

# **INSTRUCTION MANUAL**

# Automatic Upper Arm Blood Pressure Monitor

### **Model HEM-9210T**



2800028-0I Issue Date: 2021-06-21

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# Introduction

Please follow this instruction manual thoroughly for your safety.

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

#### 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.

# **Environment of Use**

Home

### **Patient Population**

Adult

# **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, preeclampsia, 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. This may result in incorrect operation of the device and/or cause an inaccurate reading.
- 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. This may result in incorrect operation of the device and/or cause an inaccurate reading.
- The air tube or the AC adapter cable may cause accidental strangulation in children, toddlers or infants.
- Contains small parts that may cause a choking hazard if swallowed by children, toddlers or 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 multioutlet 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, toddlers or infants.

⚠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 selftreatment are dangerous.
- Consult your physician before using the device if you have had a mastectomy.
- Consult your physician before using the device if you have 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.

- During measurement, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields are within 12 inches (30 cm) of this device. This may result in incorrect operation of the device and/or cause an inaccurate reading.
- 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 twist.

Do not forcibly bend or pull.
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.
- 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 of operating and storage/transport temperature, refer to
  section 6.

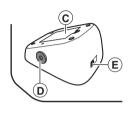
# 1. Know Your Device

#### **Contents:**

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

#### **Monitor:**

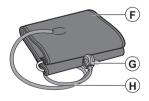




- A. Display
- B. START/STOP button

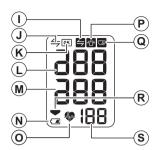
- C. Battery compartment
- D. Air jack
- E. AC adapter jack (for optional AC adapter)

# 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.)

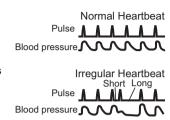
- P. Movement error symbol
- Q. Irregular heartbeat symbol
- R. Deflation symbol
- S. Pulse display

### 1.1 Display symbols

#### Irregular Heartbeat Symbol ()

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 (1871)

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 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

This device uses wireless technology (*Bluetooth*®) to communicate to applications that keep track of your blood pressure data. It will connect to the database via a Telehealth service receiver (in some cases, receiver may be your smartphone or other device provided by Telehealth service provider). Before use, thoroughly read the instruction manual included with the Telehealth service receiver 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*® receivers, and is not guaranteed to connect to all *Bluetooth*® 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:

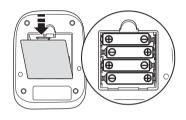
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for 30 minutes before taking a measurement.
- 2. Rest for at least 5 minutes before taking the measurement.
- Stress raises blood pressure. Avoid taking measurements during stressful times.
- 4. Measurements should be taken 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.



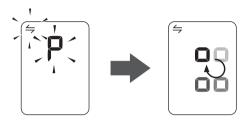
3. Replace the battery cover.

#### Notes:

- When the depleted battery symbol " " appears on the display, turn the monitor off and remove all the batteries. Replace with 4 new 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 than new batteries.
- Disposal of used batteries should be carried out in accordance with the national/local regulations for the disposal of batteries.

#### **4.** The device will start the connection process.

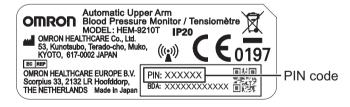
As soon as inserting the batteries, it will automatically start to connect to the Telehealth service receiver, as below.



If the display shown above does not appear, refer to "Connection failure. / Data is not being transmitted." in section 4.2.

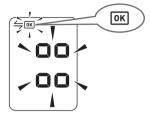
To retry connecting the Telehealth service receiver, remove batteries and press [START/STOP] button for 2-3 times. Then start with step 2 again.

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.

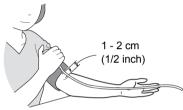
1. Connect the air plug to the unit.



#### 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. 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.

# **3.** Securely close 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 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 with your back and arm being supported.
- The arm cuff should be placed on your arm at the same level as your heart.



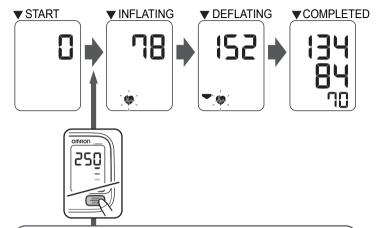
Notes:

- 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

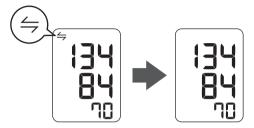
After the arm cuff starts to inflate, press and hold the [START/STOP] button until the monitor inflates 30 to 40 mmHg higher than your expected systolic pressure.

