then calculates the standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference between the time intervals is excessive.

## Safety Information

The below icons may appear in the user manual, on labeling, or on other components. They are the required standard for use.

|   |  |   |   |
|---|--|---|---|
|   | Symbol for "THE OPERATION GUIDE MUST BE READ"                              |   | Symbol for "TYPE BF APPLIED PARTS"  |
|  | Symbol for "COMPLIES WITH MDD93/42/EEC REQUIREMENTS"                       |  | Symbol for "ENVIRONMENT PROTECTION – Electrical waste products should not be disposed of with household waste. Please follow local guidelines." |
|  | Symbol for "MANUFACTURER"  |  | Symbol for "DIRECT CURRENT"   |
|  | Symbol for "SERIAL NUMBER"   |  | Symbol for "Authorized Representative in the European Community"  |
|  | Symbol for "MANUFACTURE DATE"  |  | Symbol for "Including RF transmitter"   |
|  | Caution: These notes must be observed to prevent any damage to the device. |   |   |

## CAUTION

This device is intended for adult use only. This device is intended for none-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement. Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice. If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.

When the device is used to measure patients with common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation, the best results may occur with deviation. Please consult your physician about the result.

If the cuff pressure exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the corresponding user button to stop inflation.

This equipment is not AP/APG equipment and is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The operator shall not touch output of batteries /adapter and the patient simultaneously. To avoid measurement errors, please avoid strong electromagnetic fields, radiated interference signal, or electrical fast transient/burst signal.

The user must check that the equipment functions safely and see that it is in proper working order before use. This device is contraindicated for any female who may be, suspects she is, or is pregnant. Aside from providing inaccurate readings, the effects of this device on the fetus are unknown. Manufacturer will make available upon request circuit diagrams, component parts list, etc. This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become numb, swollen, or even purple due to lacking blood supply. Please use the device in the environment indicated in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced. During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and have been found to comply with requirements of ISO 10993-5:2009 and ISO:2010. It will not cause any potential sensitization or irritation reaction. Please use ACCESSORIES and detachable parts specified/authorized by the MANUFACTURER. Otherwise, it may cause damage to the unit or danger to the user/patients.

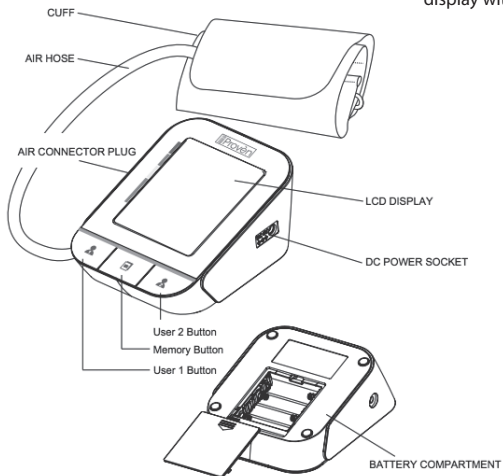
The device doesn't need to be calibrated within the two years of reliable service. Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to local guidelines. If you have any problems with this device, such as setup, maintenance, or use, please contact the iProven SERVICE PERSONNEL. Don't open or repair the device by yourself. Please report to iProven if any unexpected operations or events occur. Please use a soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.

## LCD Display Signal



| SYMBOL         | DESCRIPTION              | EXPLANATION  |
|----------------|--------------------------|--|
| <b>SYS</b>     | Systolic Blood Pressure  | Higher blood pressure number   |
| <b>DIA</b>     | Diastolic Blood Pressure | Lower blood pressure number  |
| <b>Pul/min</b> | Pulse per minute         | Beats per minute, BPM  |
|                | User 1                   | Start measurement for user 1, save and transmit the measuring result |
|                | User 2                   | Start measurement for user 2, save and transmit the measuring result |
|                | Shock reminder           | Shock will result in inaccurate reading                              |
|                | Low Battery              | Low battery and please replace the batteries.                        |
|                | mmHg                     | Measurement unit of blood pressure (1mmHg=0.133kPa)                  |
|                | kPa                      | Measurement unit of blood pressure (1kPa=7.5mmHg)                    |
|                | Memory                   | Displays the number of the measurement                               |
|                | Current Time             | Month/Day (Hour:Minute)  |
|                | Deflating                | Expels the air in the cuff   |
|                | Irregular Heartbeat      | Irregular heartbeat detection  |
|                | Heartbeat                | Heartbeat detection during the measurement                           |
|                | Data pending to transmit | Measurement data stored in the equipment                             |
|                | Data transmitting        | Data is transmitting   |
|                | Grade                    | The grade of blood pressure  |

