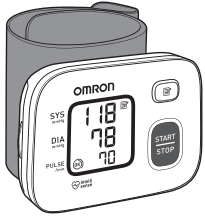


OMRON



Wrist Blood Pressure Monitor

HEM-6161 Instruction Manual

All for Healthcare 2829548-5B

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Introduction

Thank you for purchasing the OMRON HEM-6161 Wrist Blood Pressure Monitor. This blood pressure monitor is to be worn on your wrist.

This new blood pressure monitor uses the oscillometric method of blood pressure measurement. When the cuff inflates, this monitor senses the pressure pulsations of the artery underneath the cuff. The pulses are called oscillometric pulses. The electronic pressure sensor displays a digital reading of blood pressure.

Safety Instructions

This instruction manual provides you with important information about the OMRON HEM-6161 Wrist Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact your local OMRON representative before attempting to use this monitor. For specific information about your own blood pressure, consult with your physician.

Intended Use

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 21.5 cm. This monitor detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is mainly designed for general household use.

Receiving and Inspection

Remove this monitor from the packaging and inspect for damage. If this monitor is damaged, DO NOT USE and consult with your local OMRON representative.

Important Safety Information

Please read the Important Safety Information in this instruction manual before using this monitor.

Please follow this instruction manual thoroughly for your safety.

Please keep for future reference. For specific information about your own blood pressure, CONSULT WITH YOUR PHYSICIAN.

Warning Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.
- DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
- DO NOT use this monitor on an injured wrist or a wrist under medical treatment.
- DO NOT apply the wrist cuff on your wrist while on an intravenous drip or blood transfusion.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT use this monitor in oxygen rich environments or near flammable gas.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

Battery Handling and Usage

- Keep batteries out of the reach of infants, toddlers or children.

Caution Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the equipment or other property.

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor on a wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.

- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the wrist cuff when it is applied on your wrist.
- Remove the wrist cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- DO NOT use this monitor in a moving vehicle such as in a car.
- DO NOT drop or subject this monitor to strong shocks or vibrations.
- DO NOT use this monitor in places with high or low humidity or high or low temperatures. Refer to chapter 8.
- Ensure this monitor is not impairing blood circulation by observing the wrist while measurement is occurring.
- DO NOT use this monitor in high-use environments such as medical clinics or physician offices.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting, thick clothing and any accessories from your wrist while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use this monitor on persons whose wrist circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information of operating and storage/transport temperature, refer to chapter 8.
- DO NOT crease the wrist cuff excessively.
- Read and follow the “Correct Disposal of This Product” in chapter 9 when disposing of the device and any used accessories or optional parts.
- DO NOT use this monitor after the durable period has ended. Refer to chapter 8.

Battery Handling and Usage

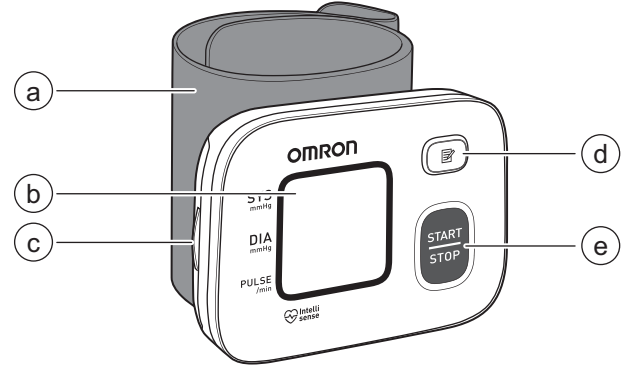
- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 2 “AAA” alkaline batteries with this monitor. DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove batteries if this monitor will not be used for a long period of time.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
- DO NOT use batteries after their expiration date.
- Periodically check batteries to ensure they are in good working condition.
- ONLY use batteries specified for this monitor. Use of unsupported batteries may damage and/or may be hazardous to this monitor.

