

EVOLV™ Upper Arm Blood Pressure Monitor

Model BP7000
Instruction Manual

9545343-5C

INTRODUCTION

Thank you for purchasing the OMRON BP7000 Blood Pressure Monitor. Your new blood pressure monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood movement through your brachial artery and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope so the monitor is simple to use.

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INTENDED USE

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 inches to 17 inches (22 cm to 42 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

IMPORTANT SAFETY INFORMATION

Please read the Important Safety Information in this instruction manual before using the unit.

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.

Contraindications

- The device is contraindicated for use in ambulatory environments.
- The device is contraindicated for use on aircraft.

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

- 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.
- DO NOT use this monitor on an injured arm or an arm under medical treatment.
- DO NOT wear the arm cuff on your arm while on an intravenous drip or blood transfusion.
- DO NOT apply or inflate the arm cuff around any body parts other than your upper arm.
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners or in oxygen rich environments.
- DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves.
- Consult your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia; or renal disease. Note that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.
- Contains small parts that may cause a choking hazard if swallowed by children, toddlers or infants.
- Keep the BATTERY out of the reach of children, toddlers and infants.
- This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. For further information on any potential restrictions refer to documentation on Bluetooth® usage by the FCC.

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.

- Stop using this monitor and consult your physician if you experience skin irritation or discomfort.
- Consult your physician before using this monitor on an arm with an arterio-venous (A-V) shunt.
- Consult your physician before using this monitor if you have had a mastectomy.
- Consult your physician before using the monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- Do not take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- Remove the arm cuff if it does not start deflating during the measurement.
- Do not use this monitor for any purpose other than measuring blood pressure.
- Do not use a mobile phone or other electrical devices that emit electromagnetic fields near this monitor except when transferring your readings to your smart device. This may result in incorrect operation of this monitor.
- Do not disassemble or attempt to repair the monitor or components. This may cause an inaccurate reading.
- Please check, by observation of the arm being used, that the monitor is not causing any impairment of patient blood circulation.
- Do not use this monitor in high-use environments such as medical clinics or physician offices.
- 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.
- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and do not talk while taking a measurement.

Data Transmission

- Do not replace the battery while your reading is being transferred to your smart device. This may result in the incorrect operation of your monitor and failure to transfer your blood pressure data.
- Do not place integrated circuit cards, magnets, metal objects, or other devices that emit electromagnetic fields near this monitor while your reading is being transferred to your smart device. This may result in the incorrect operation of your monitor and failure to transfer your blood pressure data.

Battery Handling and Usage

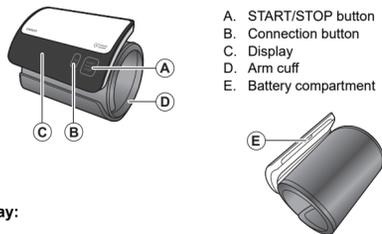
- Do not insert the batteries with their polarities incorrectly aligned.
- Use only 4 "AAA" alkaline batteries with this monitor. Do not use other types of batteries. Do not use new and used batteries together.
- Remove the batteries if the monitor will not be used for a long period of time.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult a physician immediately.
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult a physician.
- Do not use batteries after their expiration date.
- Periodically check your batteries to ensure they are in good working condition.
- Only use batteries specified for this monitor. Use of unsupported batteries may damage and/or may be hazardous to the monitor.

1. KNOW YOUR MONITOR

Contents:

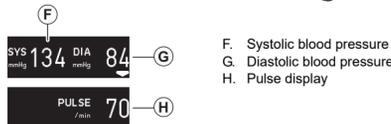
Monitor, 4 "AAA" batteries, instruction manual, quick start guide

Monitor:



- A. START/STOP button
B. Connection button
C. Display
D. Arm cuff
E. Battery compartment

Display:



- F. Systolic blood pressure
G. Diastolic blood pressure
H. Pulse display

	Connection symbol		Irregular heartbeat symbol
	Connection OFF symbol		Battery symbol (low)
	Connection ON symbol		Battery symbol (depleted)
	Movement error symbol		Deflation symbol
	SYNC symbol		Heartbeat symbol (Flashes during measurement.)

1.1 Display symbols

Connection symbol ()

Appears when transferring the data or pairing with your smart device.