## Monitor Components



### Features:

92mm x 78mm blue LCD display with white backlight

## List

1. Blood Pressure Monitor  
(BPM-2244BT)



2. Cuff (Type BF applied part)  
(about 22cm-42cm)



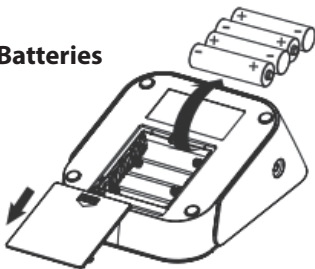
3. 4×AA batteries




4. User manual

## Installing and Replacing the Batteries

1. Open the battery cover.
2. Insert the batteries according to the polarity indications.
3. Close the battery cover.



Replace the batteries under following circumstances:

-  displays on the LCD.
- The LCD display dims.
- When powering on the monitor, the LCD doesn't light up.

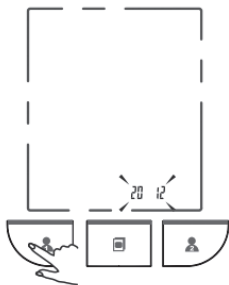


### CAUTION

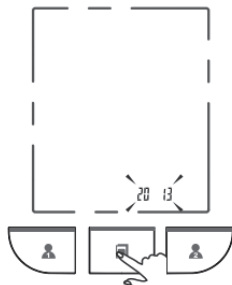
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.


## Setting Date, Time and Measurement Unit

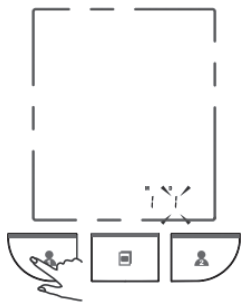
Please proceed to time setting before your initial use, so as to ensure that each record is labeled with a time stamp. (The setting range for year is 2012~2052; Time format is 24H.)



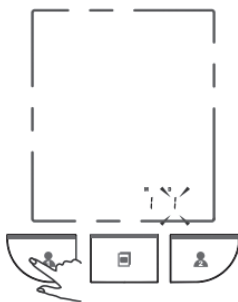
**1:** When the monitor is OFF, press and hold "User 1" button to enter Time Setting Mode.



**2:** As pictured in the right, the blinking numeral representing [YEAR]. Press  button to change the numeral. Each press will increase the numeral by one in a cycling manner.



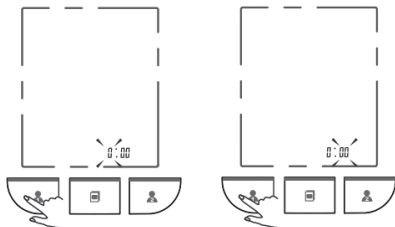
**3:** Press "User 1" button again to confirm [YEAR]. Then the numeral representing [MONTH] blinks.



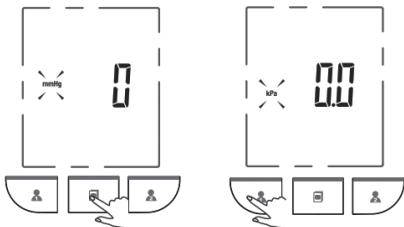
**4:** Repeat steps 2 and 3 to confirm [MONTH] and [DAY].



**5:** Repeat steps 2 and 3 to confirm [HOUR] and [MINUTE].



**6:** Repeat steps 2 and 3 to confirm the measurement unit or mmHg or kPa.





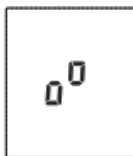
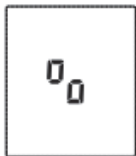
**7:** After confirming the measurement unit, the LCD will display "DONE" and the monitor will shut off.




