

OMRON

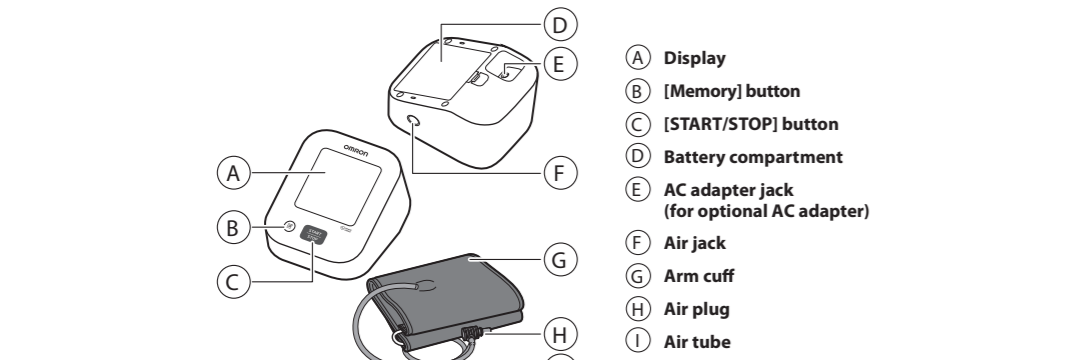
Automatic Upper Arm Blood Pressure Monitor

M2+ (HEM-7188-LE) M2 Essential (HEM-7188-E)

English

Instruction Manual 1: Safety and Other Information

For symbols information, refer to "Symbols Description" section.



Introduction

Thank you for purchasing the OMRON Automatic Upper Arm Blood Pressure Monitor. This blood pressure monitor uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

Safety Instructions

This instruction manual provides you with important information about the OMRON Automatic Upper Arm Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ AND UNDERSTAND all of these instructions. If you do not understand these instructions or have any questions, contact your OMRON retail outlet or distributor 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. The device detects the appearance of irregular heartbeats during measurement and indicates this via a symbol with the measurement result.

Intended Patients

Adult patient population
Adult population (may include patients themselves) who can understand this instruction manual.

Clinical Benefit

Patient's blood pressure can be measured non-invasively and simply in the home environment.

Type of Use

This monitor is intended to be multiple patient multiple use.

Limitation

Patient's arm circumference must be 17 - 42 cm.

Indication

This device is used by healthy individuals, patients with hypertension, patients with health-conscious individuals, in a general household situation for measuring blood pressure and pulse rate.

Receiving and Inspection

Check the device and other components from the packaging and inspect for damage. If this monitor or any other components is damaged, DO NOT USE. In contact with your OMRON retail outlet or distributor.

Important Safety Information

Read the Important Safety Information in this instruction manual before using this monitor. Follow this instruction manual thoroughly for your safety.

For further reference, For specific information about your own blood pressure, consult with your physician.

Contraindications

- DO NOT use this monitor on an injured arm or an arm under medical treatment.
- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.

Side Effects

- Taking measurements more often than necessary may cause bruising due to blood flow interference.
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied. NOTE: refer to "If your systolic pressure is more than 210 mmHg" in the end of instruction manual 2 for additional information.

- Stopping using this monitor and consult with your physician if you experience skin irritation or discomfort.

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

- DO NOT adjust medication (including altering your use of any drug or treatment) 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 and heart-related conditions.
- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.
- If you are experiencing any symptoms or concerns, consult with your physician.
- DO NOT postpone/stop regular checkups or physician visits based on the results that you are getting from this monitor.
- 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.
- To help avoid straining, keep the air tube and AC adapter cable away from infants, toddlers and children.
- DO NOT use this monitor on a child who is suspected of causing a choking hazard if swallowed by infants, toddlers and children.

AC Adapter (optional accessory) Handling and Usage

- DO NOT use the AC adapter if this monitor or the AC adapter cable is damaged. If this monitor or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

Battery Handling and Usage

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

⚠ Precaution 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.

- Consult with your physician before using this monitor on an arm where intravascular access or therapy, or an arterio-venous (AV) shunt, is present because of temporary interference to blood flow and could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy or lymph node clearance.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- ONLY inflate the arm cuff when it is applied on your upper arm.
- Remove the arm 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 or on an aircraft.
- 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 section 4.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the devices 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 or tight clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.