1. Know Your Monitor

1.1 Contents

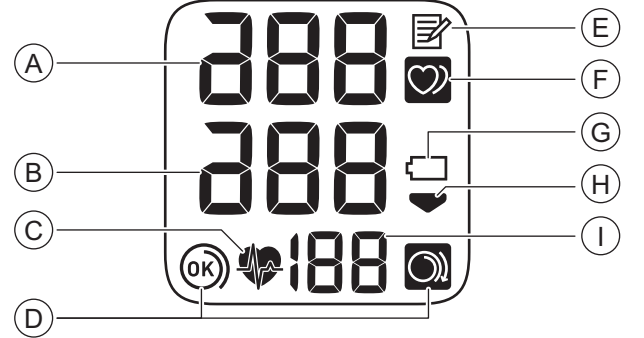
Monitor, 2 “AAA” alkaline batteries, storage case, instruction manual

1.2 Monitor



- a. Wrist cuff (Wrist circumference 13.5 cm to 21.5 cm)
- b. Display
- c. Battery compartment
- d. [Memory] button
- e. [START/STOP] button

1.3 Display and Symbols



A	Systolic blood pressure reading	
B	Diastolic blood pressure reading	
C		Heartbeat symbol Flashes while taking a measurement. Appears if your systolic blood pressure is 135 mmHg or above and/or the diastolic blood pressure is 85 mmHg or above.
D		Cuff wrap guide symbol (OK) Appears if the wrist cuff is wrapped around the wrist correctly while taking a measurement. It also appears when viewing past readings.
		Cuff wrap guide symbol (loose) Appears if the wrist cuff is not wrapped around the wrist correctly while taking a measurement. It also appears when viewing past readings.
E		Memory symbol Appears when viewing readings stored in the memory.
F		Irregular heartbeat symbol Appears along with readings when an irregular rhythm is detected 2 or more times during a measurement. An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring blood pressure. If it continues to appear, we recommend you to consult with and follow the directions of your physician.
G		Battery symbol (low) Flashes when batteries are low.
		Battery symbol (depleted) Appears when batteries are depleted.
H		Deflation symbol Appears during cuff deflation.
I	Pulse display / Memory number Pulse rate appears after the measurement. When pressing the button, the memory number appears for approximately one second before the pulse rate appears on the display.	

2013 ESH/ESC* Guidelines for the management of arterial hypertension

Definitions of hypertension by office and home blood pressure levels

	Office	Home
Systolic Blood Pressure	≥ 140 mmHg	≥ 135 mmHg
Diastolic Blood Pressure	≥ 90 mmHg	≥ 85 mmHg

These ranges are from statistical values for blood pressure.

* European Society of Hypertension (ESH) and European Society of Cardiology (ESC).

Warning

- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.

2. Preparation

2.1 Installing Batteries

1. Push down the hook of the battery cover and pull downward.
2. Insert 2 “AAA” alkaline batteries as indicated in the battery compartment.
3. Close the battery cover.

Note

- When the “” symbol flashes on the display, it is recommended you replace batteries.
- To replace batteries, turn your monitor off and remove all batteries. Then replace with 2 new alkaline batteries at the same time.
- Replacing batteries will not delete previous readings.
- The supplied batteries may have a shorter life than new batteries.
- Disposal of used batteries should be carried out in accordance with local regulations.

2.2 Blood Pressure Measurement Tips

- To help ensure an accurate reading, follow these directions:
- Stress raises blood pressure. Avoid taking measurements during stressful times.
 - Measurements should be taken in a quiet place.
 - It is important to take measurements at same times each day. Taking measurements in the morning and in the evening is recommended.
 - Remember to have a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time.

Caution

- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.

2.3 Applying the Wrist Cuff

Note

- Following steps are for applying the wrist cuff to your left wrist. When you take a measurement on your right wrist, apply the wrist cuff using the same steps as on your left wrist.
- The blood pressure can differ between the right wrist and the left wrist, and the measured blood pressure values can be different. OMRON recommends to always use the same wrist for measurement. If the values between both wrists differ substantially, please check with your physician as to which wrist to use for your measurements.

Caution

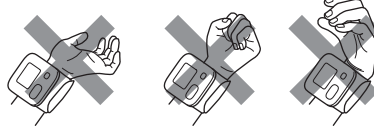
- Remove tight-fitting, thick clothing and any accessories from your wrist while taking a measurement.

