

# OMRON®

## INSTRUCTION MANUAL

### Blood Pressure Monitor

Model HEM-9200T



5130713-0C

ENGLISH

# Table of Contents

Introduction .....	3
Intended Use.....	4
Important Safety Information.....	5
1. Know Your Device .....	8
2. Preparation .....	12
3. Using the Device.....	15
4. Error Messages and Troubleshooting.....	22
5. Maintenance and Storage.....	27
6. Specifications.....	30
7. FCC/IC Statement and Trademarks .....	32
8. Limited Warranty.....	34
9. Guidance and Manufacturer's Declaration.....	35

# Introduction



Please read this instruction manual thoroughly before using the device.

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

## **Symbols Glossary**

For symbol information, visit:

[OmronHealthcare.com/symbols-glossary](http://OmronHealthcare.com/symbols-glossary)

## **Intended Use**

The 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.

## 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.
- This device is not intended to be a diagnostic device.
- 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 the injured arm or the arm under medical treatment.
- 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 the HF surgical equipment, MRI, or 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.
- Keep the battery out of reach of children.

## **Data Transmission**

- Do not use this product on aircraft or in hospitals. Please remove the battery from the unit. 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.

**⚠ 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 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. This may result in incorrect operation of the device.
- Do not disassemble the monitor or arm cuff. 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 (car, 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 where the arm cuff is applied.

### **AC Adapter (optional accessory)**

- Fully insert the power plug into the outlet.
- When disconnecting the power plug from the outlet, do not pull the power cord. Be sure to pull from the power plug safely.
- 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 the dust off from the power plug.
- Unplug monitor when not in use.
- Disconnect the power plug before cleaning.
- Use only an OMRON AC adapter designed for this device. Use of unsupported adapters may damage and/or may be hazardous to the device.

### **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.

### **General Precautions**

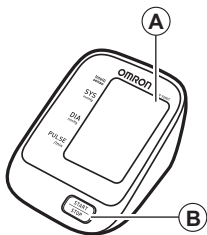
- Do not forcibly crease the arm cuff or the air tube excessively.
- Do not press the air tube while taking a measurement.
- To unplug the air plug, pull on the air plug at the connection with the monitor, not the tube itself.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- 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.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

# 1. Know Your Device

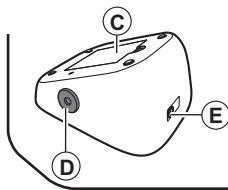
## Contents:

Monitor, arm cuff, 4 “AA” batteries, instruction manual, quick start guide

## Monitor:

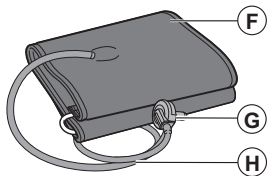


- A. Display
- B. START/STOP button



- C. Battery compartment
- D. Air jack
- E. AC adapter jack  
(for optional AC adapter)

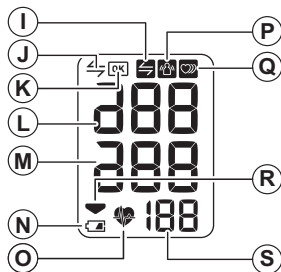
**Arm cuff:** Arm circumference 9" - 17" (22 - 42 cm)



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



## Display:



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

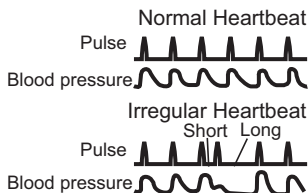
# 1.1 Display symbols

## Irregular Heartbeat Symbol (🫀)

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 (🚶)

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 (🔄)

The SYNC symbol (🔄) is displayed if device is not connected to Telehealth service receiver or when data is not transmitted successfully. Please see "Connecting 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 maybe your smart phone) 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 receiver. **“Omron Healthcare, Inc. shall not be liable for loss of use or any other special, incidental, consequential or indirect costs, expenses or damages due to improper usage of this monitor.”**

## 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. Rest for at least 5 minutes before taking the measurement.
2. Stress raises blood pressure. Avoid taking measurements during stressful times.
3. Measurements should be taken in a quiet place.
4. Remove tight-fitting clothing from your arm.

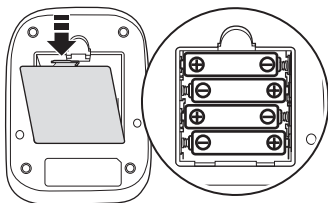
## 2. Preparation

### Battery Installation

Below procedures are ONLY done at inserting batteries.

