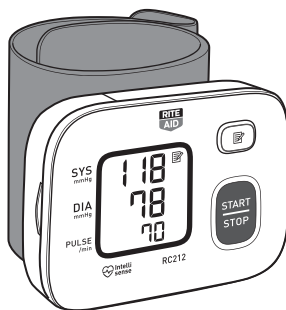


OMRON®

INSTRUCTION MANUAL

Blood Pressure Wrist Monitor - Automatic

Model RC212



ENGLISH

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Introduction

Thank you for purchasing the Rite Aid RC212 Automatic Wrist Blood Pressure Monitor. This blood pressure monitor is to be worn on your wrist. This monitor can be used by multiple users.

This new blood pressure monitor uses the oscillometric method of blood pressure measurement. When the cuff inflates, this monitor senses the pressure pulsations of the artery underneath the cuff. The pulses are called oscillometric pulses. The electronic pressure sensor displays a digital reading of blood pressure.

Safety Instructions

This instruction manual provides you with important information about the Rite Aid RC212 Automatic Wrist Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of the safety and operating instructions. **If you do not understand these instructions or have any questions, contact 1-800-634-4350 before attempting to use this monitor. 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 with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5 cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Environments of Use: Home

Patient Population: Adult

Receiving and Inspection

Remove this monitor from the packaging and inspect for damage. If this monitor is damaged, DO NOT USE and contact 1-800-634-4350.

Symbols Glossary

For symbol information, visit:

OmronHealthcare.com/symbols-glossary

Contraindications

- This monitor is contraindicated for use in ambulatory environments.
- This monitor is contraindicated for use on aircraft.

Important Safety Information

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

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.**


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

- **DO NOT** use this monitor on infants, toddlers, children or persons who cannot express themselves.
- **DO NOT** adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. **ONLY** a physician is qualified to diagnose and treat high blood pressure.
- **DO NOT** use this monitor on an injured wrist or a wrist under medical treatment.
- **DO NOT** apply the wrist cuff on your wrist while on an intravenous drip or blood transfusion.
- **DO NOT** use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized tomography (CT) scanners. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- **DO NOT** use this monitor in oxygen rich environments or near flammable gas.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. **NOTE** that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- **NEVER** diagnose or treat yourself based on your readings. **ALWAYS** consult with your physician.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

Important Safety Information

Battery Handling and Usage

- Keep batteries out of the reach of infants, toddlers or children.

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

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- Consult with your physician before using this monitor on a wrist where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury.
- Consult with your physician before using this monitor if you have had a mastectomy.
- Consult with your physician before using this monitor if you have severe blood flow problems or blood disorders as cuff inflation can cause bruising.
- DO NOT take measurements more often than necessary because bruising, due to blood flow interference, may occur.
- ONLY inflate the wrist cuff when it is applied on your wrist.
- Remove the wrist cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emits electromagnetic fields is within 12 inches (30 cm) of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.
- DO NOT use in a location where there is moisture or a risk of water splashing this monitor. This may damage this monitor.
- DO NOT use this monitor in a moving vehicle such as in a car.
- DO NOT drop or subject this monitor to strong shocks or vibrations.

Important Safety Information

- **DO NOT** use this monitor in places with high or low humidity or high or low temperatures. Refer to section 8.
- **Ensure** this monitor is not impairing blood circulation by observing the wrist while measurement is occurring.
- **DO NOT** use this monitor in high-use environments such as medical clinics or physician offices.
- **DO NOT** use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- **Avoid** bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- **Rest** for at least 5 minutes before taking a measurement.
- **Remove** tight-fitting, thick clothing and any accessories from your wrist while taking a measurement.
- **Remain** still and **DO NOT** talk while taking a measurement.
- **ONLY** use this monitor on persons whose wrist circumference is within the specified range of the cuff.
- **Ensure** that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. OMRON recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information of operating and storage/transport temperature, refer to section 8.
- **DO NOT** crease the wrist cuff excessively.
- **DO NOT** use this monitor after the durable period has ended. Refer to section 8.

