

User Manual

Blood Pressure Monitor

Model: EBP-08B

Healthcare-Manager.com

Questions or comments?

Please call toll-free:

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E-MAIL: service@healthcare-manager.com

Manufactured for

Easy Healthcare Corporation

360 Shore Dr. Unit B, Burr Ridge, IL USA 60527

Made in China

Compatible with MedM Health App



ios QR Code



Android QR Code

EBP-08B

Category Type:
Arm



Thank you for selecting Easy@Home Blood Pressure Monitor. Please read the user manual carefully to ensure the safe use of this product. Keep this manual for further reference to address any issues or questions regarding your product.

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♥ General Description

This product features blood pressure measurement, pulse rate, and memory recall. 2 year factory guarantee included on the device.

Readings taken by this blood pressure monitor EBP-08B is equivalent to those obtained by a trained professional using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using this blood pressure monitor. Please read the manual thoroughly before using this product.

Features:

- 60 mm × 64 mm Digital LCD display
- Maximum storage of 250 records per user
- Up-to-date measuring-during-inflation technology

♥ Indications for Use

The Blood Pressure Monitor is digital monitor intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

♥ Contraindications

1. The device is not suitable for use on the women who are or may be pregnant.
2. The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

♥ 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 atmospheric pressure. Then it starts inflating the arm cuff; meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and pulse rate.

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and usage.

	Date and Country of manufacture		Type BF applied part
	Direct current		Class II equipment
	General symbol for recovery/recyclable		
	Refer to instruction manual To signify that the instruction manual must be read.		
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences		
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		
	This device has not been tested for use in an MR environment and should not be used exposed to MR environments while patients are wearing the device. Keep it outside the MPI scanner room.		
IP21	It means the device could be protected against solid foreign objects of 12,5mm Φ and greater, and against vertically falling water drops.		

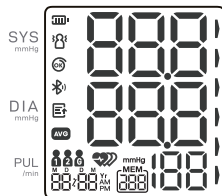
⚠ CAUTION

- * This device is intended for indoor, home use.
- * This device is not intended for public use.
- * This device is portable, but it is not intended for use during patient transport.
- * This device is not suitable for continuous monitoring during medical emergencies or operations.
- * This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
- * This device is for adults. Do not use this device on neonates or infants. Do not use it on children unless otherwise instructed by a medical professional.
- * Do not use on the women in pregnant, including pre-eclamptic, patients.
- * The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.
- * The effectiveness of this device has not been established for use:
 - on users with common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation,
 - on users with peripheral arterial disease,
 - on users undergoing intravascular therapy, or with arteriovenous (AV) shunt. Consult a medical professional before use.
- * Do not use this device for diagnosis or treatment of any health problem or disease. Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or health care professional.
- * If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
- * This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
- * Report any unexpected operation or events to the manufacturer.
- * Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
- * Warning: Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result in injury.
- * Warning: Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
- * Warning: Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
- * Warning: Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
- * Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). It is recommended to take measurements on the unaffected side.
- * Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
- * Please check that the operation of the device do not result in prolonged impairment of patient blood circulation.
- * Warning: On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
- * Warning: Do not use this device with high-frequency (HF) surgical equipment at the same time.