- 
1. Remove the battery cover.

- 
2. Insert 4 “AA” batteries as indicated in the battery compartment.



- 
3. Put back the battery cover.

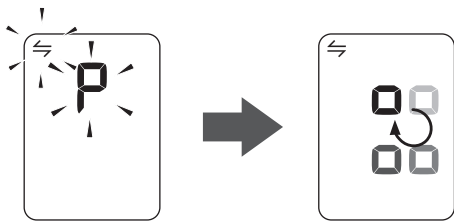
Notes:

- When the depleted battery symbol (⎓) appears on the display, turn the monitor off, then replace all batteries at the same time. Long life alkaline batteries are recommended.
- The measurement values continue to be stored in memory even after the batteries are replaced.
- The supplied batteries may have a shorter life.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

---

**4. Connect the device to the Telehealth service receiver.**

As soon as insert batteries, it will automatically start the connection process, as below.



**When the display shown above is not appeared, see “Connecting failure.” in section 4.2 first.**

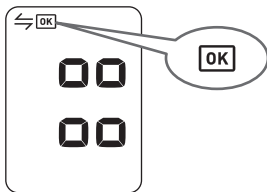
**To retry connecting the Telehealth service receiver, remove batteries and press START/STOP button for 2-3 times. Then start with step 2 again.**

**Note:** If your Telehealth service receiver asks for PIN code, enter 6 digits of PIN code on the rating label at the bottom of the device to complete.

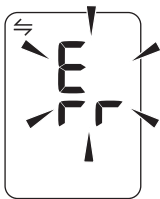
---

**5. Confirm if the device is successfully connected.**

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



**When “Err” appears, see “Connecting failure.” in section 4.2 for more detail.**



**Notes:**

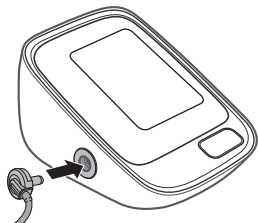
- We recommend to keep batteries all the time, even if you chose to use AC adapter.
- If only AC adapter is used without keeping batteries, above device connection process (step 4 and 5) is necessary each time you unplug and plug back the AC adapter.

## 3. Using the Device

### 3.1 Applying the Arm Cuff

Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Don't place the arm cuff over thick clothes.

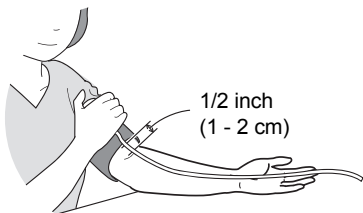
- 
1. Connect cuff plug to the unit.



- 
2. Wrap the arm cuff firmly in place around your left upper arm.

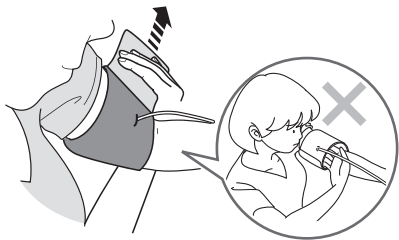


The bottom edge of the arm cuff should be 1/2 inch (1 to 2 cm) above the elbow. Air tube is on the inside of your arm and aligned with your middle finger.





3. Secure closed with the fabric fastener.



Notes:

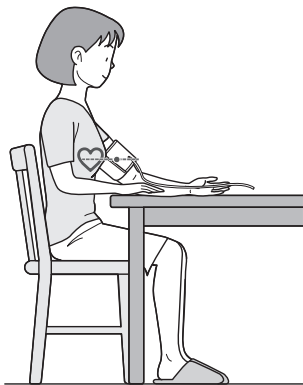
- When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube.
- The blood pressure can differ between the right arm and the left arm, and the measured blood pressure values can be different. OMRON recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician 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, under comfortable room temperature.

- Sit on 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.



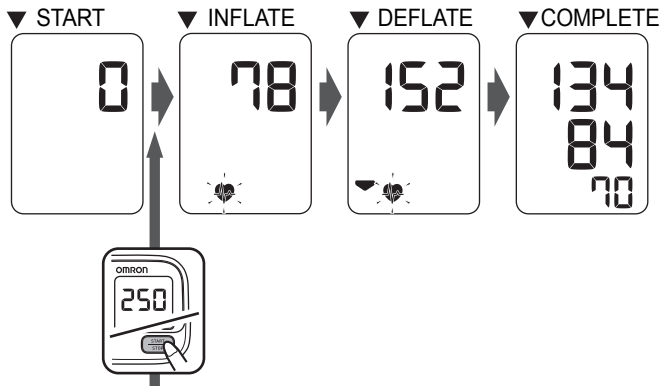
## 3.3 Taking a Measurement

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 memory cannot view on the display.