Important Safety Information

Battery Handling and Usage

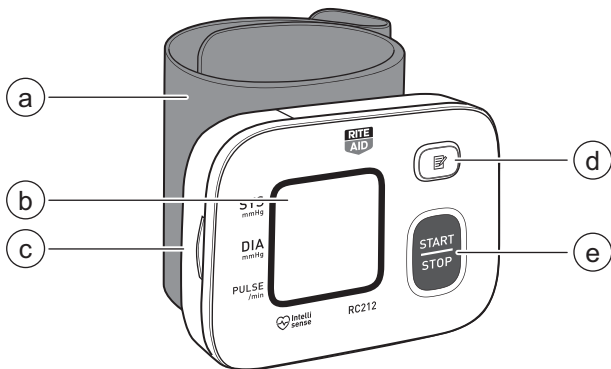
- **DO NOT** insert batteries with their polarities incorrectly aligned.
 - **ONLY** use 2 “AAA” alkaline batteries with this monitor. **DO NOT** use other types of batteries. **DO NOT** use new and used batteries together. **DO NOT** use different brands of batteries together.
 - Remove batteries if this monitor will not be used for a long period of time.
 - If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
 - If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
 - **DO NOT** use batteries after their expiration date.
 - Periodically check batteries to ensure they are in good working condition.
 - **ONLY** use batteries specified for this monitor. Use of unsupported batteries may damage and/or may be hazardous to this monitor.
-

1. Know Your Monitor

1.1 Contents

Monitor, 2 “AAA” alkaline batteries, storage case, instruction manual, quick start guide

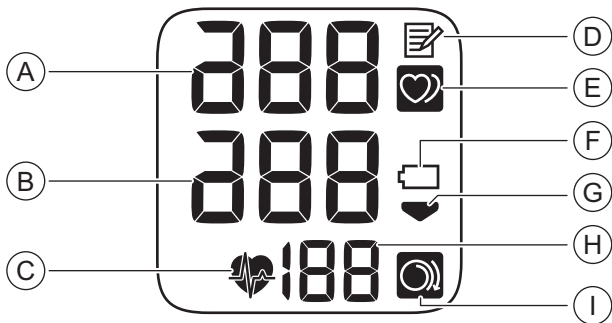
1.2 Monitor





- a. Wrist cuff
(Wrist circumference 5.3" to 8.5" (13.5 cm to 21.5 cm))
- b. Display
- c. Battery compartment
- d. [Memory] button
- e. [START/STOP] button











1. Know Your Monitor

1.3 Display and Symbols



A	Systolic blood pressure reading	
B	Diastolic blood pressure reading	
C		Heartbeat/hypertension symbol Flashes while taking a measurement. Appears if your systolic blood pressure is 130 mmHg or above and/or the diastolic blood pressure is 80 mmHg or above.
D		Memory symbol Appears when viewing readings stored in the memory.

1. Know Your Monitor

E		<p>Irregular heartbeat symbol</p> <p>Appears along with readings when an irregular rhythm is detected 2 or more times during a measurement.</p> <p>An irregular heartbeat rhythm is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while your monitor is measuring blood pressure. If it continues to appear, we recommend you to consult with and follow the directions of your physician.</p> <div data-bbox="622 252 995 532"> <p>Normal Heartbeat</p> <p>Pulse </p> <p>Blood pressure </p> <p>Irregular Heartbeat</p> <p>Pulse </p> <p>Blood pressure </p> </div>
F	 flashes	<p>Battery symbol (low)</p> <p>Flashes when batteries are low.</p>
	 appears	<p>Battery symbol (depleted)</p> <p>Appears when batteries are depleted.</p>
G		<p>Deflation symbol</p> <p>Appears during cuff deflation.</p>
H	<p>Pulse display / Memory number</p> <p>Pulse rate appears after the measurement.</p> <p>When pressing the  button, the memory number appears for approximately one second before the pulse rate appears on the display.</p>	
		<p>Cuff wrap guide symbol</p> <p>Appears if the wrist cuff is wrapped around the wrist too loosely while taking a measurement. It also appears when viewing past readings.</p>

1. Know Your Monitor

1.4 Classification of BP (Blood Pressure)

AHA (American Heart Association) defines categories of BP in adults as below.

Categories of BP in Adults*

BP Category	Systolic BP	Diastolic BP
Normal	< 120 mmHg	and < 80 mmHg
Elevated	120-129 mmHg	and < 80 mmHg
Hypertension		
Stage 1	130-139 mmHg	or 80-89 mmHg
Stage 2	≥ 140 mmHg	or ≥ 90 mmHg

* Individuals with Systolic BP and Diastolic BP in 2 categories should be designated to the higher BP category.

BP indicates blood pressure (based on an average of ≥ 2 careful readings obtained on ≥ 2 occasions).