#### 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 " $\Leftarrow$ " 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.
- ARead "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.
<u>~</u> CN	Movement during measurement.	Carefully read and repeat the steps in section 3.3.
<b>4</b>	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.

Error Display	Cause	Solution
	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.
E 1	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 5.3.
	The cuff may not be the correct size for your arm.	Measure your arm circumference to make sure that you are using the correct size cuff. Refer to section 5.3.
	Movement during	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
בכ	measurement and the arm cuff has not been inflated sufficiently.	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.
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.

Error Display Cause		Solution	
		Repeat measurement. Remain still and do not talk during	
	Movement during measurement.	measurement. Refer to section 3.3.	
<b>E</b> 5	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.	
	The cuff may not be the correct size for your arm.	Measure your arm circumference to make sure that you are using the correct size cuff. Refer to section 5.3.	
Communication failed.		Refer to "Connection failure. / Data is not being transmitted." in section 4.2.	
Er	Device error.	Contact your Telehealth service provider.	

# 4.2 Troubleshooting

If any of the below problems occur during measurement, check to make sure that no other electrical device is within 12 inches (30cm). If the problem persists, please refer to the table below.

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.

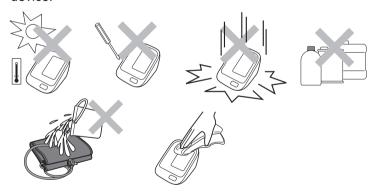
Problem	Cause and Solution
	The blood pressure monitor might not be properly placed within the receiver's transmission range and is too far from the receiver. If there are no causes of data transmission interference found near the blood pressure monitor, move the blood pressure monitor within 5 m (16 ft.) of the receiver and try again.
Connection failure. / Data is not being transmitted.	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. Then reinstall batteries.
	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 "Err" 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.

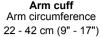
Note: Do not bend or crease the air tube excessively.

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

Arm circumference 42 - 50 cm (17" - 20")



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



Extra Large Cuff



Wide Range Cuff
• Same as the arm cuff



Small Cuff

provided with the product.

Note: Please refer to the operating instruction of the HEM-RXL31 for applying

AC Adapter

the extra large cuff.



#### **Optional Accessories List**

Name	Arm Circumference	Model	Sales area
Extra Large Cuff	42-50 cm / 17"-20"	HEM-RXL31	North America, Asia
Wide Range	22-42 cm / 9"-17"	CD-WR17	North America
Cuff	22-42 CIII / 9 - 17	HEM-RML31	Asia
Small Cuff	17-22 cm / 7"-9"	CD-CS9	North America
Siliali Culi		HEM-CS24	Asia
		HEM-ADPTW5	North America
		HHP-CM01	Asia
AC Adapter	-	HHP-OH01	Australia and New Zealand
		HHP-BH01	India

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

# Omron representative in North America

Omron representative in Asia

Call: 1-800-634-4350

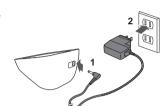
Visit: www.omronhealthcare-ap.com

Visit: OmronHealthcare.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.

 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

HFM-9210T Model

Display LCD digital display

Cuff pressure range Pressure: 0 to 299 mmHa Measurement range Pressure: 20 to 280 mmHa

Pulse: 40 to 180 beats / min

Accuracy Pressure: ±3 mmHa

Pulse: ±5% of display reading

Inflation Fuzzy-logic controlled by electric pump Deflation Automatic pressure release valve

Measurement method Oscillometric method Transmission method Bluetooth® Low Energy

Wireless Frequency range: 2.4 GHz (2400 - 2483.5 MHz)

communication Modulation: GFSK

Effective radiated power: <20 dBm

Operation mode Continuous operation

IP classification Monitor : IP20 (Optional) AC adapter (HEM-ADPTW5/HHP-CM01): IP21

> (HHP-OH01/HHP-BH01) · IP22

Rating DC6 V 4 W

4 "AA" batteries 1.5V or optional AC adapter (INPUT AC100-240V ~ Power source

50-60Hz 0.12-0.065A)