1. Press the START/STOP button.

The arm cuff will start to inflate automatically.



***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:**

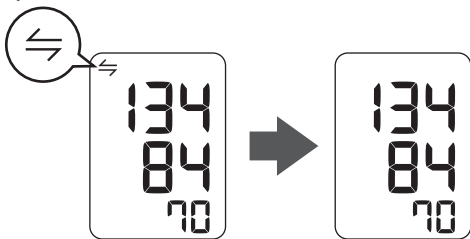
- The monitor will not inflate above 299 mmHg.

⚠ Inflating to a higher pressure than necessary may result in bruising where the arm cuff is applied.

---

## 2. Transferring measured data.

As soon as the measurement is completed, the data transfer will start automatically, as below.



**When the connection symbol (⇔) is not appeared, see “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 the condition prior 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.
- ⚠ This device is not intended to be a diagnostic device.
- ⚠ Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.
- ⚠ Inflating to a higher pressure than necessary may result in bruising where the arm cuff is applied.

## 4. Error Messages and Troubleshooting

### 4.1 Error Messages

Error Display	Cause	Solution
	Irregular heartbeats are 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.
	Connecting failure. Data is not being transmitted.	Refer "Connecting failure. Data is not being transmitted." in section 4.2.
	The batteries are low.	Recommend to replace the batteries with new ones ahead of time. Refer to section 2.
	The batteries are depleted.	Replace 4 batteries with new ones at once. Refer to section 2.

<b>Error Display</b>	<b>Cause</b>	<b>Solution</b>
<b>E1</b>	Air plug 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.
<b>E2</b>	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.
<b>E3</b>	The arm cuff was inflated exceeding the maximum allowable pressure, and then deflated automatically when inflating the arm cuff manually.	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.

Error Display	Cause	Solution
<b>E4</b>	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
<b>E5</b>	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
<b>Er</b>	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 section 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 and section 3.3.

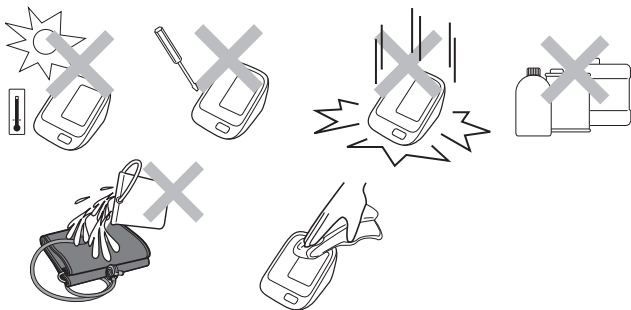
Problem	Cause and Solution
<p>Connecting failure. Data is not being transmitted.</p>	<p>The blood pressure monitor might not be properly placed within the receiver's transmission range and is too far from the receiver. If there are no causes of data transmission interference found near the blood pressure monitor, move the blood pressure monitor within 16 ft. (5 m) of the receiver and try again.</p>
	<p>The <i>Bluetooth</i>® feature on the receiver is turned off. Turn the <i>Bluetooth</i>® feature on the receiver ON, and try to transmit the readings again.</p>
	<p>The blood pressure monitor did not pair successfully to the receiver. Try to pair the devices again. Refer to section 2.</p>
	<p>The application on the receiver or destination device is not ready. Check the application then try to transmit the readings again. Refer to section 2. If the ERR symbol is on the screen after checking the application, contact your Telehealth service provider.</p>

## 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 by immersing them in water.
- Do not use gasoline, thinners or similar solvents to clean the device.



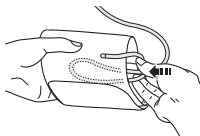
- Use a soft dry cloth, or a soft cloth moistened with neutral soap to clean on the monitor and the arm cuff.
- Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the device or components.

## 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

### Arm cuff

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



CD-WR17

(Model: HEM-RML31)

- Same as the arm cuff provided with the product.