## Pair-up the Blood Pressure Monitor with Your Device

Before you start pairing, download the iProven Health app from the Apple appstore or Google playstore; search for: iProven Health.


1. Turn on Bluetooth and open the app on your smartphone.
2. When the monitor is OFF, press and hold the  button (User 2) to  start pairing. The below symbols will be shown on the LCD alternatively, indicating pair-up is proceeding.

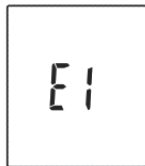


3. Then please select the user ID you want to connect with your mobile device on the app to continue the pair-up.

**I SUCCEED**, symbol  will be shown on the LCD.



**If FAIL**, symbol  will be shown on the LCD.



4. The monitor will shut off after Pair-up process is complete.

**Notes:** List of compatible devices:

For iOS devices: The operating system must be iOS 8 or more, such as iPhone 4S, iPhone 5/5C/5S, iPhone 6/6 Plus and so on.  
For Android devices: The operating system must be 4.3 or higher.

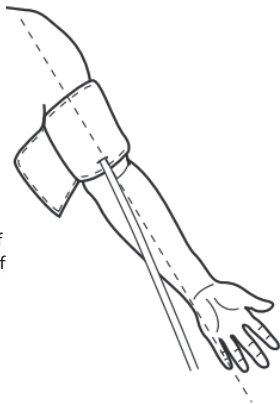
Bluetooth Module No.: AW8001  
RF Frequency Range: 2402 MHz to 2480 MHz  
Output Power Range: 0 dBm  
Supply Voltage: 1.8-3.6 V  
Transmitting Distance: 10 meters

## Fastening the Cuff

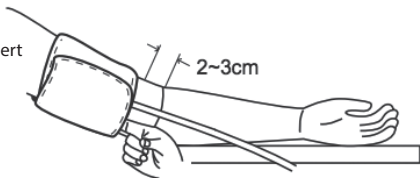
**1.** Wrap the cuff around your upper arm, then position the tube off-center toward the inner side of arm in line with pinky finger.

Or position the artery mark  $\phi$  over the main artery (on the inside of your arm).

Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.

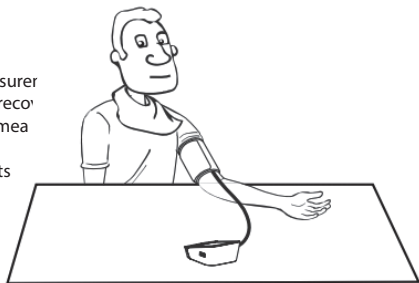


**2.** The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



**3.** Sit comfortably with your left arm resting on a flat surface.

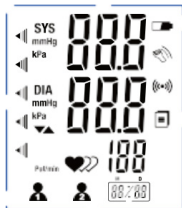
Rest for 5 minutes before measuring.  
Wait at least 3 minutes between measurements.  
This allows your blood circulation to recover.  
For a meaningful comparison, try to measure under similar conditions.  
For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.



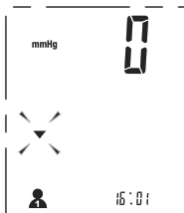
## Start Measurement

When the monitor is off, press the User 1 button to turn on the monitor, and it will finish the whole measurement and then save the measured data for User 1. The same for User 2. Take user 1 for example.

1. When the monitor is off, press the User 1 button to turn on the monitor



LCD display



Adjust to zero



Inflating and measuring.



Display and save the results.  
The data transmission will proceed.


2. Press the User 1 button to power off, otherwise it will turn off within one minute.



### Tips:

- A. After finishing the whole measurement, press another user button, and the blood monitor will begin measuring again.
- B. Maximum 60 records can be saved both for user 1 and user 2.

## Recall the Records


1. When the monitor is OFF, press  button to access the memory.



2. The LCD will display the latest measuring result of the user ID which completes the last measurement.

\*The record number, measuring date and measuring time will be displayed alternatively.