1. Apply the wrist cuff to your left wrist.
Roll up sleeve. Make sure your sleeve is not rolled up too tightly on your arm. This may constrict the flow of blood in your arm.
 2. Put your wrist through the cuff loop.
Your palm and monitor display should both face upward.
 3. Position the wrist cuff leaving a clearance of 1 to 2 cm between the cuff and the bottom of your palm.
 4. Wrap the wrist cuff firmly around your wrist. Do not apply over clothing.
Check to make sure that there is no gap between your wrist and the cuff.
- Note**
- Make sure the wrist cuff does not cover the protruding part of the wrist bone on the outside of your wrist.

2.4 Sitting Correctly

To take a measurement, you need to be relaxed and comfortably seated in a room with a comfortable temperature. Place your elbow on the table to support your arm.

- Sit in a chair with your legs uncrossed and your feet flat on the floor.
- Sit with your back and arm being supported.
- Your monitor must be approximately the same level as your heart. If the monitor is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.



3. Using Your Monitor

3.1 Taking a Measurement

Note

- To stop the measurement, press the [START/STOP] button once to deflate the wrist cuff.

Caution

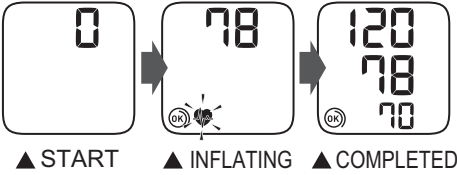
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Remain still and DO NOT talk while taking a measurement.

- Press the [START/STOP] button.
All symbols appear on the display before starting the measurement.
- Remain still and do not move or talk until the entire measurement process is completed.
As the cuff inflates, your monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation.
The “” symbol flashes at every heartbeat.

Note

- The “” symbol appears if the wrist cuff is wrapped around the wrist correctly.
- When the “” symbol is displayed, the wrist cuff is not applied correctly. Press the [START/STOP] button to turn your monitor off, then apply the cuff correctly.

After your monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed.
If either the systolic or the diastolic reading is high (refer to section 1.3), the “” symbol appears.



- Press the [START/STOP] button to turn your monitor off.
Note
 - Your monitor will automatically turn off after 2 minutes.
 - Wait 2-3 minutes between measurements. The wait time allows the arteries to decompress and return to their pre-measurement form. You may need to increase the wait time depending on your individual physiological characteristics.

4. Using Memory Function

Your monitor automatically stores up to 30 readings.

4.1 Viewing the Readings Stored in Memory

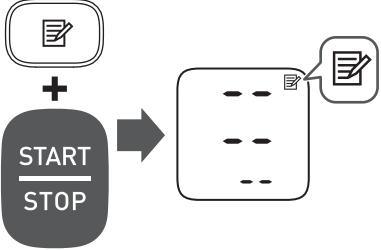
- Press the button.

The Memory number appears for one second before the pulse rate is displayed. The most recent reading set is numbered “1”.
Note
 - If there are no readings stored in the memory, the screen to the right is displayed.
 - If the reading is high (refer to section 1.3), the “” symbol appears.
 - If the memory is full, the monitor will delete the oldest readings.
- Press the button repeatedly to scroll through the previous readings stored in the memory.

5. Other Settings

5.1 Deleting All Readings Stored in Memory

- Press the button, then the “” symbol appears.
- While holding the button down, press and hold the [START/STOP] button for more than 2 seconds.



Note

- All readings will be deleted. You cannot partially delete the readings stored in the memory.

6. Error Messages and Troubleshooting

In case of any of the below problems occur during measurement, first check that no other electrical device is within 30cm. If the problem persists, please refer to the table below.