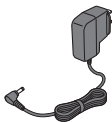
Arm circumference  
7" - 9" (17 - 22 cm)



CD-CS9

(Model: HEM-CS24)

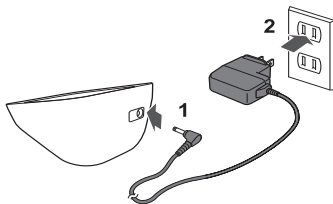
### AC Adapter



HEM-ADPTW5



### *Using the Optional 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

<b>Model</b>	HEM-9200T
<b>Display</b>	LCD digital display
<b>Measurement range</b>	Pressure: 0 to 299 mmHg Pulse: 40 to 180 beats / min.
<b>Accuracy</b>	Pressure: $\pm 3$ mmHg or 2% of reading Pulse: $\pm 5\%$ of display reading
<b>Inflation</b>	Fuzzy-logic controlled by electric pump
<b>Deflation</b>	Automatic pressure release valve
<b>Measurement method</b>	Oscillometric method
<b>IP classification</b>	IP 20
<b>Power source</b>	4 "AA" batteries 1.5V or optional AC adapter (INPUT AC100-240V 50/60Hz 0.12A)
<b>Battery life</b>	Approximately 1000 measurements (using new alkaline batteries)
<b>Operating temperature / humidity</b>	50°F to 104°F (10°C to 40°C) / 15 to 90% RH
<b>Storage temperature / humidity / air pressure</b>	-4°F to 140°F (-20°C to 60°C) / 10 to 95% RH / 700 to 1060 hPa
<b>Weight</b>	Monitor : Approximately 10 oz. (290 g) not including batteries Arm cuff : Approximately 6 oz. (170 g)
<b>Dimensions</b>	Monitor : Approximately 4 1/4" (w) $\times$ 3 1/8" (h) $\times$ 5 1/2" (l) (107 mm $\times$ 79 mm $\times$ 141 mm) Arm cuff : Approximately 5 3/4" $\times$ 23 1/2" (air tube: 29 1/2") (145 mm $\times$ 594 mm (air tube: 750 mm))
<b>Cuff circumference</b>	9" to 17" (220 to 420 mm)
<b>Contents</b>	Monitor, arm cuff, 4 "AA" batteries, instruction manual, quick start guide
<b>Applied part</b>	 = Type BF
<b>Protection against electric shock</b>	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, the 5th phase was used on 85 subjects for determination of diastolic blood pressure.
- This device has not been validated for use on pregnant patients.
- IP classification is degrees of protection provided by IEC 60529.

## 7. FCC/IC 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.

This device complies with part 15 of FCC Rules and Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

### 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).





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.



The *Bluetooth*<sup>®</sup> word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by OMRON HEALTHCARE Co., Ltd. is under license. Other trademarks and trade names are those of their respective owners.

## 8. Limited Warranty

Your HEM-9200T Automatic 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, and only to products purchased from an Omron authorized seller who is subject to and follows Omron's quality control standards, unless otherwise prohibited by law.

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. SOME STATES DO NOT ALLOW LIMITATIONS ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

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

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.

## 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**


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.

<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
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.  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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
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.			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
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 % $U_T$ (>95 % dip in $U_T$ ) for 0.5 cycle	<5 % $U_T$ (>95 % dip in $U_T$ ) 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 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles	40 % $U_T$ (60 % dip in $U_T$ ) for 5 cycles	
	70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles	70 % $U_T$ (30 % dip in $U_T$ ) for 25 cycles	
	<5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec.	<5 % $U_T$ (>95 % dip in $U_T$ ) for 5 sec.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: $U_T$ is the A.C. mains voltage prior to application of the test level.			

### Guidance and manufacturer's declaration - electromagnetic immunity

OMRON BPM including AC-adaptor is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON BPM including AC-adaptor 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the OMRON BPM including AC-adaptor and cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.</p> <p><b>Recommend separation distance</b></p> $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	<p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

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.

<sup>a</sup> 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-adaptor is used exceeds the applicable RF compliance level above, the OMRON BPM including AC-adaptor 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-adaptor.

<sup>b</sup> 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.



**OMRON HEALTHCARE Co., Ltd.**

53, Kunotsubo, Terado-cho,  
Muko, Kyoto, 617-0002 JAPAN

Distributed by:

**OMRON HEALTHCARE, INC.**

2895 Greenspoint Pkwy.

Hoffman Estates, IL 60169 USA

1-800-634-4350

[OmronHealthcare.com](http://OmronHealthcare.com)

© 2021 OMRON HEALTHCARE, INC.

Made in Japan