Display/Problem	Possible Cause	Solution
	appears, or the monitor is turned off unexpectedly during a measurement.	Apply the arm cuff correctly, then take another measurement. Refer to section 4 of instruction manual 2. Remain still and sit correctly during measurement. The irregular heartbeat symbol continues to appear, if you continue to consult with your physician.
	does not flash during a measurement.	Replaces all 4 batteries with new ones if recommended. Refer to section 3 of instruction manual 2.
	flashes	Batteries are depleted. Immediately replace all 4 batteries with new ones if recommended in section 3 of instruction manual 2.
	R and I	Nothing appears on the display of the monitor. Check the battery installation for proper placement. Refer to section 4 of instruction manual 2. Battery polarities are not properly aligned. Check the battery installation for proper placement. Refer to section 4 of instruction manual 2. Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the arm cuff, may affect your blood pressure. Review sections 2, 4 and 5 of instruction manual 2.
	Nothing appears on the display of the monitor.	Check the battery installation for proper placement. Refer to section 4 of instruction manual 2. Battery polarities are not properly aligned. Check the battery installation for proper placement. Refer to section 4 of instruction manual 2. Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the arm cuff, may affect your blood pressure. Review sections 2, 4 and 5 of instruction manual 2.
	Readings appear too high or too low.	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 the batteries. If the problem still persists, contact your OMRON retail outlet or distributor.
	Any other problem occurs.	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 the batteries. If the problem still persists, contact your OMRON retail outlet or distributor.

5 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.

2 Limited Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you a high level of comfort, provided that it is properly operated and maintained as described in the instruction manual.

This product is warranted by OMRON for a period of 5 years after the date of purchase. The proper construction, workmanship and materials of this product is warranted by OMRON. During this period of warranty OMRON will, without charge for labour or parts, repair or replace the defect product or any defective component. This warranty does not cover any of the following:

- Transport costs and fees of transport.
- Failure or wear of optional parts or other attachments other than the unattached persons.
- Periodic check-ups and maintenance.
- Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted by OMRON.
- Costs arising due to non-acceptance of a claim (those will be charged for).
- Damages of any kind including personal caused accidentally or from misuse.
- Calibration service is not included within the warranty.
- Optional parts have a one (1) year warranty from date of purchase. Optional parts include, but are not limited to the following items: cuff and cuff tube.

7 Guidance and Manufacturer's Declaration

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Please report to the manufacturer and the competent authority of the Member State to which you are established about any serious incident that has occurred in relation to this device.

3 Maintenance

3.1 Maintenance

To protect your monitor from damage, follow the directions below. Repairs or modifications not approved by the manufacturer will void the user warranty.

⚠ Precaution

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

3.2 Storage

- Store your monitor and other components in a clean, safe location.
- Gently fold the air tube into the arm cuff. Note: Do not bend or crush the air tube excessively.
- Do not store your monitor and other components:
 - in your monitor and other components are wet.
 - in locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
 - in locations exposed to vibrations or shocks.

3.3 Wiping the Monitor

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to wipe your monitor and arm cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners or similar solvents to wipe your monitor and arm cuff or other components.

3.4 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 authorized OMRON dealer or the OMRON Customer Service at the address given on the packaging or attached literature.

4 Error Messages and Troubleshooting

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Memory	Stores up to 30 readings
Contents	Monitor, arm cuff (HEM-RML31 for HEM-7188-LE/HEM-C24 for HEM-7188-E), 4 "AA" batteries, Instruction Manual 1 and 2
Protection against electric shock	Internally powered (ME equipment when using only batteries). Class II ME equipment (when using optional AC adapter)
Applied part	Type BF (arm cuff)

Note

- These specifications are subject to change without notice.
- This monitor is clinically investigated according to the requirements of EN ISO 81069-2:2014 and complies with EN ISO 81069-2:2019+A1:2020+A2:2024 (excluding pregnant and lactating patients). In the clinical validation study, 35 was used on 85 subjects for determination of diastolic blood pressure.
- IP classification is degree of protection provided by enclosures in accordance with IEC 60529. This monitor and optional AC adapter are protected against solid foreign objects of 12.5 mm diameter and greater such as a finger. The monitor and optional AC adapter are protected against liquid ingress. The optional AC adapter HHP-BFH01 is protected against oblique falling water drops which may cause issues during a normal operation.
- Operation mode classification complies with IEC 60601-1.

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6 Important Information regarding Electromagnetic Compatibility (EMC)

This device conforms to the EN 60601-1-2:2015+A1:2021 Electromagnetic Compatibility (EMC) standard. Further information in accordance with this EMC standard is available at: <https://healthcare.omron.com/electro-magnetic-compatibility>. Refer to the EMC information for this device on the website.

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