⚠ CAUTION

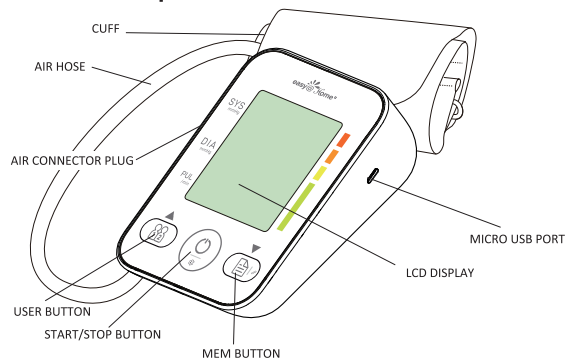
- * Warning: This device is not AP/APG equipment. Do not use the device where flammable anesthetic are present, or in environments mixture with air of with oxygen or nitrous oxide.
- * The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- * Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
- * You can use this device to take your own measurement, no third-party operator is required.
- * Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
- * The device may require up to 30 minutes to warm up / cool down from the minimum / maximum storage temperature before it is ready for use.
- * Warning: Excessive cuff tube lengths could cause strangulation if you don't manage them properly.
- * Warning: Do not touch output of the batteries/adaptor and the user simultaneously.
- * Adaptor is specified as a part of ME EQUIPMENT.
- * Warning: The power cord is considered the disconnect device for isolating this equipment from supply mains. Do not position the equipment so that it is difficult to reach or disconnect.
- * The blood pressure monitor, its adaptor, and the cuff are suitable for use within the patient environment.
- * Warning: Do not use this device if you are allergic to polyester, nylon, or plastic.
- * Warning: Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
- * Warning: If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
- * No calibration is required within two years of reliable service.
- * Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
- * At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
- * It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg).
- * Warning: Do not use the device while under maintenance, or being serviced.
- * Store your device, cuff and adaptor in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
- * Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
- * Warning: Keep the device, cuff, and batteries away from children as they may pose a risk of choking or strangulation if used improperly.
- * Clean both device and cuff with a soft, dry cloth. If necessary use a dampened cloth and natural detergent. Do not use alcohol, benzene, or other harsh chemicals.
- * Do not wash the cuff in a washing machine or dishwasher!
- * The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
- * Dispose of accessories, detachable parts, and the device according to the local guidelines.

♥ LCD display signal



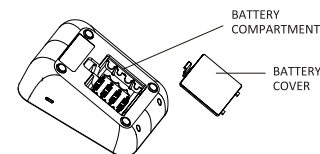
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	The high pressure measured.
DIA	Diastolic blood pressure	The low pressure measured.
mmHg	mmHg	Measurement Unit of the blood pressure.
PUL	Pulse/minute	Measurement Unit of Pulse Rate.
	Heartbeat	Heartbeat detected during measurement.
	Irregular heartbeat	Irregular heartbeat detected during measurement. See page 25 for more information.
	User ID	appears when the monitor is operated by User 1. appears when the monitor is operated by User 2. appears when the monitor is operated by guest User "G". NOTE: User 1 and User 2, each with 250 memory spaces; User G, no memory space.
	Data pending to transmit	Measurement data stored in the equipment, pending to transmit.
	Bluetooth transfer icon	Appears when the bluetooth is working or remains along with the measurement record when the data transmission fails.
	Battery Indicator	Indicate the current battery.
	Excessive Body Motion Detector	Appears when excessive body movement, especially of the arm the cuff is worn, is detected during the measurement. NOTE: The measured blood pressure reading may not be accurate if the icon is displayed.
	Automated cuff wrap detection	appears when the cuff is wrapped correctly.
	Memory display	Indicate it is in the memory mode and which group of memory it is.
	Current Time	Time and date (year/month/day; hour:minute)
	Blood pressure level	Indicates the blood pressure level.
	Average value	Displays average of last 3 readings.

♥ Monitor Components



Component list of pressure measuring system:

1. Cuff
2. Air pipe
3. PCBA
4. Pump
5. Valve



♥ Item List

1. Blood Pressure Monitor (EBP-08B)



3. 4x AAA batteries



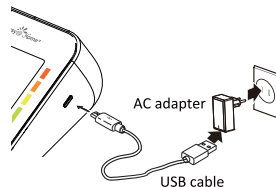
2. Cuff (Type BF applied part)
22 cm to 42 cm
(about 9 - 17 inches)



4. USB cable
5. User manual
6. Carry bag

♥ Power Supply

1. Battery powered mode:
6V DC 4× AAA batteries
 2. AC adapter powered mode: 5V  1A
(Not included)
(Please only use AC adapter authorized by the manufacturer!)
- Please unplug the adapter to depart from the using utility power, when you finish the measurement.

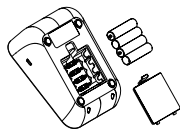


⚠ CAUTION

In order to get the best effect and protect your monitor, please use the right batteries which comply with local safety standard.

♥ Installing and Replacing the Batteries

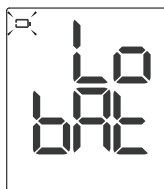
- Open the battery cover.
- Install or replace 4x AAA size batteries as indicated in the battery compartment.
- Place the battery cover back.



