

Automatic Upper Arm Blood Pressure Monitor

Model HEM-9210T
Instruction Manual



2800028-0A

Introduction

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 presence of irregular heartbeats during measurement and gives a warning signal with the measurement result.

Please follow this instruction manual thoroughly for your safety. Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR PHYSICIAN.

Important Safety Information

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

General Usage
 Do NOT adjust medication based on measurement results from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat high blood pressure.
 Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases.
 Note that PATIENT motion, trembling, shivering may affect the measurement reading.

Do not use the device on an injured arm or an arm under medical treatment.
 Stop using the device and consult your physician if you experience skin irritation or other troubles.
 Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion.
 Consult your physician before using the device on the arm with an arterio-venous (A-V) shunt.
 Do not use the device with other medical electrical (ME) equipment simultaneously.
 Do not use the device in the area of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI), or computerized tomography (CT) scanner exists, or in the oxygen rich environment.
 The air tube or the AC adapter cable may cause accidental strangulation in infants.

Contains small parts that may cause a choking hazard if swallowed by infants.
Data Transmission
 Do not use this product on an aircraft or in hospitals. Please remove the battery and AC adapter from the device. This product emits radio frequencies (RF) in the 2.4 GHz band, use of this product in locations where RF is restricted is not recommended.
 The use of RF in this product is licensed for use by the FCC, for further information on any potential restrictions refer to documentation on Bluetooth® usage by the FCC.

AC Adapter (optional accessory)
 Do not use the AC adapter if the device or the power cord is damaged. Turn off the power and unplug the power cord immediately.
 Plug the AC adapter into the appropriate voltage outlet. Do not use in a multi-outlet plug.
 Never plug in or unplug the power cord from the electric outlet with wet hands.
 Do not disassemble or attempt to repair the AC adapter.

Battery Usage
 Keep the battery out of reach of children.

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

General Usage
 Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.
 Consult your physician before using the device for any of the following conditions:
 • If you have had a mastectomy.
 • People with severe blood flow problems or blood disorders as cuff inflation can cause bruising.

Do not take measurements more often than necessary. It may cause bruising due to blood flow interference.
 Remove the arm cuff if it does not start deflating during the measurement.
 Do not use this device on infants or persons who cannot express their intentions.
 Do not use the device for any purpose other than measuring blood pressure.
 Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement results.
 Do not use a mobile phone or other devices that emit electromagnetic fields near the device except when in use for wireless communications. This may result in incorrect operation of the device.
 Do not disassemble or attempt to repair the device or components. This may cause an inaccurate reading.
 Do not use in a location with moisture, or a location where water may splash on the device. This may damage the device.
 Do not use the device in a moving vehicle. For example, the car or airplane.
 Read "What to do if your systolic pressure is more than 210 mmHg" of this instruction manual, if your systolic pressure is known to be more than 210 mmHg. Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied.

Data Transmission
 Do not replace the battery or unplug the AC adapter when in use for wireless communications. This may result in incorrect operation of the device or damage to the data.
 Do not place integrated circuit cards, magnets, metal objects, or other devices that emit electromagnetic fields near the device when in use for wireless communications. This may result in incorrect operation of the device or damage to the data.

AC Adapter (optional accessory)
 Fully insert the power plug into the outlet.
 When disconnecting the power plug from the outlet, be sure to safely pull from the power plug. Do not pull from the power cord.
 When handling the power cord, take care not to do the following:
 Do not damage. Do not break it.
 Do not tamper with it. Do not forcibly bend or pull.
 Do not twist. Do not bundle during use.
 Do not pinch. Do not place under heavy objects.

Wipe any dust off of the power plug.
 Unplug the monitor when not in use.
 Disconnect the power plug before cleaning.

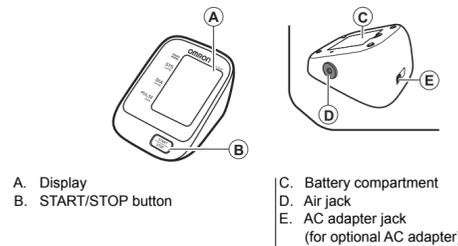
Battery Usage
 Do not insert the batteries with their polarities incorrectly aligned.
 Use only 4 "AA" alkaline or manganese batteries with this device. Do not use other types of batteries. Do not use new and used batteries together.
 Remove the batteries if the device will not be used for three months or more.
 If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult a physician immediately.
 Use the battery within recommended period mentioned to it.