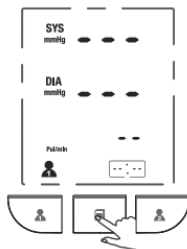
|  |                                       |                                  |
|--|---------------------------------------|----------------------------------|
|  1/20 | M D<br>8 8                            | 16:01                            |
| The Order Number of the measurement is 1.<br>20 records in total.                      | The corresponding date is August 8th. | The corresponding time is 16:01. |

3. Press  button to rotate the history records.

4. When in the memory mode, press the User 1 button to recall the measurement history of User 1, or press the User 2 button to recall the measurement history of User 2.




5. When no history stored for the specific user in the monitor, press  button and the LCD will display as pictured to the right.



### CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

## Delete the Records

1. When under the memory mode, press and hold  button for 3 seconds to clear the memory.




2. When the LCD display “dEL ALL”, press  button to confirm.





3. The LCD will display “dEL dOnE” and then shut off.




4. If you wish to stop clearing the memory, you may press the other button, rather than  button to turn off the monitor, or wait until the monitor shuts off.

## Data Transmission

1. With LS802-B successfully pair-up with your mobile device, the measurement data will be automatically transmitted to your mobile device via Bluetooth.
2. The symbol  will disappear after successful data transmission, and you may check your personal health data stored in your mobile device.
3. If the data transmission fails, the symbol  will remain. The pending measurement data will be transmitted to your mobile device when next measurement is complete.



### CAUTION

Interference may occur in the vicinity of equipment marked with the following symbol  and BPM-2244BT may be interfering electrical equipment. Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever possible. Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement. To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

#### How to mitigate possible interference?

1. The range between the device and BT end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.
2. To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

## Tips for Measuring

Measurements may be inaccurate if taken under the following circumstances.



Within 1 hour  
after dinner or drinking



Immediate measurement  
after tea, coffee, smoking



Within 20 minutes  
after taking a bath



When talking or moving your fingers



In a very cold environment



When you want to discharge urine

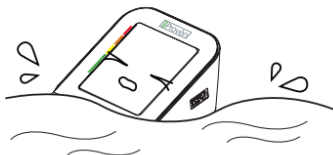


## Maintenance

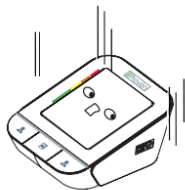
To obtain the best performance, please follow instructions below.



Place in a dry place and avoid sunshine



Avoid immersing in water. Clean with a dry cloth as needed.



Avoid shaking and collisions



Avoid dusty environments and unstable temperature surroundings.



Use a slightly damp cloth to remove dirt.

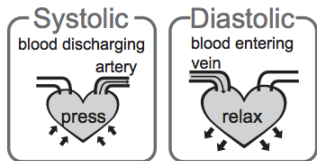


Avoid washing the cuff.



## What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



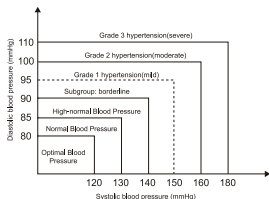
## What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



### CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.



| Level<br>Blood Pressure (mm Hg) | Optimal | Normal  | High-normal | Mild    | Moderate | Severe |
|---------------------------------|---------|---------|-------------|---------|----------|--------|
| SYS                             | <120    | 120-129 | 130-139     | 140-159 | 160-179  | ≥180   |
| DIA                             | <80     | 80-84   | 85-89       | 90-99   | 100-109  | ≥110   |

## Irregular Heartbeat Detection

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.



### CAUTION

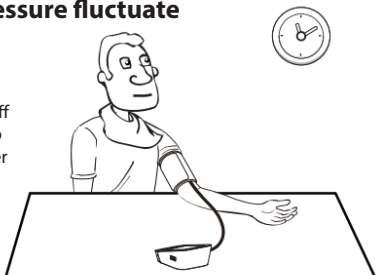
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

## Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.



## Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

### What you need to pay attention to when you measure your blood pressure at home:

If the cuff is tied properly.

If the cuff is too tight or too loose.

If the cuff is tied on the upper arm.