Source: AHA/ACC 2017 High Blood Pressure Clinical Practice Guideline

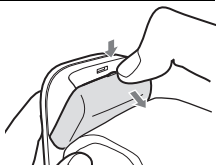
Warning

- NEVER diagnose or treat yourself based on your readings. ALWAYS consult with your physician.

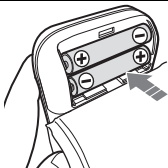
2. Preparation

2.1 Installing Batteries

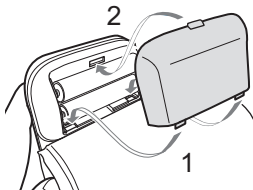
1. Push down the hook of the battery cover and pull downward.




2. Insert 2 “AAA” alkaline batteries as indicated in the battery compartment.



3. Close the battery cover.



Note

- When the “” symbol flashes on the display, it is recommended you replace batteries.
- To replace batteries, turn your monitor off and remove all batteries. Then replace with 2 new alkaline batteries at the same time.
- Replacing batteries will not delete previous readings.
- The supplied batteries may have a shorter life than new batteries.
- Disposal of used batteries should be carried out in accordance with local regulations.

2. Preparation

2.2 Blood Pressure Measurement Tips

To help ensure an accurate reading, follow these directions:

- Stress raises blood pressure. Avoid taking measurements during stressful times.
- Measurements should be taken in a quiet place.
- It is important to take measurements at same times each day. Taking measurements in the morning and in the evening is recommended.
- Remember to have a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time.

Caution

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

2. Preparation

2.3 Applying the Wrist Cuff

Note

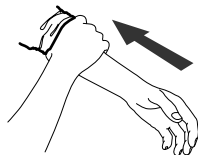
- Following steps are for applying the wrist cuff to your left wrist. When you take a measurement on your right wrist, apply the wrist cuff using the same steps as on your left wrist.
- The blood pressure can differ between the right wrist and the left wrist, and the measured blood pressure values can be different. OMRON recommends to always use the same wrist for measurement. If the values between both wrists differ substantially, please check with your physician as to which wrist to use for your measurements.

Caution

- Remove tight-fitting, thick clothing and any accessories from your wrist while taking a measurement.

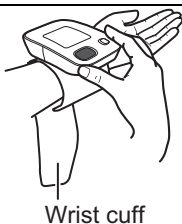
1. Roll up sleeve.

Make sure your sleeve is not rolled up too tightly on your arm. This may constrict the flow of blood in your arm.



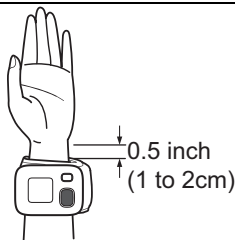
2. Put your wrist through the cuff loop.

Your palm and monitor display should both face upward.



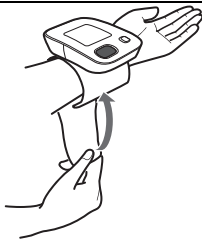
2. Preparation

3. Position the wrist cuff leaving a clearance of 0.5 inch (1 to 2 cm) between the cuff and the bottom of your palm.



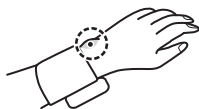
4. Wrap the wrist cuff firmly around your wrist. Do not apply over clothing.

Check to make sure that there is no gap between your wrist and the cuff.



Note

- Make sure the wrist cuff does not cover the protruding part of the wrist bone on the outside of your wrist.

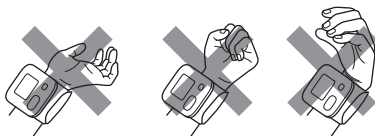
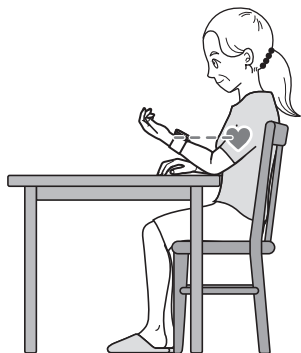


2. Preparation

2.4 Sitting Correctly

To take a measurement, you need to be relaxed and comfortably seated in a room with a comfortable temperature. Place your elbow on the table to support your arm.

- Sit in a chair with your legs uncrossed and your feet flat on the floor.
- Sit with your back and arm being supported.
- Your monitor must be approximately the same level as your heart. If the monitor is too high above your heart, your blood pressure will be artificially low. If the monitor is too low below your heart, your blood pressure will be artificially high.
- Relax your wrist and hand. Do not bend your wrist back, clench your fist, or bend your wrist forward.



