

PMD Blood Pressure Monitor

User Manual










MEASURING BLOOD PRESSURE BASICS

The PMD Blood Pressure Monitor uses the oscillometric principle to measure your blood pressure and pulse rate. Blood pressure fluctuates continually day and night. Any physical activity or excitement will influence your blood pressure. Because of this, it is unusual to obtain identical multiple blood pressure readings. This is why it is recommended that you measure your blood pressure at approximately the same time every day.

1. Relax for 5 minutes before taking your blood pressure.
2. Sit comfortably at a table when measuring your blood pressure.
3. The cuff should be placed at the same level as your heart.
4. Do not talk or move during a measurement.
5. Use the same arm every time.
6. Remove the batteries from the device if it is not used for a month or more to avoid battery leakage.
7. This blood pressure monitor is designed for adults and should not be used on children.
8. It is not recommended for people with serious arrhythmia to use this device.
9. Do not use any other cuff than the one supplied by the distributor.

WHAT YOUR DEVICE SHOULD LOOK LIKE

 The explanation of symbols on the display:

-  Bluetooth Symbol
-  Synchronization
-  Symbol Release Air
-  Symbol Memory Indicator
-  Low Battery Indicator
-  Irregular Heartbeat Symbol

Blood Pressure Level Classification Indicator





Memory/Sync button


Start/Stop button

HOW TO USE YOUR BLOOD PRESSURE MONITOR

1. BATTERIES

- a. Open the battery cover at the back of the device.
- b. Load four "AAA" size batteries. Please pay attention to polarity.
- c. Close the battery cover.

 When the display shows the battery symbol  replace all the batteries with new ones. Rechargeable batteries are not suitable for this monitor.

 The monitor, the batteries and the cuff must be disposed of according to local regulations at the end of their usage.

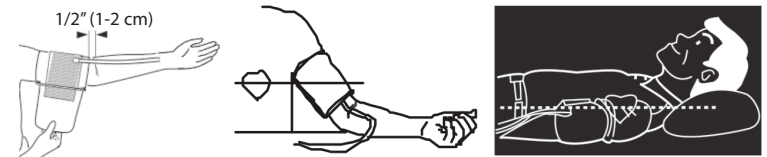
2. SETTING THE DATE AND TIME

Insert the batteries in the device and press the on button to turn on and synch the device to the PMD Portal on your tablet. The time and date will automatically be updated. If you change the batteries, please reset the time and date.

3. HOW TO PLACE THE CUFF ON YOUR ARM

The PMD Blood Pressure Monitor has a universal size cuff. This means that it will fit any arm with a circumference between 22 and 42cm. If your arm is too large to fit in this cuff, you might consider using a wrist blood pressure monitor.

- a. Place the cuff tube downwards, around a bare arm about 2cm above the elbow joint.
- b. Sit with your feet flat on the floor without crossing your legs. While seated, place your palm upside in front of you on a flat surface such as a table.
Lying Down During Measurement: (You can also lie on your back and place your left arm straight along your side with your hand palm-side up.) Position the air tube in the middle of your arm in line with your middle finger.



- c. Close the cuff with the Velcro fastener.
- d. The cuff should fit comfortably around your arm. You should be able to insert one finger between your arm and the cuff.

Note: If the cuff becomes dirty, remove it from the monitor and wipe it with a lightly moistened soft cloth. Then air-dry the cuff. Do not machine wash. Cleaning the cuff after every 200 measurements is recommended.

4. CONNECTING THE CUFF TO THE DEVICE

Once you have determined that the cuff fits your arm (22 – 42cm), simply insert the cuff connector into the socket on the side of the monitor. Ensure that the connector is completely inserted to avoid air leakage. If the device gives an E4 error message — first check that the tubing is properly inserted into the monitor.

Avoid compression or restriction of the connection tubing during measurement which may cause inflation error, or harmful injury due to continuous cuff pressure.

5. TAKING A BLOOD PRESSURE MEASUREMENT


- a. After placing the cuff on your arm and relaxing for a few minutes, press the "START/STOP" button. All display characters are shown for self-test, please contact the service center if a segment is missing.
- b. The monitor will inflate the cuff and then slowly release pressure from the cuff as the blood pressure is measured. When the measurement is finished the blood pressure and pulse rate will be displayed on the display. The result will automatically be sent to your portal.

- c. If an Irregular Heartbeat (IHB) is detected during a measurement, the IHB symbol will be displayed (blinking). If an IHB is detected, the results of the blood pressure measurement may be inaccurate. Please consult your healthcare provider for an accurate assessment.
- d. Your results will appear on the tablet screen. Press yes to accept, your results will now be added and trended.
- e. The monitor will automatically switch off after one minute to save the batteries. Alternatively, you can press the "START/STOP" button to turn off the monitor manually.
- f. At any time during a measurement, you can interrupt a measurement by pressing the "START/STOP" button.