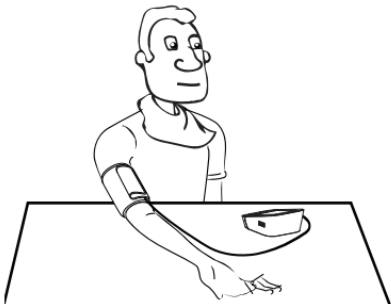
If you feel anxious.

Taking 2-3 deep breaths before beginning will be better for measuring.



Advice: Relax yourself for 4-5 minutes until you calm down.

## Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



**This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.**

| PROBLEM                | SYMPTOM   | CHECK THIS  | REMEDY  |
|------------------------|---|---|---|
| <b>No power</b>        | Display will not light up.  | Batteries are exhausted.                                  | Replace with new batteries  |
|                        |   | Batteries are inserted incorrectly.                       | Insert the batteries correctly  |
| <b>Low batteries</b>   | Display is dim or shows  +  0 | Batteries are low.  | Replace with new batteries  |
| <b>Error message</b>   | E 1 shows   | Communication error                                       | Check if the APP is on, operate and send the data again.  |
|                        | E 3 shows   | The cuff is not secure.                                   | Readjust the cuff and relax for a moment and then measure again.  |
|                        | E10 or E11 shows  | The monitor detected motion while measuring.              | Movement can affect the measurement. Relax for a moment and then measure again.   |
|                        | E20 shows   | The measurement process does not detect the pulse signal. | Loosen the clothing on the arm and then measure again   |
|                        | E21 shows   | The treatment of the measurement failed.                  | Relax for a moment and then measure again.  |
|                        | EExx, shows on the display.   | A calibration error occurred.                             | Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions. |
| <b>Warning message</b> | " out " shows   | Out of measurement range                                  | Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.  |

|   |  |
|---|--|
| <b>Power supply</b>                           | Battery powered mode: 6VDC 4×AA-size batteries<br>AC adaptor powered mode: 6V $\overline{\text{---}}$ 1A<br>(Can be supplied by AC adaptor model UE08WCP-060100SPA !)(Not Included)              |
| <b>Display mode</b>                           | Digital LCD V.A. = 78mm x 92mm   |
| <b>Measurement mode</b>                       | Oscillographic testing mode  |
| <b>Measurement range</b>                      | Rated cuff pressure:<br>0mmHg~300mmHg(0kPa ~ 40kPa)<br>Measurement pressure:<br>SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa)<br>DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa)<br>Pulse value: (40-199)beat/minute |
| <b>Accuracy</b>                               | Pressure:<br>5℃~40℃ within $\pm 0.4$ kPa (3 mmHg)<br>Pulse Value: $\pm 5\%$  |
| <b>Working condition</b>                      | Temperature: 5℃ to 40℃<br>Relative Humidity $\leq 85\%$ RH<br>Atmospheric Pressure: 86kPa-106 kPa  |
| <b>Storage &amp; transportation condition</b> | Temperature: -20℃ to 60℃<br>Relative Humidity: 10%RH-93%RH<br>Atmospheric Pressure: 50kPa-106 kPa  |
| <b>Measurement perimeter of the upper arm</b> | About 22cm - 42cm  |
| <b>Weight</b>                                 | Approx. 514g (Excluding the dry cells)   |
| <b>External dimensions</b>                    | Approx. 120mm×160mm×69mm   |
| <b>Attachment</b>                             | 4×AA batteries, 1×user manual, 1×storage bag   |
| <b>Mode of operation</b>                      | Continuous operation   |
| <b>Degree of protection</b>                   | Type BF applied part   |
| <b>Device Classification</b>                  | Battery Powered Mode: Internally Powered ME Equipment<br>AC Adaptor Powered Mode: Class II ME Equipment  |
| <b>IP Classification</b>                      | IP22   |
| <b>Software Version</b>                       | V01  |

WARNING: No modification of this equipment is allowed.