Connection OFF symbol ()

Appears when Bluetooth is off.

Connection ON symbol ()

Appears when Bluetooth is on.

Movement error symbol ()

The movement error symbol will display when your body is moving during measurement. If the movement symbol displays, remove the monitor and wait for 2 to 3 minutes. After 2 to 3 minutes, remain still and take another measurement.

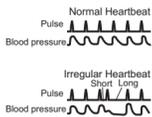
SYNC symbol ()

- When the SYNC symbol appears on the display, make sure that your monitor has been pairing with the smart device or transfer the data.
- When the SYNC symbol appears on the display, transfer the data before the measurements are deleted. Maximum internal memory is for 100 measurements. The oldest value will be deleted when this is reached before transferring.

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 along 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.



Battery symbol (low) ()

Appears when the batteries are low.

Battery symbol (depleted) ()

Appears when the batteries are depleted.

Deflation symbol ()

Flashes while arm cuff is deflating.

Heartbeat symbol ()

Flashes while taking a measurement.

2013 ESH/ESC Guidelines for the management of arterial hypertension

Definitions of hypertension by office and home blood pressure levels

	Office	Home
Systolic Blood Pressure	≥140 mmHg	≥135 mmHg
Diastolic Blood Pressure	≥90 mmHg	≥85 mmHg

These are from statistical values for blood pressure.

1.2 Before Taking a Measurement

To help ensure an accurate reading, follow these directions:

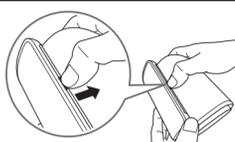
- ▲ Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for 30 minutes before taking a measurement.
- ▲ Rest for at least 5 minutes before taking the measurement.

- Stress raises blood pressure. Avoid taking measurements during stressful times.
- Measurements should be taken in a quiet place.
- Keep a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time. Try to measure your blood pressure at the same time each day for consistency.

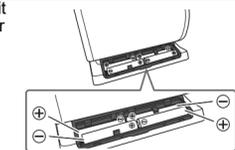
2. PREPARATION

2.1 Battery Installation

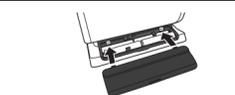
1. Remove the battery cover. Insert your fingernail into the slot of the battery cover, and push downwards to remove the cover.



2. Insert battery, slide over so it is secured inside the circular battery positioner. Then insert the second battery.



3. Replace the battery cover.



When the batteries have been securely placed in this monitor, the message below will appear on the screen:



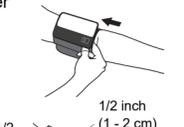
Notes:

- 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 the 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.
- When the batteries are replaced, the words "Please pair this device," or "Pairing not completed. No data transfer." will appear on the display. Press the [] button to pair with the smart device or transfer the data before taking a measurement.

2.2 Applying the Arm Cuff

▲ Remove tight-fitting or thick clothing from your arm while taking a measurement.

1. Apply the arm cuff to your left upper arm.



The bottom edge of the arm cuff should be 1/2 inch (1 to 2 cm) above the elbow. The display should be in clear view and easy to read, positioned slightly on the inside of your arm.

2. Securely close with the fabric fastener.



Notes:

- 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.
- Positioning the monitor with the [START/STOP] button toward the body makes it easier to use the monitor.

2.3 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. USING THE MONITOR WITHOUT A SMART DEVICE

You can use this blood pressure monitor without pairing to a smart device.

3.1 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.
- When using this blood pressure monitor without a smart device, you will not be able to view your prior readings stored in the memory.
- Do not use the monitor with any other electrical device simultaneously. This may result in incorrect operation of the monitor.

1. Press the [START/STOP] button.

The arm cuff will start to inflate.



The following symbols indicate incorrect measurement

- If "Please rereasure" and any of these symbols below are displayed, please take another measurement and try again.



2. Remove the arm cuff.

3. Write down your SYS/DIA and Pulse readings, along with the date and time of your measurement on a piece of paper to keep a record of your history.

▲ 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.

4. USING THE MONITOR WITH A SMART DEVICE

4.1 Pairing Your Monitor with a Smart Device

The date and time on your monitor will automatically be set when you pair it with your smart device.

