

Instruction Manual

1
OMRON

Automatic Upper Arm Blood Pressure Monitor M2 Basic (HEM-7121J-E)

Read Instruction manual **①** and **②** before use.

FR Lire le mode d'emploi **①** et **②** avant l'utilisation.

DE Lesen Sie vor der Verwendung die Gebrauchsanweisung **①** und **②**.

IT Leggere il manuale di istruzioni **①** e **②** prima dell'uso.

ES Lea el manual de instrucciones **①** y **②** antes del uso.

RU Прочтите руководство по эксплуатации **①** и **②** перед использованием.

TR Kullanmadan önce, kullanım kılavuzu **①** ve **②**'yi okuyun.

PL Przed rozpoczęciem korzystania z ciśnieniomierza należy przeczytać instrukcję obsługi **①** i **②**.

PT Leia o Manual de instruções **①** e **②** antes de utilizar.

AR اقرأ دليل الإرشادات **①** و**②** قبل الاستخدام.

All for Healthcare

C€0197

EN
FR
DE
IT
ES
RU
TR
PL
PT
AR
Symbols

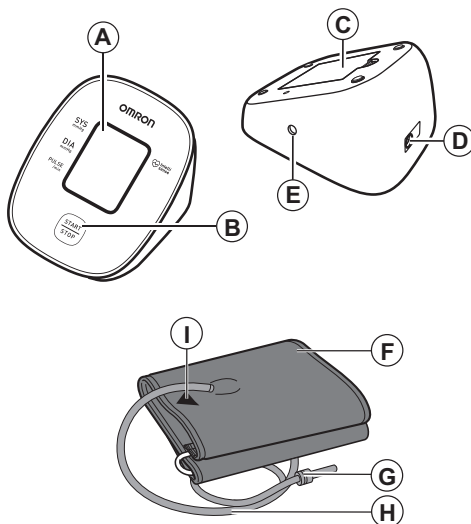
Symboles / Symbole / Simboli / Símbolos /
Символы / Semboller / Symbole /
Símbolos / الرمز

Overview

FR Présentation générale
DE Überblick
IT Presentazione del prodotto
ES Descripción general

RU Описание прибора
TR Genel Bakış
PL Przegląd
PT Descrição geral

نظرة عامة **AR**



| | |
|----------|---|
| A | Display FR Affichage DE Display IT Display ES Pantalla RU Дисплей TR Ekran PL Wyświetlacz PT Visor الشاشة AR |
| B | [START/STOP] button FR Bouton [START/STOP] DE [START/STOP]-Taste IT Pulsante [START/STOP] ES Botón [START/STOP] RU Кнопка [START/STOP] TR [START/STOP] PL Przycisk [START/STOP] PT Botão [START/STOP] [START/STOP] (تأثير/إيقاف) AR |
| C | Battery compartment FR Compartiment des piles DE Batteriefach IT Alloggiamento batterie ES Compartimento de las pilas RU Отсек для элементов питания TR Pil bölüümü PL Komora baterii PT Compartimento das pilhas حجرة البطاريات AR |
| D | AC adapter jack FR Prise pour l'adaptateur secteur DE Netzteilanschluss IT Presa per alimentatore CA ES Toma del adaptador de CA RU Гнездо адаптера переменного тока TR AC adaptörü prizi PL Gniazdko zasilacza PT Entrada do adaptador de CA مقبس مهربي التيار المتردد AR |

| | | | | |
|----------|-----------------|--|--|---------------------------------|
| E | Air jack | FR Prise à air DE Luftschlauchbuchse IT Presa per il tubo dell'aria ES Toma de aire | RU Воздушное гнездо TR Hava jakı PL Przyłącze powietrza PT Tomada de ar | AR مقبس خرطوم الهواء |
| | Arm cuff | FR Brassard DE Manschette IT Bracciale ES Manguito | RU Манжета компрессионная TR Kolluk PL Mankiet PT Braçadeira | AR الشريط المضاعط للترأخ |
| | Air plug | FR Prise de gonflage DE Luftschlauchstecker IT Attacco del tubo dell'aria ES Conector para tubo de aire | RU Воздушный штекер TR Hava tapası PL Wtyczka przewodu powietrza PT Ficha de ar | AR قابس خرطوم الهواء |
| | Air tube | FR Tuyau à air DE Luftschlauch IT Tubo dell'aria ES Tubo de aire | RU Воздуховодная трубка TR Hava borusu PL Przewód powietrza PT Tubo de ar | AR خرطوم الهواء |
| | | | | |

| | | | | |
|----------|---------------|--|--|-------------------------|
| I | Marker | FR Marque DE Markierung IT Contrassegno ES Marcador | RU Маркер TR İşaretçi PL Znacznik PT Marcador | AR علامة التحديد |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

1. 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.

1.1 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.**

1.2 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 gives a warning signal with readings. It is mainly designed for general household use.

1.3 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 OMRON retail outlet or distributor.

2. Important Safety Information

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

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



2.1 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 arm or an arm under medical treatment.
- DO NOT apply the arm cuff on your arm 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.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.
- This product contains small parts that may cause 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 batteries out of the reach of infants, toddlers and children.



2.2 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 an arm where intravascular access or therapy, or an arteriovenous (A-V) 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.
- 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 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 emit 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 6.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.

- 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 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 thick clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm 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 on operating and storage/transport temperature, refer to section 6.
- DO NOT use this monitor after the durable period has ended. Refer to section 6.
- DO NOT crease the arm cuff or the air tube excessively.
- DO NOT fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow.
- To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.
- ONLY use the AC adapter, arm cuff, batteries and accessories specified for this monitor. Use of unsupported AC adapters, arm cuffs and batteries may damage and/or may be hazardous to this monitor.
- ONLY use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- 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 section 6 of instruction manual ② for additional information.
- Read and follow the "Correct Disposal of This Product" in section 7 when disposing of the device and any used accessories or optional parts.

EN

EN2

AC Adapter (optional accessory) Handling and Usage

- Fully insert the AC adapter into the outlet.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the AC adapter cable.
- When handling the AC adapter cable:
 - Do not damage it. / Do not break it. / Do not tamper with it.
 - DO NOT pinch it. / Do not forcibly bend or pull it. / Do not twist it.
 - DO NOT use it if it is gathered in a bundle.
 - DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this monitor.

Battery Handling and Usage

- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 4 "AA" alkaline or manganese 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.

2.3 General Precautions

- When you take a measurement on the right arm, the air tube should be at the side of your elbow. Be careful not to rest your arm on the air tube.



- Blood pressure may differ between the right and left arm, and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.
- When using an optional AC adapter, make sure not to place your monitor in a location where it is difficult to plug and unplug the AC adapter.









Battery Handling and Usage

- Disposal of used batteries should be carried out in accordance with local regulations.
- The supplied batteries may have a shorter life span than new batteries.




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. Please use the Blood Pressure Diary to keep records of several readings over a certain period of time. To download PDF files of the diary, visit www.omron-healthcare.com.

3. Error Messages and Troubleshooting

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

| Display/Problem | Possible Cause | Solution |
|--|--|--|
|  appears or the arm cuff does not inflate. | The [START/STOP] button was pressed while the arm cuff is not applied. | Press the [START/STOP] button again to turn the monitor off. After inserting the air plug securely and applying the arm cuff correctly, press the [START/STOP] button. |
| | Air plug is not completely plugged into the monitor. | Insert the air plug securely. |
| | The arm cuff is not applied correctly. | Apply the arm cuff correctly, then take another measurement. Refer to section 4 of instruction manual (2). |
| | Air is leaking from the arm cuff. | Replace the arm cuff to the new one. Refer to section 9 of instruction manual (2). |
|  appears or a measurement cannot be completed after the arm cuff inflates. | <p>You move or talk during a measurement and the arm cuff does not inflate sufficiently.</p> <p>Due to the systolic pressure is above 210 mmHg, a measurement cannot be taken.</p> | <p>Remain still and do not talk during a measurement. If "E2" appears repeatedly, inflate the arm cuff manually until the systolic pressure is 30 to 40 mmHg above your previous readings. Refer to section 6 of instruction manual (2).</p> |
|  appears | The arm cuff is inflated exceeding the maximum allowable pressure. | Do not touch the arm cuff and/or bend the air tube while taking a measurement. If inflating the arm cuff manually, refer to section 6 of instruction manual (2). |
|  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. | <p>Apply the arm cuff correctly, then take another measurement. Refer to section 4 of instruction manual (2).</p> <p>Remain still and sit correctly during a measurement.</p> <p>If the "" symbol continues to appear, we recommend you to consult with your physician.</p> |
|  appears  does not flash during a measurement | | |

EN

| Display/Problem | Possible Cause | Solution |
|--|--|--|
|  appears | The monitor has malfunctioned. | Press the [START/STOP] button again. If “Er” still appears, contact your OMRON retail outlet or distributor. |
|  appears | Batteries are low. | Replacing all 4 batteries with new ones is recommended. Refer to section 3 of instruction manual (2). |
|  appears or the monitor is turned off unexpectedly during a measurement | Batteries are depleted. | Immediately replace all 4 batteries with new ones. Refer to section 3 of instruction manual (2). |
| Nothing appears on the display of the monitor. | Battery polarities are not properly aligned. | 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 section 2 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, remove all batteries and wait for 30 seconds. Then re-install batteries. If the problem still persists, contact your OMRON retail outlet or distributor. | |

4. 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 every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.

This product is warranted by OMRON for a period of 3 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 parts.

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 include, but are not limited to the following items:
cuff and cuff tube.

Should warranty service be required please apply to the dealer whom 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 services, contact us for information:
www.omron-healthcare.com

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.

5. Maintenance

5.1 Maintenance

To protect your monitor from damage, 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.

5.2 Storage

- Store your monitor and other components in a clean, safe location.
- 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.

5.3 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean 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 clean your monitor and arm cuff or other components.

5.4 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 the OMRON Customer Service at the address given on the packaging or attached literature.

EN

6. Specifications

| | | | |
|--|--|-------------------------|----------------------------------|
| Product description | Automatic Upper Arm Blood Pressure Monitor | | |
| Product category | Electronic Sphygmomanometers | | |
| Model (code) | M2 Basic (HEM-7121J-E) | Display | LCD digital display |
| Cuff pressure range | 0 to 299 mmHg | Pulse measurement range | 40 to 180 beats / min. |
| Blood pressure measurement range | 20 to 280 mmHg | | |
| Accuracy | Pressure: ± 3 mmHg / Pulse: $\pm 5\%$ of display reading | | |
| Inflation | Automatic by electric pump | Deflation | Automatic pressure release valve |
| Measurement method | Oscillometric method | Operating mode | Continuous operation |
| IP classification | Monitor: IP20 / Optional AC adapter: IP21 (HHP-CM01) or IP22 (HHP-BFH01) | | |
| Rating | DC6 V 4.0 W | Applied part | Type BF (arm cuff) |
| Power source | 4 "AA" batteries 1.5 V or optional AC adapter (INPUT AC 100 - 240 V 50 - 60 Hz 0.12 - 0.065 A) | | |
| Battery life | Approximately 1000 measurements (using new alkaline batteries) | | |
| Durable period (Service life) | Monitor: 5 years / Cuff: 5 years / Optional AC adapter: 5 years | | |
| Operating conditions | +10 to +40 °C / 15 to 90% RH (non-condensing) / 800 to 1060 hPa | | |
| Storage / Transport conditions | -20 to +60 °C / 10 to 90% RH (non-condensing) | | |
| Contents | Monitor, arm cuff (HEM-CR24), 4 "AA" batteries, Instruction Manual (1) and (2) | | |
| Protection against electric shock | Internally powered ME equipment (when using only batteries) Class II ME equipment (optional AC adapter) | | |
| Weight | Monitor: approximately 250 g (not including batteries) / Arm cuff: approximately 130 g | | |
| Dimensions (approximately value) | Monitor: 112 mm (W) × 82 mm (H) × 140 mm (L) Arm cuff: 145 mm × 466 mm (air tube: 600 mm) | | |
| Cuff circumference applicable to the monitor | 170 to 420 mm (included arm cuff: (220 to 320 mm)) | | |
| Memory | Last measurement | | |

Note

- These specifications are subject to change without notice.
- This monitor is clinically investigated according to the requirements of ISO 81060-2:2013 (excluding pregnant and pre-eclampsia patients). In the clinical validation study, K5 was 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 monitor and optional AC adapter are protected against solid foreign objects of 12.5 mm diameter and greater such as a finger. The optional AC adapter HHP-CM01 is 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.
- Operating mode is classification in accordance with IEC 60601-1.

7. 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.



EN

8. Important Information Regarding Electromagnetic Compatibility (EMC)

HEM-7121J-E conforms to EN60601-1-2:2015 Electromagnetic Compatibility (EMC) standard.

Further documentation in accordance with this EMC standard is available at

www.omron-healthcare.com

Refer to the EMC information for HEM-7121J-E on the website.

9. Guidance and Manufacturer's Declaration

- 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.
- 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.

10. Classification of BP (Blood Pressure)

2018 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.

EN8