Anytime the battery is low, it will display the icon "Lo bAt" & . It will power off automatically after 5 seconds.

Replace the batteries if:

- The low battery symbol appears on the display.
- When any button is pressed and nothing is displayed on the screen.



Low Battery

⚠ CAUTION

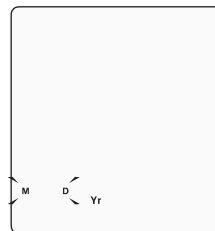
- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose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

♥ Setting the Date and Time

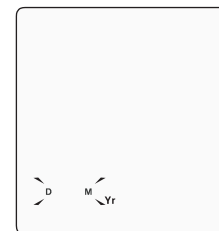
It is important to set the date and time before using your blood pressure monitor for the first time, so that a correct time stamp can be assigned to each record that is stored in the memory.

(The setting range of the year: 2021—2050, Time format: 24H / 12H)

1. When the monitor is off, press and hold the  button to display the date format. Press the  or  button to switch the date format between [month/day/year] and [day/month/year].

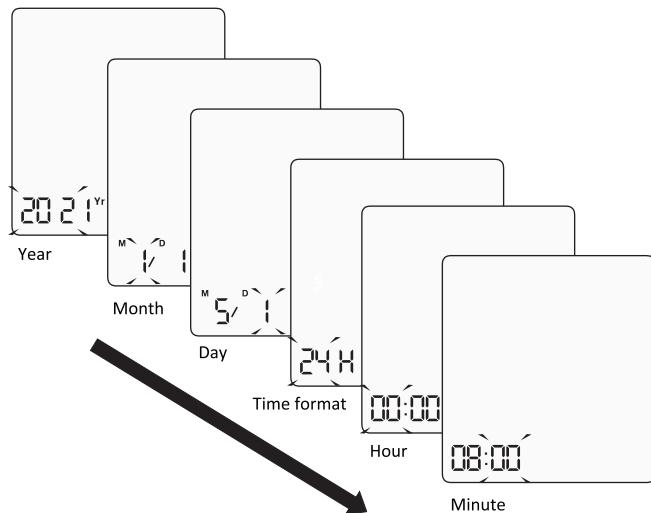


[month/day/year] format

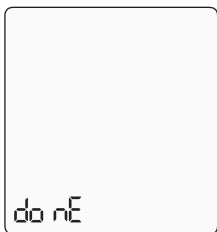


[day/month/year] format

2. Press the  button to confirm the date format, then the year will flash. Press the  or  button to change the year.
Press and hold the  button to quickly advance the years.
Press and hold the  button to quickly go backwards through the years.
3. Press the  button to confirm the year, then the month will flash. Repeat the same steps to change the month, day, time format, hour, and minute.

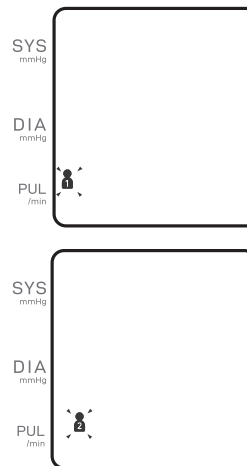


4. After confirming the minute, the LCD will display "do nE" and the monitor will shut off after several seconds.

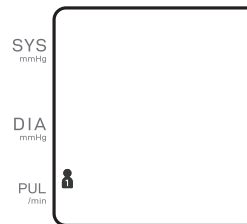


♥ Select the User ID

1. When the monitor is off, press "USER" button, the LCD will display the user ID and blink. Press "USER" button again to toggle the user ID between user 1 and user 2.



2. Press "START/STOP" button to confirm your choice, then the User ID will not blink and the monitor will turn off within several seconds.



♥ Tie the cuff

1. Remove all jewelry, such as watches and bracelets from your left arm.

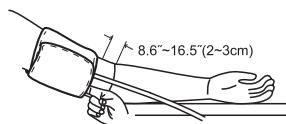
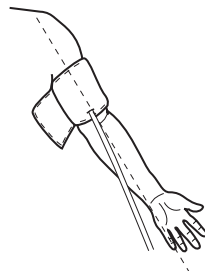
Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.

2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.

3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the pinky finger. Or position the artery mark Φ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 0.78 (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.