Review the list of compatible smart devices at: OmronHealthcare.com

1. Make sure the Bluetooth® in your smart device is turned on.

2. Download and install the free "OMRON connect" app on your smart device.



* If you already have the "OMRON connect" app, and have created your account, visit the "Manage Devices" in the "Profile" section of the "OMRON connect" app to add this new device.

3. Open the app on your smart device and follow the set-up and pairing instructions.

4. Confirm the monitor is connected successfully. If the monitor is connected successfully to the smart device, "OK" will appear on the display.



If "Error" appears, refer to section 5.1 for more detail.



For more information, visit OmronHealthcare.com

Notes:

- If you use any other app instead of "OMRON connect", the date and time may not be automatically set. If you need to set the date and time, pair your monitor or transfer the data by using "OMRON connect" app.
- The date/time will only be set for future measurements taken after the measurement that was transferred. It will not be saved to the measurement that was just transferred.
- Please be aware that OMRON will not be responsible for the loss of data and/or information.

4.2 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.
- This monitor will store 100 measurements. Stored measurements cannot be viewed on the monitor's display. You will need to use the "OMRON connect" app to view all measurements prior to the most recent reading taken.
- Do not use a mobile phone or other electrical devices that emit electromagnetic fields near this monitor except when transferring your readings to your smart device. This may result in incorrect operation of this monitor.

1. Press the [START/STOP] button.

The arm cuff will start to inflate.



The following symbols indicate incorrect measurement

- If "Please rereasure" and any of these symbols below are displayed, please take another measurement and try again.



2. Remove the arm cuff.

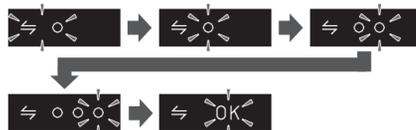
3. Transfer your readings.

Please make sure your monitor is within 16 ft. (5 m) of your smart device and your "OMRON connect" app is active.

As soon as your measurement is complete, tap the "sync" icon in the Omron connect app on your smart device to transfer your readings.

Transferring your readings later

1. Open the app on your smart device and then follow the instructions.
2. Press [] button to transfer your readings.



- If your readings are successfully transferred to your smart device, "OK" will flash on the display.

If "Error" appears, refer to section 5.1 for more detail.



Notes:

- When the SYNC symbol " " appears on the display, transfer the data immediately before the readings are deleted.
- When the Connection OFF symbol " " appears on the display, turn on the Bluetooth® feature of your monitor. (Refer to section 4.3)
- Once you send your readings to the app, the data cannot be sent again to the app or smart device.

4. After your readings have been transferred to the "OMRON connect" app, press the [START/STOP] button to turn the monitor off.

Notes:

- The monitor will automatically turn off after 2 minutes.
- Wait 2-3 minutes before taking another measurement. Waiting between measurements allows the arteries to return to the condition they were prior to taking the measurement.
- If you use any other app instead of "OMRON connect", the data may not be displayed correctly after sending.

▲ 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.

Data Transfer With Multiple Smart Devices

Once you transfer your data to a smart device, that data can no longer be transferred again to the same smart device, nor to another smart device.

About Multiple Users

To share your blood pressure monitor with other people, please refer to the "Help" section in the "OMRON connect" app.

4.3 Turning "OFF" Bluetooth®

Turn off the Bluetooth® in your monitor in the following areas where use of wireless equipment is prohibited.

- On aircraft • In hospitals • While aboard
- Your monitor comes with the Bluetooth® already turned on.

1. Turn your monitor power off if it is on by pressing the [START/STOP] button on the monitor.

2. Press and hold the [] button for more than 10 seconds. Release the [] button when " " appears on the display. When the " " is blinking, you have now turned the Bluetooth® off in your monitor.



3. Press the [START/STOP] button to turn the monitor off. Note: The monitor will automatically turn off after 2 minutes.

How to turn "ON" Bluetooth®

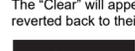
Perform the following step when the power has been off. Press and hold the [] button for more than 2 seconds and then release the [] button when " " appears on the display. The " " will blink to show that the Bluetooth® in your monitor has been turned on.

- 4.4 Restoring Your Monitor to the Default Settings
To delete all the information stored in your monitor, follow the instructions below. Make sure that your monitor is turned off. It will be off when the screen is not showing numbers or symbols.

1. While holding the [] button down, the Connection symbol " " and "P" appear on the display, and then press the [START/STOP] button for more than 5 seconds.



2. When the "Clear" symbol appears on the display, release the [] button and [START/STOP] button. The "Clear" will appear on the display when your monitor settings have reverted back to their original.



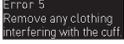
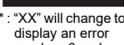
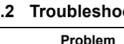
3. Press the [START/STOP] button to turn the monitor off.

Notes:

- The monitor will automatically turn off after 2 minutes.
- Reverting to initial settings of this monitor will not delete the information in the app.
- When using this monitor again, first delete the registration of monitor in the app and then pair your monitor.

5. ERROR MESSAGES AND TROUBLESHOOTING

5.1 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 2.2. If this error continues to appear, contact your physician.
	Movement during measurement.	Carefully read and repeat the steps in section 4.2.
	The batteries are low.	Recommend replacement of all 4 batteries with new ones. Refer to section 2.1.
	The batteries are depleted or battery polarities are not properly aligned.	Immediately replace 4 batteries with new ones. Refer to section 2.1. Confirm the batteries are properly inserted with polarities correctly aligned. Refer to section 2.1.
	Connection failure. Data is not being transmitted.	Refer to "Connection failure. Data is not being transmitted." in section 5.2.
	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 2.2.
	The arm cuff was inflated exceeding the maximum allowable pressure, and then deflated automatically.	Do not touch the arm cuff while taking a measurement. Refer to section 4.2.
	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 4.2.
	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 2.2.
	Device error.	Please contact customer service.

5.2 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 2.1.
Measurement values appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and how you apply the arm cuff, may affect your blood pressure. Review the section 1.2, 2.3 and 4.2.
Connection failure. / Data is not being transmitted.	The blood pressure monitor might not be properly placed within the smart device's transmission range and is too far from the smart device. 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 smart device and try again.
	The Bluetooth ® feature of the smart device is turned off. Turn on the Bluetooth ® feature of the smart device and your monitor, and try sending the data again.
	The Bluetooth ® feature of the blood pressure monitor is turned off. Refer to "To turn "ON" the Bluetooth ®" in "4.3 Turning "OFF" the Bluetooth ®".
	The blood pressure monitor did not pair successfully to the smart device. Try to pair the devices again. Refer to "Pair Your Monitor with a Smart Device" in section 4.1. Confirm your smart device compatibility with this monitor at OmronHealthcare.com
	The application on the smart device is not ready. Check the application then try sending the data again. Refer to "Pair Your Monitor with a Smart Device" in section 4.1. If the "Error" symbol still displays after checking the application, contact customer service.

6. MAINTENANCE, STORAGE AND CLEANING

6.1 Maintenance

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

- Store the monitor and the components in a clean, safe location.
- Do not wash the monitor and any components or immerse them in water.
- Do not use gasoline, thinners or similar solvents to clean the monitor.
- Changes or modification not approved by the manufacturer will void the user warranty.

 Do not disassemble or attempt to repair the monitor or components.

6.2 Storage

Do not store the monitor in the following situations:

- If the monitor 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.

6.3 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth, or a soft cloth moistened with neutral soap to clean on the monitor and the arm cuff, and then wipe it with a dry cloth.

7. DISPOSAL

Dispose of the monitor and components according to applicable local regulations. Unlawful disposal may cause environmental pollution.

8. SPECIFICATIONS

Model	BP7000 (REF) HEM-7600T-Z
Display	OLED display
Cuff pressure range	Pressure: 0 to 299 mmHg
Measurement range	Pressure: 40 to 260 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 rapid deflation
Measurement method	Oscillometric method
Transmission method	Bluetooth ® Smart
Wireless communication	Frequency range : 2.4 GHz (2400 - 2483.5 MHz) Modulation : GFSK Effective radiated power : <20 dBm IP 22
IP classification	4 "AAA" batteries 1.5V
Power source	Approximately 300 measurements (using new alkaline batteries)
Battery life	Monitor : 5 years
Durable period (Service life)	50°F to 104°F (10°C to 40°C) / 15 to 90% RH (non-condensing) / 800 to 1060 hPa
Operating conditions	-4°F to 140°F (-20°C to 60°C) / 10 to 90% RH (non-condensing)
Storage / Transport conditions	Monitor : Approximately 8 1/2 oz. (240 g) not including batteries
Weight	Monitor : Approximately 3 1/2" (w) x 4 5/8" (h) x 1" (l) (85 mm x 120 mm x 20 mm) (not including the arm cuff)
Dimensions	9" to 17" (22 to 42 cm)
Arm circumference	Monitor, 4 "AAA" batteries, instruction manual, quick start guide
Contents	Type BF Internally powered ME equipment
Applied part	Type BF
Protection against electric shock	Internally powered ME equipment

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.
- This monitor 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, and against oblique falling water drops which may cause issues during a normal operation.

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.

9. SYMBOL DESCRIPTIONS / DEFINITIONS

	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
	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.
Note	Provides additional information to clarify a point in the text.
	Please consult this instruction manual
	Applied part - Type BF Degree of protection against electric shock (leakage current)
	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.
	Catalogue number
	Manufacturer
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Artery mark

10. FCC STATEMENT

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

11. LIMITED WARRANTY

Your BP7000 Upper Arm Blood Pressure Monitor, excluding batteries, is warranted to be free from defects in materials and workmanship appearing within 5 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 covered by the above warranty. Replacement is our only responsibility and your only remedy under the above warranty.

To obtain warranty service contact Customer Service by calling **1-800-634-4350** for the address of the inspection center and the return shipping and handling fee.

Enclose the original printed receipt. Include a letter, with your name, address, phone number, and description of the specific problem. Pack the product carefully to prevent damage in transit. Because of possible loss in transit, we recommend insuring the product with return receipt requested.

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12. GUIDANCE AND MANUFACTURER'S DECLARATION

OMRON Blood Pressure Monitor (BPM)

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 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 is to measure a blood pressure and a pulse rate and using the memory function.

The BPM 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 battery-operated BPM is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON battery-operated BPM should assure that it is used in such environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The OMRON battery-operated BPM 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	Not Applicable.	The OMRON battery-operated BPM 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	Not Applicable.	

Guidance and manufacturer's declaration - electromagnetic immunity

OMRON battery-operated BPM is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON battery-operated BPM 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	Contact discharge: ±5 kV Air discharge: ±8 kV	Contact discharge: ±5 kV Air discharge: ±15 kV	The relative humidity should be at least 5 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable.	Not Applicable.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not Applicable.	Not Applicable.
Voltage dips, short interruptions and voltage variations on power supply inlets IEC 61000-4-11	<5 % U _r (>95 % dip in U _r) for 0.5 cycle	Not Applicable.	Not Applicable.
	40 % U _r (60 % dip in U _r) for 5 cycles	Not Applicable.	
	70 % U _r (30 % dip in U _r) for 25 cycles	Not Applicable.	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	<5 % U _r (>95 % dip in U _r) for 5 sec.	Not Applicable.	Magnetic fields from common appliances are not expected to affect the device.
	3 A/m	30 A/m	

Note: U_r is the A.C. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration - electromagnetic immunity

OMRON battery-operated BPM is intended for use in the electromagnetic environment specified below. The customer or the user of this OMRON battery-operated BPM 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	Not Applicable.	Portable and mobile RF communications equipment should be used no closer to any part of the OMRON battery-operated BPM including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.
			Recommend separation distance
Radiated RF IEC 61000-4-3	3 V/m	10 V/m	$d = 0.35 \sqrt{P}$ 80 MHz to 800 MHz $d = 0.70 \sqrt{P}$ 800 MHz to 2.5 GHz 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 battery-operated BPM is used exceeds the applicable RF compliance level above, the OMRON battery-operated BPM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OMRON battery-operated BPM.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the OMRON battery-operated BPM			
OMRON battery-operated BPM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this OMRON battery-operated BPM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OMRON battery-operated BPM 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 Not Applicable.	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.70 \sqrt{P}$
0.01	Not Applicable.	0.035	0.070
0.1	Not Applicable.	0.11	0.22
1	Not Applicable.	0.35	0.70
10	Not Applicable.	1.1	2.2
100	Not Applicable.	3.5	7.0

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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