**Battery life** Approximately 1000 measurements (using new alkaline batteries)

Durable period Monitor: 5 years (Service life) Cuff: 1 year

(Optional) AC adapter: 5 years

10°C to 40°C (50°F to 104°F) / 15 to 90% RH (non-condensing) / Operating conditions 700 to 1060 hPa

Storage / transport -20°C to 60°C (-4°F to 140°F) / 10 to 95% RH (non-condensing) / conditions

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 (cuff)

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 monitor is clinically investigated according to the requirements of ISO 81060-2:2013 and complies with ISO 81060-2:2013 and ISO 81060-2:2018+A1:2020
- 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. The device and AC adapter are protected against solid foreign objects of 12 mm diameter and greater such as a finger. The AC adapters (HEM-ADPTW5/HHP-CM01) are protected against vertically falling water drops which may cause issues during a normal operation. Other AC adapters (HHP-OH01 and HHP-BH01) are protected against oblique falling water drops which may cause issues during a normal operation.

# **C** € 0197

- 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

Symbols description		
Ţi	Consult instructions for use	
<b>③</b>	Refer to instruction manual	
☀	Applied part - Type BF Degree of protection against electric shock (leakage current)	
	Class II equipment. Protection against electric shock (Optional AC adapter)	
Polarity of d. c. power connector (Optional AC adapter)		
	For indoor use only (Optional AC adapter)	
$((\bullet))$	Non-ionizing electromagnetic radiation	

Symbols description		
SN	Serial number	
1	Temperature limit	
<u></u>	Humidity limitation	
<b>∳•∮</b>	Atmospheric pressure limitation	
LOT	Batch code	
<b>□</b> or <b>□</b>	Identifier of cuffs compatible for the device	
<b>A</b>	Cuff positioning indicator for the left arm	
ART. or O	Artery mark	
INDEX	Range pointer and brachial artery alignment position	
MIN RANGE MAX	Range indicator of arm circumferences to help selection of the correct cuff size.	
	Manufacturer	
EC REP	Authorized representative in the European Community	

Symbols description		
	Crossed out wheelie bin	
$\bigcirc$ or $\bigcirc$	Efficiency Level of power supply	
<b>&amp;</b>	RCM compliance mark, which indicates compliance with electrical safety, EMC, EME & telecommunications requirements in Australia, as applicable to the product.	
0	SMPS incorporating a short-circuit-proof safety isolating transformer (inherently or non-inherently)	
-(Is)-	SMPS (Switch mode power supply unit)	
MD	Medical device	
	Date of manufacture	

#### About a wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur.

If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

# 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).



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.

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, 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.

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 IEC60601-1-2:2014

#### Important information regarding Electro Magnetic Compatibility (EMC)

This device manufactured by OMRON HEALTHCARE Co., Ltd. conforms to IEC60601-1-2:2014 Electro Magnetic Compatibility (EMC) standard.Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified or provided by OMRON could result in increased electromagnetic emission or decreased electromagnetic immunity of the device and result in improper operation.
- During measurement, the use of the device adjacent to or stacked with other device should be avoided because it could result in improper operation. In case such use is necessary, the device and other device should be observed to verify that they are operating normally.
- During measurement, Portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the device, including cables specified by OMRON. Otherwise, degradation of the performance of the device could result.
- Refer to further guidance below regarding the EMC environment in which the device should be used.

#### Table 1 - EMISSION Limits and Compliance

Phenomenon	EMISSION Limits	Compliance
Conducted and radiated RFEMISSIONS	CISPR 11	Group1, Class B
Voltage fluctuations and flicker	See IEC 61000-3-3	Complies

Table 2 - IMMUNITY TEST LEVELS

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air for enclosure port
Radiated RF electromagnetic fields	IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz for enclosure port
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 3
Electrical fast transients / bursts	IEC 61000-4-4	±2 kV for Input a.c. power port 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±0.5kV, ±1 kV for Input a.c. power port
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz 80 % AM at 1 kHz for Input a.c. power port
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz and 60Hz for enclosure port
Voltage dips	IEC 61000-4-11	0 % $U_T$ ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for Input a.c. power port
		$0~\%~U_T$ ; 1 cycle and $70~\%~U_T$ ; 25/30 cycles single phase: at $0^\circ$ for Input a.c. power port
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycle for Input a.c. power port
Note: U⊤ is the A.C. mains voltage prior to application of the test level.		

Table 3 - Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	. 1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

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