Display/ Problem	Possible Cause	Solution
appears or the wrist cuff does not inflate.	The wrist cuff is not applied correctly.	Apply the wrist cuff correctly, then take another measurement. Refer to section 2.3.
	Air is leaking from the wrist cuff.	Contact local OMRON representative.
appears	The wrist cuff is overinflated exceeding 300 mmHg.	Do not touch the wrist cuff while taking a measurement.
appears	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement.
appears	The pulse rate is not detected correctly.	Apply the wrist cuff correctly, then take another measurement. Refer to section 2.3. Remain still and sit correctly during a measurement. If the “” symbol continues to appear, we recommend you to consult with your physician.
appears		
appears		
appears	The monitor is malfunctioned.	Press the [START/ STOP] button again. If “Er” still appears, contact local OMRON representative.
flashes	Batteries are low.	Replacing all batteries with 2 new alkaline batteries is recommended. Refer to section 2.1.
appears or the monitor is turned off unexpectedly during a measurement	Batteries are depleted.	Immediately replace all batteries with 2 new alkaline batteries. Refer to section 2.1.
	Batteries are completely depleted.	
No power. Nothing appears on the display of the monitor.	Battery polarities are not properly aligned.	Check the battery installation for proper placement. Refer to section 2.1.
Readings appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the wrist cuff, may affect your blood pressure. Review sections 2.2 - 2.4 and chapter 3.	
Any other problems occur.	Press the [START/STOP] button to turn the monitor off, then press it again to take a measurement. If the problem continues, remove all batteries and wait for 30 seconds. Then re-install batteries. If the problem still persists, contact local OMRON representative.	

7. Maintenance

7.1 Maintenance

To protect your monitor from damage, please follow the directions below:

- Changes or modifications not approved by the manufacturer will void the user warranty.

Caution

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

7.2 Storage

Keep your monitor in the storage case when not in use.

- Store your monitor in a clean, safe location.

Do not store your monitor:

- If your monitor is wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.

7.3 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with neutral soap to clean your monitor and wrist cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and wrist cuff in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and wrist cuff.

7.4 Calibration and Service

- The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorised OMRON dealer or local OMRON representative at the address given on the packaging or attached literature.

8. Specifications

Product description	Wrist Blood Pressure Monitor
Model	HEM-6161
Display	LCD digital display
Cuff pressure range	0 to 299 mmHg
Blood pressure measurement range	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg
Pulse measurement range	40 to 180 beats / min.
Accuracy	Pressure: ±3 mmHg Pulse: ±5% of display reading
Inflation	Automatic by electric pump
Deflation	Automatic rapid deflation
Measurement method	Oscillometric method
Operation mode	Continuous operation
IP classification	IP 22
Rating	DC3 V 3.0 W
Power source	2 “AAA” alkaline batteries 1.5V
Battery life	Approximately 300 measurements (using new alkaline batteries)
Durable period (Service life)	5 years
Operating conditions	+10°C to +40°C / 15 to 90% RH (non-condensing) / 800 to 1060 hPa
Storage / Transport conditions	-20°C to +60°C / 10 to 90% RH (non-condensing)
Weight	Approximately 85 g not including batteries
Dimensions	Approximately 84 mm (w) × 62 mm (h) × 21 mm (l) (not including the wrist cuff)
Measurable wrist circumference	13.5 to 21.5 cm
Memory	Stores up to 30 readings
Contents	Monitor, storage case, 2 “AAA” alkaline batteries, instruction manual
Protection against electric shock	Internally powered ME equipment
Cuff Material	Nylon and polyester
Applied part	Type BF (wrist cuff)
Maximum temperature of the applied part	Lower than +48°C

Note

- These specifications are subject to change without notice.
- In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure.
- This monitor is clinically investigated according to the requirements of ISO 81060-2:2013.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This monitor is protected against solid foreign objects of 12.5 mm diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation.
- This device has not been validated for use on pregnant patients.

9. Guidance and Manufacturer’s Declaration



- This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive).
- This blood pressure monitor is designed according to the European Standard EN1060, Non-invasive sphygmomanometers Part 1: General Requirements and Part 3: Supplementary requirements for electromechanical blood pressure measuring systems.
- This OMRON product is produced under the strict quality system of OMRON HEALTHCARE Co., Ltd., Japan. The Core component for OMRON blood pressure monitors, which is the Pressure Sensor, is produced in Japan.

Symbols description	
	Applied part - Type BF Degree of protection against electric shock (leakage current)
IP XX	Ingress protection degree provided by IEC 60529
	CE Marking
	Serial number
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Need for the user to consult this instruction manual.
	Indicates the correct positioning for the monitor on the wrist Measurable wrist circumference
	Battery
	Direct current

Important information regarding Electro Magnetic Compatibility (EMC)

HEM-6161 manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at <http://www.omronhealthcare-ap.com/emc-information>. Refer to the EMC information for HEM-6161 on the website.

Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life.
To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.
Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

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