## Storage:



## Complied European Standards List

|                                 |   |
|---------------------------------|---|
| Risk management                 | ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices   |
| Labeling                        | EN 980:2008 Symbols for use in the labelling of medical devices   |
| User manual                     | EN 1041: 2008 Medical equipment manufacturers to provide information  |
| General Requirements for Safety | EN 60601-1: 2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance<br>IEC/EN 60601-1-11: 2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment |
| Electromagnetic compatibility   | IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests  |
| Performance requirements        | EN 1060-1:1995+A2:2009 Non-invasive blood pressure Part 1: General requirements<br>EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system  |
| Clinical investigation          | EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process  |
| Usability                       | IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability<br>IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices   |
| Software life-cycle processes   | IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes  |

# EMC Guidance


**Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS**

| <b>Guidance and manufacturer's declaration – electromagnetic emissions</b>   |                   |   |
|--|-------------------|---|
| The device is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the device should assure that it is used in such an environment. |                   |   |
| <b>Emissions test</b>  | <b>Compliance</b> | <b>Electromagnetic environment – guidance</b>   |
| RF emissions<br>CISPR 11   | Group 2           | The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF emissions<br>CISPR 11   | Class B           |   |
| Harmonic emissions<br>IEC 61000-3-2  | Not applicable    |   |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3  | Not applicable    |   |

**Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic  
IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS**

| <b>Guidance and manufacturer's declaration – electromagnetic immunity</b>   |   |   |  |
|---|---|---|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment. |   |   |  |
| <b>IMMUNITY test</b>  | <b>IEC 60601 test level</b>   | <b>Compliance level</b>   | <b>Electromagnetic environment – guidance</b>  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2  | ± 6 kV contact<br>± 8 kV air  | ± 6 kV contact<br>± 8 kV 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<br>IEC 61000-4-4  | ± 2 kV for power supply lines<br>± 1 kV for input/output lines  | ± 2 kV for power supply lines   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5  | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth  | ± 1 kV line(s) to line(s)   | 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<br>IEC 61000-4-11  | <5 % $U_T$<br>(>95 % dip in $U_T$ ) for 0,5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$ ) for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$ ) for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$ ) for 5 s | <5 % $U_T$<br>(>95 % dip in $U_T$ ) for 0,5 cycle<br><br>40 % $U_T$<br>(60 % dip in $U_T$ ) for 5 cycles<br><br>70 % $U_T$<br>(30 % dip in $U_T$ ) for 25 cycles<br><br><5 % $U_T$<br>(>95 % dip in $U_T$ ) for 5 s | Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8  | 3 A/m   | 3 A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.  |   |   |  |

**Table 4 – Guidance and MANUFACTURER'S declaration –  
electromagnetic IMMUNITY  
for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

| Guidance and manufacturer's declaration – electromagnetic immunity  |                             |                  |  |
|---|-----------------------------|------------------|--|
| The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.   |                             |                  |  |
| IMMUNITY test   | IEC 60601 TEST LEVEL        | Compliance level | Electromagnetic environment – guidance   |
| Conducted RF<br>IEC 61000-4-6   | 3 Vrms<br>150 kHz to 80 MHz | 3 Vrms           | <p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> $d = 1.167 \sqrt{P}$  |
| Radiated RF<br>IEC 61000-4-3  | 3 V/m<br>80 MHz to 2,5 GHz  | 3 V/m            | $d = 1.167 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.333 \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| 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.  |                             |                  |  |
| <p>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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p> |                             |                  |  |



**Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING**

| Recommended separation distances between portable and mobile RF communications equipment and the device  |  |   |  |
|--|--|---|--|
| The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. |  |   |  |
| Rated maximum output power of transmitter<br>W   | Separation distance according to frequency of transmitter<br>m |   |  |
|  | 150 kHz to 80 MHz<br>$d = 1,167 \sqrt{P}$                      | 80 MHz to 800 MHz<br>$d = 1,167 \sqrt{P}$ | 800 MHz to 2,5 GHz<br>$d = 2,333 \sqrt{P}$ |
| 0,01   | 0.117  | 0.117                                     | 0.233                                      |
| 0,1  | 0.369  | 0.369                                     | 0.738                                      |
| 1  | 1.167  | 1.167                                     | 2.333                                      |
| 10   | 3.690  | 3.690                                     | 7.378                                      |
| 100  | 11.67  | 11.67                                     | 23.33                                      |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (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.   |  |   |  |

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