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



5. Sit comfortably with your tested arm resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.

6. Helpful tips for the person being measured, especially for those with hypertension:

- Rest for 5 minutes before first measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- Take the measurement in a silent room.
- Relax as much as possible and do not move and talk during the measurement procedure.



- The cuff should maintain at the same level as the right atrium of the heart.
- Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.
- Keep your back against the backrest of the chair.
- 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 the Measurement

Before you start the measurement, download the MedM Health app from APP Store or Google Play, and turn on the Bluetooth. Install the APP, and register an account. Then set your personal information (Gender, Birthday, Height, Weight, Name etc).

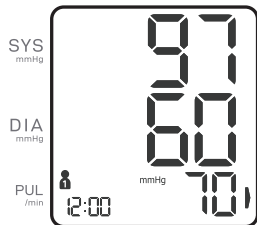
1. When the monitor is off, press "START/STOP" button, the LCD will display the user ID and blink. At this time, you can press "USER" button to select User 1 or User 2 or User G (guest), or wait for about 5 seconds to enter the measurement mode automatically.

In measurement mode, the latest measurement record will display, start the "cuff wrap detection" and complete the whole measurement automatically.

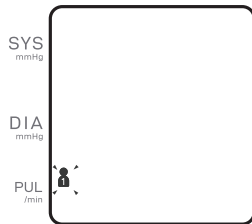
(Example shown below for User 1)

Note: When the selected user has no history of memory records, or if the selected user is guest User G, it will start the "cuff wrap detection" directly and complete the whole measurement automatically.

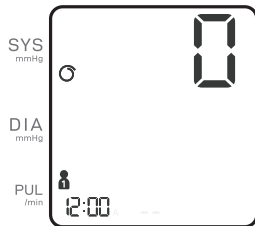
Display the latest record.



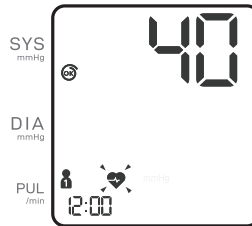
Select the User ID



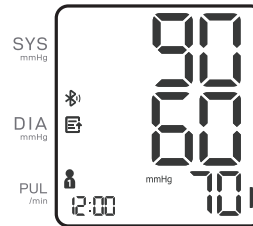
Automated cuff wrap detection.



Inflating and measuring.



Display, save and transmit the measurement result.



2. The monitor will save and transfer the measurement result after measurement. (Make sure both Bluetooth and App are ON during the transfer)

If successful, both symbols "❌" and "📶" will disappear, and then the monitor will power off automatically.

If unsuccessful, the monitor will power off automatically. (The symbol 📶 will display during the next measurement)

3. Press "START/STOP" button to turn off, otherwise the device will power off after approximately 1 minute.

Tip 1: Anytime you want to stop the measurement, press "START/STOP" button.

Tip 2: Both User 1 and User 2 can store maximum 250 records each. When you pass that limit, every time you take the measurement, the monitor will prompt "FULL" first and the oldest record will be erased from the history record after the measurement.

Tip 3: User G (guest) , no memory space.

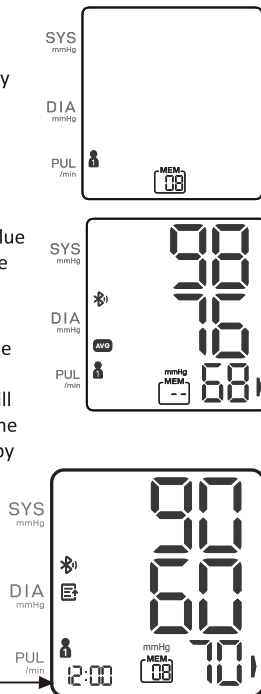
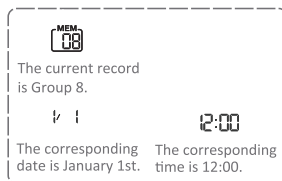
♥ Memory Recall

1. When the monitor is off, pressing "MEM" button will display the current user ID and the total memory records. Press "USER" button to toggle the user ID between User 1 and User 2, or wait for about 5 seconds to enter the memory recall mode automatically.

*The LCD will display the average value of the latest three records. When there is less than three records for a user, it will display the latest record.

