

OMRON

Automatic Upper Arm Blood Pressure Monitor

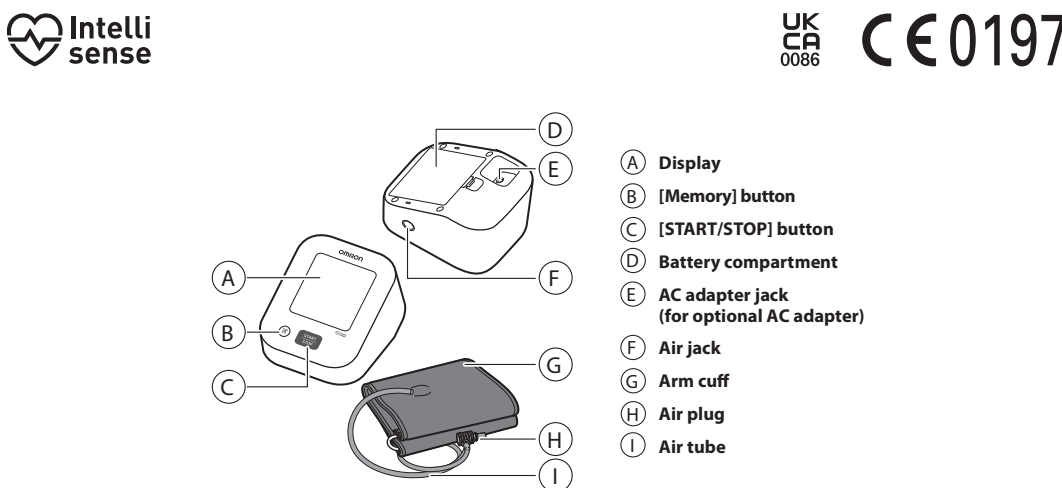
M2+ (HEM-7188-LE)

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

Intended Users

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

Patients with or 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 monitor and other components from the packaging and inspect for damage. If this monitor or any other components is damaged, DO NOT USE and consult 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 specific information about your own blood pressure, consult with your physician.

Contraindications

- DO NOT use this monitor on an injured arm or on an arm under treatment.
- DO NOT apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- 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 confusion due to blood flow interference while taking a measurement.
- 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.
- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.

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 blood pressure readings.
- Take medication as prescribed by your physician. ONLY your 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) scanning 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 strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.

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 intravenous access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow 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 humidity 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	Apply the arm cuff correctly, then take another measurement. Refer to section 4 of instruction manual 2.
	appears	The pulse rate is not detected correctly.
	does not flash during a measurement	
	flashes	Batteries are low.
	and	Batteries are depleted.
	Nothing appears on the display of the monitor.	Check the battery installation for proper placement. Refer to section 3 of instruction manual 2.
	Readings appear too high or too low.	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.
	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, wait for 30 seconds. Then re-install the batteries. If the problem still persists, contact your OMRON retail outlet or distributor.

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 this 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 labor or parts, repair or replace any defect product or any defective part.

The warranty does not cover any of the following:

- A. Transport costs and risks of transport.
- B. Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
- C. Periodic check-ups and maintenance.
- D. Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
- E. Costs arising due to non-acceptance of a claim (those will be charged for).
- F. Damages of any kind including personal caused accidentally or from misuse.
- G. Calibration service is not included within the warranty.
- H. Optional parts have a one (1) year warranty from date of purchase.

Optional parts, and those not limited to the following items: cuff and cuff tube.

Should warranty service be required please apply to the dealer where the product was purchased from or an authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised retailer. If you have difficulties in finding OMRON customer service, contact our website (www.omron-healthcare.com) for contact information.

Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.

The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

3 Maintenance

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

- DO NOT use cleaning methods not approved by the manufacturer will void the user warranty.

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

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 crease the air tube excessively.

- Do not store your monitor and other components:
- If 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.

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 your monitor and arm cuff or other components in water.
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Memory	Stores up to 30 readings
Contents	Monitor: arm cuff (HEM-RML31 for HEM-7188-LE / HEM-CR24 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 81060-2:2014 and complies with EN ISO 81060-2:2014+A1:2020+A2:2024 (excluding pregnant and pre-eclampsia patients), the clinical validation study. It is used on 85 subjects for determination of diastolic blood pressure. • IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This AC adapter and the 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 HHP-CM01 and HHP-AM01 are protected against vertically falling water drops which may cause issues during a normal operation. 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.

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.

6 Important Information regarding Electromagnetic Compatibility (EMC)

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

7 Guidance and Manufacturer's Declaration

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.

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

OMRON

Automatyczny ciśnieniomierz naramienny

M2+ (HEM-7188-LE)

M2 Essential (HEM-7188-E)

Język polski

Instrukcja obsługi 1: Informacje dotyczące bezpieczeństwa i pokrewne

Informacje o symbolach znajdujące się w punkcie „Opis symboli”.



Wprowadzenie

Dziękujemy za zakup automatycznego ciśnieniomierza naramiennego OMRON. Ciśnieniomierz wykorzystuje oscylometryczną metodę pomiaru ciśnienia krwi. Oznacza to, że urządzenie wykrywa ruch krwi w tętnicy naramiennej i przekształca go w odczyt cyfrowy.

Instrukcje bezpieczeństwa

Niniejsza instrukcja zawiera istotne informacje o automatycznym ciśnieniomierzu naramiennym OMRON. Aby zapewnić sobie i innym bezpieczeństwo i prawidłowe korzystanie z ciśnieniomierza, należy PRZECZYTAC I ZASTANOWIĆ wszystkie podane instrukcje. W razie niezrozumienia wywołanych problemów lub przed podjęciem próby użycia ciśnieniomierza prosimy o kontakt z punktem sprzedaży detalicznej produktów firmy OMRON lub ich dystrybutor. W celu uzyskania szczegółowych informacji na temat ciśnienia krwi użytkownika urządzenia należy skonsultować z lekarzem.

Przeznaczenie

Urządzenie to jest ciśnieniomierzem cyfrowym przeznaczonym do pomiaru ciśnienia krwi i tętna u pacjentów dorosłych. Urządzenie wykrywa nieregulujące się serce podczas pomiaru i informuje o tym za pomocą symbola wyświetlanego wraz z wynikiem pomiaru.

Docelowi pacjenci

Populacja pacjentów dorosłych

Docelowi użytkownicy

Ciśnieniomierz należy używać TYLKO u osób, których obwód ramienia mieści się w zakresie podanym dla mankieta.

Należy dopinąć, aby przed pomiarem ciśnieniomierz osiągnął temperaturę pokojową. Dokonywanie pomiaru po ekstremalnym zmianie temperatury może prowadzić do niedokładnego odczytu.

Zaleca się, aby po przechowywaniu ciśnieniomierza w temperaturze skrajnie niskiej lub skrajnie wysokiej poczekać średnio 2 godziny, aż urządzenie ogrzeje się lub ostygnie przed użyciem.

Przeznaczony do użytku w warunkach normalnych. Nie należy używać w warunkach ekstremalnych.

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