CLASSIFICATION OF BLOOD PRESSURE




BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (upper number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120–129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130–139	or	80 - 89
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	and/or	HIGHER THAN 120

6. TROUBLESHOOTING SECTION

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD shows low battery icon 	Low Battery	Change the batteries.
LCD shows "Er 0"	Pressure system is unstable before measurement	Don't move and try again.
LCD shows "Er 1"	Failed to detect systolic pressure	
LCD shows "Er 2"	Failed to detect diastolic pressure	
LCD shows "Er 3"	Pneumatic system is blocked or the cuff is too tight during inflation	Apply the cuff correctly and try again.
LCD shows "Er 4"	Pneumatic system leakage or the cuff is too loose during inflation	
LCD shows "Er 5"	Cuff pressure is above 300mmHg	Measure again after five minutes. If the monitor is still abnormal, please contact the distributor.
LCD shows "Er 6"	More than 3 minutes with the cuff pressure above 15 mmHg	
LCD shows "Er 7"	EEPROM accessing error	
LCD shows "Er 8"	Device parameter checking error	
LCD shows "Er 9"	Pressure sensor parameter error	Remove batteries, wait 5 minutes then reinstall.
No response when you press button or load battery	Incorrect operation or strong electromagnetic interference	

7. GENERAL SAFETY AND PRECAUTIONS

1. Carefully read the user guide before operating the device.
2. Consult your physician for any of the following situations:
 - a) The application of the cuff over a wound or inflamed area.
 - b) The application of the cuff on the arm on the side of a mastectomy.
 - c) Simultaneous use with other medical monitoring equipment on the same limb.
 - d) The application of the cuff on any limb with intravascular access or therapy, or an arteriovenous (A-V) shunt.
 - e) The blood circulation of the user needs to be checked.
3. Do not use this product in a moving vehicle as this may result in inaccurate measurements.

4. The IHB symbol will be displayed under 2 sets of circumstances:
 - a) The coefficient of variation (CV) of pulse period >25%.
 - b) The difference of adjacent pulse period is $\geq 0.14s$ and more than 53% of the total number of pulse readings falls within this definition.
5. Please do not use any cuff other than that supplied as this may result in inaccurate measurements.
6. The monitor will show 'HI' or 'Lo' as technical alarm on LCD if the determined blood pressure (systolic or diastolic) is outside the rated range specified in part SPECIFICATIONS. In this case, you should consult a physician or check if you followed the operating instructions. The technical alarm condition (outside the rated range) is pre-set in the factory and cannot be adjusted or inactivated. This alarm condition is assigned as low priority according to IEC 60601-1-8. The technical alarm is non-latching and needs no reset. The signal displayed on LCD will disappear automatically after about 8 seconds.
 -  This Monitor is designed for adults and should never be used on infants, young children or patients with preeclampsia.
 -  This product might not meet its performance specifications if stored or used outside the specified temperature and humidity ranges.
 -  Please do not share the cuff with any infectious person to avoid cross-infection.
7. Prolonged over-inflation of the cuff may cause bruises on your arm.

8. CARE AND MAINTENANCE








1. Do not drop the monitor or subject it to strong impacts.
2. Avoid high temperature and direct exposure to the sun. Do not immerse the monitor in water.
3. If this monitor is stored near freezing temperatures, allow it to acclimate to room temperature before use.
4. Do not attempt to disassemble this monitor.
5. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended that the performance of this monitor be checked every 2 years.
7. Please clean the monitor with a soft dry cloth. Do not use any abrasive or volatile cleaners.
8. It is recommended that if the cuff is used in a hospital or a clinic, it be disinfected twice a week. Wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with Ethyl alcohol (75-90%). Then air dry the cuff.
10. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open-close cycles of the closure.

9. WARRANTY

This device has been developed and validated by the manufacturer with a team of medical specialists and engineers to be user friendly and clinically accurate. It has been validated against the ESH Standard (European Society of Hypertension) and can be used in a home, medical or clinical environment. The device carries a two-year warranty.

If you have any questions regarding the aftersales or usage of the product, please contact the distributor.

10. EXPLANATION OF SYMBOLS ON PACKAGING

	Symbol for "THE OPERATION GUIDE MUST BE READ"
	Symbol for "Warning"
	Symbol for "Type BF Applied Parts" (cuff only)
	Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority for recycling advice".
	Symbol for "KEEP DRY"
	Symbol for "Distributor"
	Symbol for "DATE OF MANUFACTURE"
SN	Symbol for "SERIAL NUMBER"

11. SPECIFICATIONS

Product name: PMD Blood Pressure Monitor

Model: 10000218

Classification: Internally powered, type BF applied part; IPX0, No AP or APG;

Continuous operation

Monitor: 98 x 98 x 46mm

Cuff circumference: 22 - 42cm

Weight: 348g (batteries and cuff included)

Measuring method: Oscillometric method, automatic inflation and measurement

Memories: 99

Power Source: 4X1.5 Size AAA Batteries

Measurement range:

Cuff pressure: 0 – 300mmHg

Systolic: 60 - 260mmHg

Diastolic: 40 - 199mmHg

Pulse rate: 40 - 180 beats/minute

Measuring accuracy: Pressure: ± 3 mmHg, Pulse rate: $\pm 5\%$

Environmental temperature for operation: 10~40°C

Environmental humidity for operation: $\leq 85\%$

Environmental temperature for storage: -20~50°C

Environmental humidity for storage: $\leq 85\%$ Environmental pressure: 80~105kPa

Battery life: Approximately 250 readings

This blood pressure measurement system includes accessories: pump, valve, cuff, and sensor.

Note: These specifications are subject to change without notice.

The quality of this wireless device has been verified and conforms to the provisions of the IEC 60601-1:2005 corr.1 (2006) + corr.2 (2007)/EN 60601-1:2006/AC:2010 (Medical electrical equipment – Part 1: General requirements for safety); IEC 60601-1-2:2007 /EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment – Part 1: General requirements for safety; Collateral Standard-Electromagnetic compatibility - Requirements and tests); EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements); EN 1060-3: 1997 + A1: 2005 + A2: 2009

(Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems); IEC80601-2-30:2009+Cor.ÅF2010 (Medical electrical equipment –Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers).

In order to avoid potential electromagnetic or other interference, it is suggested that the Wireless Blood Pressure Monitor should be operated at least 10 meters away from electric or wireless devices (e.g. routers, microwave oven, etc.).

FOR SERVICE OR ASSISTANCE, CONTACT:

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