2. Press "USER" or "MEM" button to see the next measurement record. Each press of "USER" or "MEM" button will adjust the measurement record to the next ("USER") or previous ("MEM") by one in a cyclical manner.

Date and Time will display alternately.



⚠ CAUTION

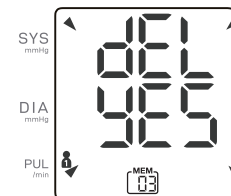
The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (250) is dropped from the list once 250 records is surpassed.

♥ Delete the Records

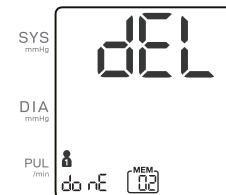
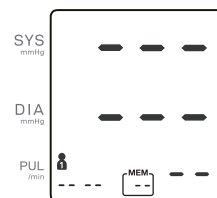
Delete the result by following the steps below.
(Example shown below for User 1)

A: Delete one record

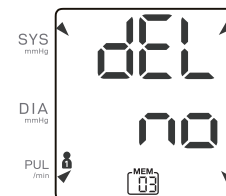
1. When the monitor is in the memory recall mode, find the record you want to delete. Then press and hold "MEM" button for about 3 seconds, the LCD will display the current memory group for the user and show a blinking "dEL yES".



2. Press "START/STOP" button to confirm deletion and the LCD will display "dEL dOnE" along with the previous memory group.
Note: If there is no record, the following display will be shown.

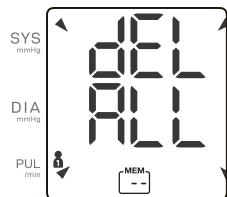


If you wish to stop clearing the memory, press "MEM" or "USER" button. When the LCD display "dEL no" and blink, press "START/STOP" button to cancel deletion and return to the main screen.

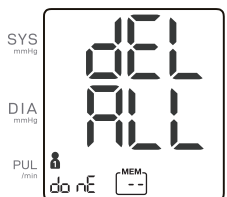


B: Delete all records

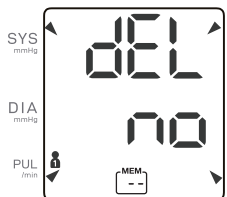
1. When the monitor is in the memory recall mode, press and hold "MEM" button and "USER" button for 5 seconds, the LCD will display "dEL ALL" + User ID + .



2. Press "START/STOP" button to confirm deletion, the LCD will display "dEL do nE" + User ID + .

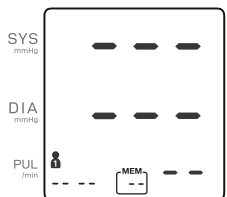


If you wish to stop clearing the memory, press "MEM" or "USER" button. When the LCD display "dEL no" and blink, press "START/STOP" button to cancel deletion.

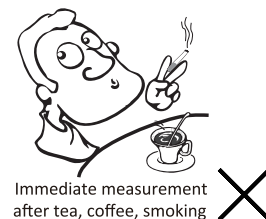


3. Once deleted, your readings cannot be restored. The LCD will display "--" like the picture on the right.

Press "START/STOP" button to turn off the monitor, otherwise it will power off automatically after about 1 minute.

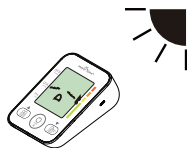
**♥ Tips for Measurement**

Measurements may be inaccurate if taken in the following circumstances.



♥ Maintenance

In order to get the best performance, please follow the instructions below.



Put in a dry place and avoid the sunshine



Avoid intense shaking and collisions



Using wet cloths to remove dirt



Avoid touching water, clean it with a dry cloth.



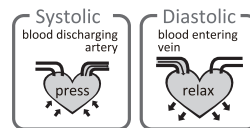
Avoid dusty and unstable temperature environment



Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

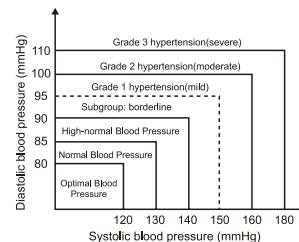
♥ What are systolic pressure and diastolic pressure?

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. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Level	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 Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculates the average; if there are two or more pulse intervals, the difference between each interval and the average is more than the average value of $\pm 25\%$, or if there are four or more pulse intervals, the difference between each interval and the average is more than the average value of $\pm 15\%$, the irregular heartbeat symbol appears on the display after the measurement results have appeared.