3. Using Your Monitor

3.1 Taking a Measurement

Note

- To stop the measurement, press the [START/STOP] button once to deflate the wrist cuff.

Caution


- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.
- Remain still and DO NOT talk while taking a measurement.

1. Press the [START/STOP] button.


All symbols appear on the display before starting the measurement.

2. Remain still and do not move or talk until the entire measurement process is completed.


As the cuff inflates, your monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation.

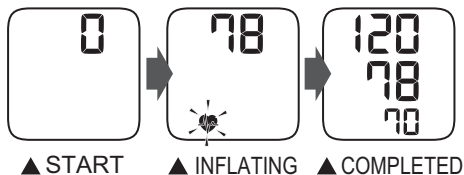
The “” symbol flashes at every heartbeat.

Note

- When the “” symbol is displayed, the wrist cuff is not tight enough. Press the [START/STOP] button to turn your monitor off, then apply the cuff correctly.

3. Using Your Monitor

After your monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure and pulse rate are displayed. If either the systolic or the diastolic reading is high (refer to sub-section 1.3), the “” symbol appears.



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

Note

- Your monitor will automatically turn off after 2 minutes.
- Wait 2-3 minutes between measurements. The wait time allows the arteries to decompress and return to their pre-measurement form. You may need to increase the wait time depending on your individual physiological characteristics.


4. Using Memory Function

Your monitor automatically stores up to 30 readings.

Note

- This monitor can be used by multiple users. When you use memory function with other users, track (or manage) your own readings appropriately.


4.1 Viewing the Readings Stored in Memory

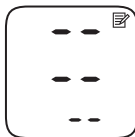
1. Press the  button.




The Memory number appears for one second before the pulse rate is displayed. The most recent reading set is numbered “1”.

Note




- If there are no readings stored in the memory, the screen to the right is displayed.
- If the reading is high (refer to sub-section 1.3), the “” symbol appears.
- If the memory is full, the monitor will delete the oldest readings.

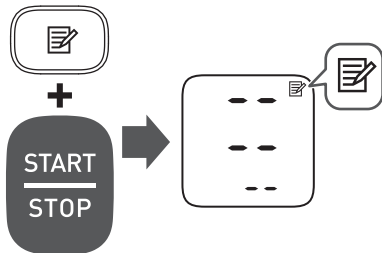


2. Press the  button repeatedly to scroll through the previous readings stored in the memory.

5. Other Settings

5.1 Deleting All Readings Stored in Memory

1. Press the  button, then the “” symbol appears.
2. While holding the  button down, press and hold the [START/STOP] button for more than 2 seconds.










Note




- All readings will be deleted. You cannot partially delete the readings stored in the memory.

6. Error Messages and Troubleshooting

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

Display/ Problem	Possible Cause	Solution
 appears or the wrist cuff does not inflate.	The wrist cuff is not applied correctly.	Apply the wrist cuff correctly, then take another measurement. Refer to sub-section 2.3.
	Air is leaking from the wrist cuff.	Contact your OMRON retail outlet or distributor.
 appears	The wrist cuff is overinflated exceeding 300 mmHg.	Contact customer service. Refer to section 10.
 appears	You move or talk during a measurement. Vibrations disrupt a measurement.	Remain still and do not talk during a measurement.
 appears	The pulse rate is not detected correctly.	Apply the wrist cuff correctly, then take another measurement. Refer to sub-section 2.3. Remain still and sit correctly during a measurement. If the “  ” symbol continues to appear, we recommend you to consult with your physician.
 appears		
 appears		

6. Error Messages and Troubleshooting

Display/ Problem	Possible Cause	Solution
 appears	The monitor is malfunctioned.	Press the [START/STOP] button again. If “Er” still appears, contact customer service. Refer to section 10.
 flashes	Batteries are low.	Replacing all batteries with 2 new alkaline batteries is recommended. Refer to sub-section 2.1.
 appears or the monitor is turned off unexpectedly during a measurement	Batteries are depleted.	Immediately replace all batteries with 2 new alkaline batteries. Refer to sub-section 2.1.
No power. Nothing appears on the display of the monitor.	Batteries are completely depleted.	
	Battery polarities are not properly aligned.	Check the battery installation for proper placement. Refer to sub-section 2.1.
Readings appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the wrist cuff, may affect your blood pressure. Review sub-sections 2.2 - 2.4 and section 3.	

6. Error Messages and Troubleshooting

Display/ Problem	Possible Cause	Solution
Any other problems occur.	Press the [START/STOP] button to turn the monitor off, then press it again to take a measurement. If the problem continues, remove all batteries and wait for 30 seconds. Then re-install batteries. If the problem still persists, contact customer service. Refer to section 10.	

7. Maintenance

7.1 Maintenance

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

- Changes or modifications not approved by the manufacturer will void the user warranty.

Caution

- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

7.2 Storage

Keep your monitor in the storage case when not in use.

- Store your monitor in a clean, safe location.

Do not store your monitor:

- If your monitor is wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.

7.3 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with neutral soap to clean your monitor and wrist cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and wrist cuff in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and wrist cuff.

7.4 Disposal

Dispose of your monitor and other components according to applicable local regulations.

Unlawful disposal may cause environmental pollution.

8. Specifications

Model	RC212 <small>REF</small> HEM-6161-RA
Display	LCD digital display
Cuff pressure range	0 to 299 mmHg
Blood pressure measurement range	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg
Pulse measurement range	40 to 180 beats / min.
Accuracy	Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of display reading
Inflation	Automatic by electric pump
Deflation	Automatic rapid deflation
Measurement method	Oscillometric method
Operation mode	Continuous operation
IP classification	IP 22
Rating	DC3 V 3.0 W
Power source	2 "AAA" alkaline batteries 1.5V
Battery life	Approximately 300 measurements (using new alkaline batteries)
Durable period (Service life)	5 years
Operating conditions	+50°F to +104°F (+10°C to +40°C) / 15 to 90% RH (non-condensing) / 800 to 1060 hPa
Storage / Transport conditions	-4°F to +140°F (-20°C to +60°C) / 10 to 90% RH (non-condensing)
Weight	Approximately 3.0 oz. (85 g) not including batteries
Dimensions	Approximately 3.3" (w) × 2.4" (h) × 0.8" (l) (84 mm × 62 mm × 21 mm) (not including the wrist cuff)


8. Specifications

Measurable wrist circumference	5.3" to 8.5" (13.5 to 21.5 cm)
Memory	Stores up to 30 readings
Contents	Monitor, 2 "AAA" alkaline batteries, storage case, instruction manual, quick start guide
Protection against electric shock	Internally powered ME equipment
Applied part	Type BF (wrist cuff)
Maximum temperature of the applied part	Lower than +118.4°F (+48°C)

Note

- 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 monitor is protected against solid foreign objects of 12.5 mm diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation.

Pictogram on the Product

	Indicates the correct positioning for the monitor on the wrist.
--	---

9. 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.

This device complies with part 15 of the FCC Rules. 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.

10. Limited Lifetime Warranty

Your Rite Aid RC212 Automatic Wrist Blood Pressure Monitor, excluding the batteries, is warranted to be free from defects in materials and workmanship for the 5 year durable period (Service life) of this product when used in accordance with the instruction provided with the unit. The wrist cuff is warranted to be free from defects in materials and workmanship for one year from the date of purchase when used in accordance with the instruction provided with unit. The above warranties extend only to the original retail purchaser.

The Limited Lifetime Warranty will not apply if the damage is caused by subjecting the product to any but the specified power source or voltage; old or worn batteries; alterations or repairs by unauthorized persons; misuse, abuse, damage during transit, lack of reasonable care with respect to the product, failure to follow the written instructions enclosed and professional use.

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

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

You must include a copy of your purchase receipt for warranty coverage to apply. 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.

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.

10. Limited Lifetime Warranty

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

This warranty provides you with specific legal rights, and you may have other rights that vary by jurisdiction. Because of special local requirements, some of the above limitations and exclusions may not apply to you.

FOR CUSTOMER SERVICE

Call toll free:

1-800-634-4350

11. Guidance and Manufacturer's Declaration

OMRON Battery-operated Blood Pressure Monitor

Information for Accompanying Documents in the Scope of IEC60601-1-2:2014

Important information regarding Electro Magnetic Compatibility (EMC)

RC212 conforms to IEC60601-1-2:2014 Electro Magnetic Compatibility (EMC) standard.
Further documentation in accordance with this EMC standard is available at OmronHealthcare.com/emc. Refer to the EMC information for RC212 on the website.



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