General Precautions
 Do not forcibly crease the arm cuff or the air tube excessively.
 Do not fold or kink the air tube while taking a measurement. This may cause harmful injury by interrupting blood flow.
 To unplug the air plug, pull on the air plug at the connection with the monitor, not the tube itself.
 Do not drop the monitor or subject the device to strong shocks or vibrations.
 Do not inflate the arm cuff when it is not wrapped around your arm.
 Do not use the device outside the specified environment. It may cause an inaccurate reading.
 Use only an AC adapter, arm cuff, batteries and etc, specified for this device. Use of unsupported adapters, arm cuff and batteries may damage and/or may be hazardous to the device.
 Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.
 Please check (for example, by observation of the limb concerned) if the device is not causing a prolonged impairment of PATIENT blood circulation.

1. Know Your Device

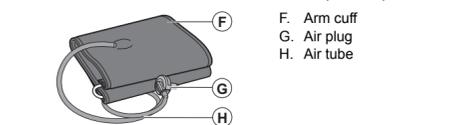
Contents:
 Monitor, arm cuff, battery set, instruction manual, quick start guide

Monitor:



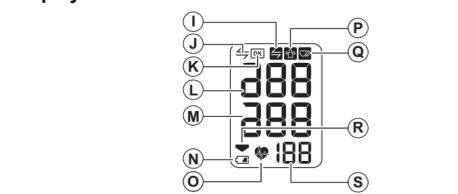
- A. Display
- B. START/STOP button
- C. Battery compartment
- D. Air jack
- E. AC adapter jack (for optional AC adapter)

Arm cuff: Arm circumference 22 - 42 cm (9" - 17")



- F. Arm cuff
- G. Air plug
- H. Air tube

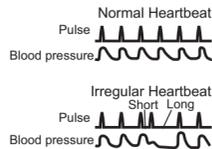
Display:



- I. SYNC symbol
- J. Connection symbol
- K. OK symbol
- L. Systolic blood pressure
- M. Diastolic blood pressure
- N. Battery symbol (low/depleted)
- O. Heartbeat symbol (Flashes during measurement.)
- P. Movement error symbol
- Q. Irregular heartbeat symbol
- R. Deflation symbol
- S. Pulse display

1.1 Display symbols

Irregular Heartbeat Symbol (E)
 When the monitor detects an irregular rhythm two or more times during the measurement, the irregular heartbeat symbol will appear on the display with the measurement values.
 An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure.
 If the irregular heartbeat symbol displays with your measurement results, we recommend you consult your physician. Follow the directions of your physician.



Movement Error Symbol (E)
 The movement error symbol is displayed if you move your body during the measurement. Please remove the arm cuff, and wait 2 - 3 minutes. Take another measurement, remain still during measurement.

SYNC Symbol (E)
 The SYNC symbol is displayed if the device is not connected to Telehealth service receiver or if measured data is not transmitted successfully. Please refer to "Connection failure. / Data is not being transmitted." in section 4.2.

1.2 Wireless Function

Before use, thoroughly read the instruction manual included with the Telehealth service receiver (in some cases, receiver may be your smartphone) being used with this blood pressure monitor for instruction about your monitor to Telehealth service receiver, and receiver transmission range. It will be necessary for the blood pressure monitor to be within the receiver's transmission range to successfully transfer data. This Omron blood pressure monitor is designed to connect to specific Bluetooth® Smart receivers, and is not guaranteed to connect to all Bluetooth® Smart compatible devices and Telehealth service receivers. "OMRON HEALTHCARE Co., Ltd. cannot accept liability for any damages incurred due to impaired operation or data loss, etc. that occur through the use of this product."

1.3 Before Taking a Measurement

To help ensure an accurate reading, follow these directions:
 1. Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for 30 minutes before taking a measurement.
 2. Rest for at least 5 minutes before taking the measurement.
 3. Stress raises blood pressure. Avoid taking measurements during stressful times.
 4. Measurements should be taken in a quiet place.
 5. Remove tight-fitting clothing from your arm.

2. Preparation

Battery Installation
 Below connection process (step 4 and 5) can only be completed when inserting batteries.

1. Remove the battery cover.
2. Insert 4 "AA" batteries as indicated, into the battery compartment.
3. Replace the battery cover.
4. The device will start the connection process.
 As soon as inserting the batteries, it will automatically start to connect to the Telehealth service receiver, as below.



If the display shown above does not appear, refer to "Connection failure. / Data is not being transmitted." in section 4.2. To retry connecting the Telehealth service receiver, remove batteries and press [START/STOP] button for 2-3 times. Then start with step 2 again.

Note: If your Telehealth service receiver asks for a PIN code, enter the digits of the PIN code located on the rating label at the bottom of the device.

5. Confirm the device is successfully connected.
 If the device is connected successfully to the Telehealth service receiver, OK symbol "OK" will appear on the display, as shown below.



If "Err" appears, refer to "Connection failure. / Data is not being transmitted." in section 4.2 for more detail.



Notes:
 • We recommend keeping batteries in the device at all times, even if you choose to use the AC adapter.
 • If only the AC adapter is used without keeping the batteries in the device, the device connection process (steps 4 and 5) is necessary each time you unplug and plug back the AC adapter.

3. Using the Device

3.1 Applying the Arm Cuff

Remove tight-fitting clothing from your left upper arm. Do not place the arm cuff over thick clothing.

1. Connect the air plug to the unit.
2. Wrap the arm cuff firmly in place around your left upper arm.
3. Securely close with the fabric fastener.

The bottom edge of the arm cuff should be 1/2 inch (1 to 2 cm) above the elbow. The air tube is on the inside of your arm and aligned with your middle finger.

Note: Please refer to the operating instruction of the HEM-RXL31 for applying the extra large cuff.

Notes:
 • When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube.
 • The blood pressure can differ between the right arm and the left arm, and the measured blood pressure values can be different. Omron recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician as to which arm to use for your measurements.

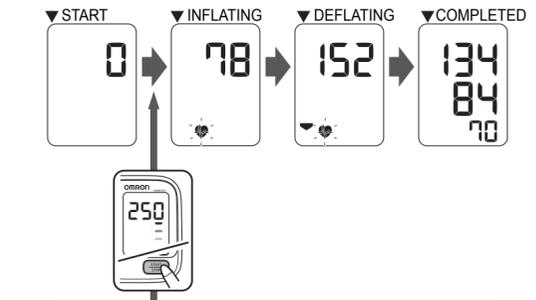
3.2 How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated, at a comfortable room temperature.
 Sit in a chair with your legs uncrossed and your feet flat on the floor.
 Sit upright with your back straight.
 Sit with your back and arm being supported.
 The arm cuff should be placed on your arm at the same level as your heart.

3.3 Taking a Measurement

Notes:
 • To stop the measurement, press the [START/STOP] button once to deflate the arm cuff.
 • Remain still and do not talk while taking a measurement.
 • The reading is stored in the memory and cannot be viewed on the display.

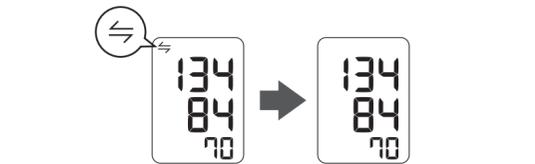
1. Press the [START/STOP] button.
 The arm cuff will automatically start to inflate.



What to do if your systolic pressure is more than 210 mmHg
 After the arm cuff starts to inflate, press and hold the [START/STOP] button until the monitor inflates 30 to 40 mmHg higher than your expected systolic pressure.
Notes:
 • The monitor will not inflate above 299 mmHg.
 • Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied.

2. Transfer your readings.

As soon as the measurement is completed, your readings will be automatically transferred, as shown below.



If the connection symbol "E" does not appear, refer to "Connection failure. / Data is not being transmitted." in section 4.2 for more detail.

3. After data transfer is completed, press the [START/STOP] button to turn the monitor off. It will automatically turn off after 2 minutes.

Note: Wait 2-3 minutes before taking another measurement. Waiting between measurements allows the arteries to return to their prior condition to taking a measurement.

4. Remove the arm cuff.

Do NOT adjust medication based on measurement results from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat high blood pressure.

Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.

Read "What to do if your systolic pressure is more than 210 mmHg" of this instruction manual, if your systolic pressure is known to be more than 210 mmHg. Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied.

4. Error Messages and Troubleshooting

4.1 Error Messages

Error Display	Cause	Solution
	Irregular heartbeat is detected.	Remove the arm cuff. Wait 2 - 3 minutes and then take another measurement. Repeat the steps in section 3.3. If this error continues to appear, contact your physician.
	Movement during measurement.	Carefully read and repeat the steps in section 3.3.
	Connection failure. / Data is not being transmitted.	Refer to "Connection failure. / Data is not being transmitted." in section 4.2.
	The batteries are low.	Recommend to replace 4 batteries with new ones at this time. Refer to chapter 2.
	The batteries are depleted.	Immediately replace the 4 batteries with new ones. Refer to chapter 2.
E1	Air plug is disconnected.	Insert the plug securely. Refer to section 3.1.
	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 5.3.
E2	Movement during measurement and the arm cuff has not been inflated sufficiently.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
		If "E2" appears repeatedly, inflate the arm cuff manually until it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
E3	The arm cuff was inflated exceeding the maximum allowable pressure, and then deflated automatically.	Do not touch the arm cuff and/or bend the air tube while taking a measurement. Do not inflate the arm cuff more than necessary. Refer to section 3.3.
E4	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
E5	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
E7r	Communication failed.	Refer to "Connection failure. / Data is not being transmitted." in section 4.2.
E7r	Device error.	Contact your Telehealth service provider.

4.2 Troubleshooting

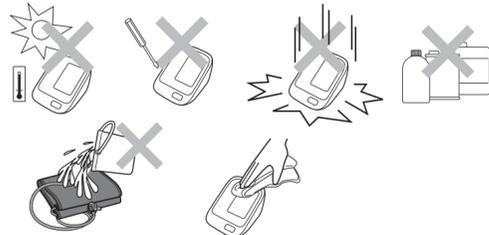
Problem	Cause and Solution
No power. No display appears on the monitor.	Replace all batteries with new ones. Check the battery installation for proper placement of the battery polarities. Refer to chapter 2.
Measurement values appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and how you wrap the cuff, may affect your blood pressure. Review the section 1.3, 3.2 and 3.3.
Connection failure. / Data is not being transmitted.	The blood pressure monitor might not be properly placed within the receiver's transmission range and is too far from the receiver. If there are no causes of data transmission interference found near the blood pressure monitor, move the blood pressure monitor within 5 m (16 ft.) of the receiver and try again. The Bluetooth® feature on the receiver is turned off. Turn on the Bluetooth® feature on the receiver. To retry connecting the Telehealth service receiver, remove batteries and press [START/STOP] button for 2-3 times. The blood pressure monitor did not pair successfully to the receiver. Try to pair the devices again. Refer to chapter 2. The application on the receiver or destination device is not ready. Check the application then try to transmit the readings again. Refer to chapter 2. If the "Er" symbol is on the screen after checking the application, contact your Telehealth service provider.

5. Maintenance and Storage

5.1 Maintenance

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

- Store the device and the components in a clean, safe location.
- Do not use any abrasive or volatile cleaners.
- Do not wash the device and any components or immerse them in water.
- Do not use gasoline, thinners or similar solvents to clean the device.



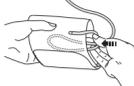
- Use a soft dry cloth, or a soft cloth moistened with neutral soap to clean on the monitor and the arm cuff.
- Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the device or components.

5.2 Storage

1. Unplug the air plug from the air jack.

2. Gently fold the air tube into the arm cuff.

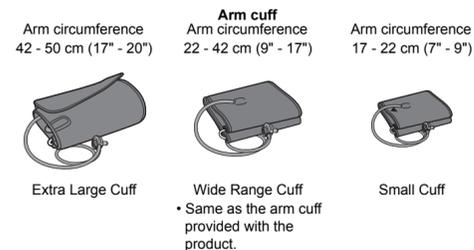
Note: Do not bend or crease the air tube excessively.



Do not store the device in the following situations:

- If the device is wet.
- Locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- Locations exposed to vibrations, shocks or where it will be at an angle.

5.3 Optional Accessories



Note: Please refer to the operating instruction of the HEM-RXL31 for applying the extra large cuff.

AC Adapter



Optional Accessories List

Name	Arm Circumference	Model	Sales area
Extra Large Cuff	42-50 cm / 17"-20"	HEM-RXL31	North America, Asia
Wide Range Cuff	22-42 cm / 9"-17"	CD-WR17	North America
		HEM-RML31	Asia
Small Cuff	17-22 cm / 7"-9"	CD-CS9	North America
		HEM-CS24	Asia
AC Adapter	-	HEM-ADPTW5	North America
		AC ADAPTER-S	Asia

Note: Please check with your Telehealth service provider or local OMRON representatives for the appropriate optional parts models

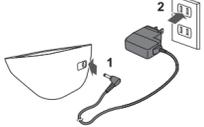
Omron representative in North America
Call: 1-800-634-4350
Visit: OmronHealthcare.com

Omron representative in Asia
Visit: www.omronhealthcare-ap.com

Using the Optional AC Adapter

Note: Make sure to use an easily accessible power socket in which to connect and disconnect the AC adapter.

1. Insert the AC adapter plug into the AC adapter jack on the rear side of the monitor.



2. Plug the AC adapter into an electrical outlet.

To disconnect the AC adapter, unplug the AC adapter from the electrical outlet first, and then remove the AC adapter plug from the monitor.

6. Specifications

Model	HEM-9210T
Display	LCD digital display
Cuff pressure range	Pressure: 0 to 299 mmHg
Measurement range	Pressure: 20 to 280 mmHg Pulse: 40 to 180 beats / min.
Accuracy	Pressure: ±3 mmHg Pulse: ±5% of display reading
Inflation	Fuzzy-logic controlled by electric pump
Deflation	Automatic pressure release valve
Measurement method	Oscillometric method
Transmission method	Bluetooth® Version 4.0 (Low Energy support)
Wireless communication	Frequency range : 2.4 GHz (2400 - 2483.5 MHz) Modulation : GFSK Effective radiated power : <20 dBm
IP classification	IP 20
Rating	DC6 V 4 W
Power source	4 "AA" batteries 1.5V or optional AC adapter (INPUT AC100-240V 50/60Hz 0.12A)
Battery life	Approximately 1000 measurements (using new alkaline batteries)
Durable period (Service life)	Monitor : 30000 times Cuff : 10000 times
Operating conditions	10°C to 40°C (50°F to 104°F) / 15 to 90% RH / 700 to 1060 hPa
Storage / transport conditions	-20°C to 60°C (-4°F to 140°F) / 10 to 95% RH / 700 to 1060 hPa
Weight	Monitor : Approximately 290 g (10 oz.) not including batteries Arm cuff : Approximately 170 g (6 oz.)
Dimensions	Monitor : Approximately 107 (w) mm × 79 (h) mm × 141 (l) mm (4 1/4" × 3 1/8" × 5 1/2") Arm cuff : Approximately 145 mm × 594 mm (air tube: 750 mm) (5 3/4" × 23 1/2" (air tube: 29 1/2"))
Cuff circumference	22 to 42 cm (9" to 17")
Contents	Monitor, arm cuff, battery set, instruction manual, quick start guide
Applied part	Type BF
Protection against electric shock	Internally powered ME equipment (When using only the batteries) Class II ME equipment (Optional AC adapter)

Notes:

- 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 device is clinically investigated according to the requirements of ISO81060-2:2013.
- This device has not been validated for use on pregnant patients.
- IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of 12 mm diameter and greater such as a finger.

CE 0197

- This device fulfills 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	
	Need for the user to consult the instruction manual
	Need for the user to follow the instruction manual thoroughly for your safety
	Applied part - Type BF Degree of protection against electric shock (leakage current)
	Applied part - Type B Degree of protection against electric shock (leakage current) (Optional AC adapter)
	Class II equipment. Protection against electric shock (Optional AC adapter)
	Indication of connector polarity (Optional AC adapter)
	For indoor use only (Optional AC adapter)
	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
	Serial number
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	LOT number
	Identifier of cuffs compatible for the device
	Cuff positioning indicator for the left arm
	Marker on the cuff to be positioned above the artery
	Range pointer and brachial artery alignment position
	Range indicator of arm circumferences to help selection of the correct cuff size.

Product production date is integrated in a Serial or LOT number, which placed on the Rating Label and sales package: the first 4 digits mean year of production, the next 2 digits - month of production.

About a wireless communication interference

This Product operates in the unlicensed ISM band at 2.4GHz. In case this Product is used around the other wireless devices including microwave and wireless LAN, which operate same frequency band of this Product, there is a possibility that interference occurs between this Product and such other devices. If such interference occurs, please stop the operation of other devices or relocate this Product before using this Product or do not use this Product around the other wireless devices.

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.



7. FCC/IC/RE Statement and Trademarks

FCC CAUTION

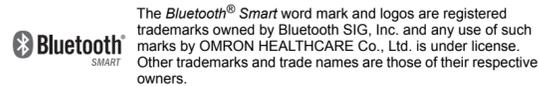
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note:

- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the receiving antenna.
 - Increase the separation between the equipment and receiver.
 - Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
 - Consult the dealer or an experienced radio/TV technician for help.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

This equipment complies with FCC/IC radiation exposure limits set forth for an uncontrolled environment and meets the FCC radio frequency (RF) Exposure Guidelines and RSS-102 of the IC radio frequency (RF) Exposure rules. This equipment has very low levels of RF energy that are deemed to comply without testing of specific absorption ratio (SAR).



Hereby, OMRON HEALTHCARE Co., Ltd., declares that the radio equipment type HEM-9210T is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address: www.omron-healthcare.com

8. Limited Warranty

Your HEM-9210T Automatic Upper Arm Blood Pressure Monitor, excluding batteries, is warranted to be free from defects in materials and workmanship appearing within 2 years from the date of purchase, when used in accordance with the instructions provided with the monitor. The above warranty extends only to the original retail purchaser.

We will, at our option, replace without charge any monitor or arm cuff covered by the above warranty. Replacement is our only responsibility and your only remedy under the above warranty.

THE FOREGOING IS THE SOLE WARRANTY PROVIDED BY OMRON IN CONNECTION WITH THIS PRODUCT, AND OMRON HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IMPLIED WARRANTIES AND OTHER TERMS THAT MAY BE IMPOSED BY LAW, IF ANY, ARE LIMITED IN DURATION TO THE PERIOD OF THE ABOVE EXPRESS WARRANTY.

OMRON SHALL NOT BE LIABLE FOR LOSS OF USE OR ANY OTHER SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT COSTS, EXPENSES OR DAMAGES.

This warranty provides you with specific legal rights, and you may have other rights which vary from state to state. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Should guarantee service be required, please contact your Telehealth service provider.

9. Guidance and Manufacturer's Declaration

OMRON Blood Pressure Monitor (BPM) including AC-adapter
Information for accompanying documents in the scope of IEC60601-1-2:2007

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Medical devices manufactured by OMRON Healthcare conform to this IEC60601-1-2:2007 standard for both immunity and emissions.

Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified by OMRON, with the exception of cables sold by OMRON as replacement parts for internal components, may result in increased emission or decreased immunity of the device.
- The medical devices should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the medical device should be observed to verify normal operation in the configuration in which it will be used.
- Refer to further guidance below regarding the EMC environment in which the device should be used.
- The MEDICAL ELECTRICAL EQUIPMENT BPM including AC-adapter needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this documentations.
- The Essential Performance of the BPM including AC-adapter is to measure a blood pressure and a pulse rate and using the memory function.

The BPM including AC-adapter may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

Guidance and manufacturer's declaration - electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The OMRON BPM including AC-adapter uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The OMRON BPM including AC-adapter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
OMRON BPM including AC-adapter is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON BPM including AC-adapter should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply inputlines IEC 61000-4-11	<5 % U _r (>95 % dip in U _r) for 0.5 cycle	<5 % U _r (>95 % dip in U _r) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the OMRON BPM including AC-adapter requires continued operation during power mains interruption, it is recommended that the OMRON BPM including AC-adapter be powered from an uninterruptible power supply.
	40 % U _r (60 % dip in U _r) for 5 cycles	40 % U _r (60 % dip in U _r) for 5 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	70 % U _r (30 % dip in U _r) for 25 cycles	70 % U _r (30 % dip in U _r) for 25 cycles	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
	<5 % U _r (>95 % dip in U _r) for 5 sec.	<5 % U _r (>95 % dip in U _r) for 5 sec.	
Note: U _r is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
OMRON BPM including AC-adapter is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON BPM including AC-adapter should assure that it is used in such environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 V rms 150 kHz to 80 MHz	3 V rms	Portable and mobile RF communications equipment should be used no closer to any part of the OMRON BPM including AC-adapter and cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance $d = 1.2 \sqrt{P}$
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:
Note1: At 80 MHz and 800 MHz, the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OMRON BPM including AC-adapter is used exceeds the applicable RF compliance level above, the OMRON BPM including AC-adapter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OMRON BPM including AC-adapter. ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distance between portable and mobile RF communications equipment and the OMRON BPM including AC-adapter				
OMRON BPM including AC-adapter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this OMRON BPM including AC-adapter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OMRON BPM including AC-adapter as recommended below, according to the maximum output power of the communications equipment.				
Output Power of Transmitter in Watt	Separation distance according to frequency of transmitter in meter			
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.				

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