⚠ CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat 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 every day. 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 can vary more.
3. Wait at least 3 minutes for another measurement.



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

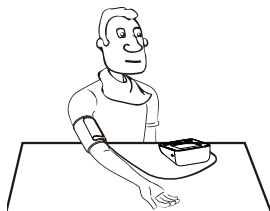
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

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.

♥ Trouble Shooting

If any abnormality arises during use, please check the following points:

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display can not light up.	Batteries are exhausted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
High Battery	H bAt shows	The battery is too high.	Replace with new batteries.
Low Battery	Lo bAt &  shows	The battery is too low.	Replace with new batteries.
Error message	E 1 shows	The cuff is not wrapped or wrapped incorrectly, or the cuff air plug is loose.	Refasten the cuff and insert air tube plug correctly then measure again.
	E 2 or  shows	Excessive body motion (such as shaking of the arm with the cuff on) or weak pulse is detected during measuring.	Relax for 5 minutes. And then keep still, measure again.
	E 3 shows	Pulse is not detected during measuring.	Loosen the clothing on the arm and then measure again.
	E 4 shows	The measurement failed.	Relax for 5 minutes and measure again.
	EEx shows	Hardware error (X can be some digital symbol, such as 1, 2, etc.)	Turn off monitor and measure again. If EEx still appears on the display, please contact the retailer or our customer service.
	Err & Usb shows	Adapter error	Replace with the authorized adapter
Warning message	out shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

NOTE: If the product still does not work, contact our professional customer service team. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

♥ Specifications

Power supply	Battery powered mode: 6V DC 4× AAA batteries AC adapter powered mode: 5V  1A (Not included).
Display mode	Digital LCD V.A. 60 mm × 64 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0 mmHg ~ 299 mmHg (0 kPa ~ 39.9 kPa) Measurement pressure: SYS: 60 mmHg ~ 230 mmHg (8.0 kPa ~ 30.7 kPa) DIA: 40 mmHg ~ 130 mmHg (5.3 kPa ~ 17.3 kPa) Pulse value: (40-199) beat/minute
Accuracy	Pressure: 5°C - 40°C within ±3 mmHg (0.4 kPa) Pulse value: ±5%
Normal working condition	A temperature range: +41°F to +104°F(+5°C to +40°C) A relative humidity range:15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa An atmospheric pressure range: 700 hPa to 1060 hPa
Storage & transportation condition	Temperature: -4°F to +140°F(-20°C to +60°C) A relative humidity range of ≤ 93%, non- condensing, at a water vapor pressure up to 50 hPa
Measurement perimeter of the upper arm	About 22 cm to 42 cm (about 9 - 17 inches)
Weight	Approx.216 g (Excluding the batteries and cuff)
External dimensions	Approx.100 mm × 129 mm × 45 mm
Attachment	4× AAA batteries, user manual, USB cable, carry bag
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Device Classification	Battery Powered Mode: Internally Powered ME Equipment
Software Version	A01
Bluetooth Module information	Bluetooth module No.: B2084 RF frequency range: 2402 MHz to 2480 MHz Output power range: ≤ -2.5 dBm Supply voltage: 1.8-3.6 V Transmitting distance: 10 meters

♥ EMC Guidance

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

Warning: Don't be near the 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 equipment EBP-Q8B including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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	Comply

WARNING: No modification of this equipment is allowed.

♥ EMC Guidance

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

Warning: Don't be near the 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 equipment EBP-08B including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

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Emissions test	Compliance
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Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1.8	0,3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5k Hz deviation 1 kHz sine	2	0,3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0,2	0,3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	2	0,3	9
	5500						
	5785						

♥ FCC Statement

FCC ID: OU9TMB2080-B

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.

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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 off 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.

FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

♥ Complied Standards List

Risk management	EN ISO 14971 / ISO 14971 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1 / ISO 15223-1 Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. Part 1: General requirements
User manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013+A12:2014 / IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015 / IEC 60601-1-11:2015 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	EN 60601-1-2:2015 / IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type IEC 80601-2-30:2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN ISO 81060-2:2019/ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization