



New Product Information Sheet

Specifications subject to change
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Model (code): **RS2 (HEM-6161-E)**

Product description: *Automatic Wrist Blood Pressure Monitor*

Product category: *Electronic Sphygmomanometers*

Model (code): *RS2 (HEM-6161-E)*



LEGAL MANUFACTURER

OMRON HEALTHCARE Co., Ltd
53, Kunotsubo, Terado-cho, Muko, KYOTO,
617-0002 Japan

PRODUCTION FACILITY

OMRON HEALTHCARE MANUFACTURING VIETNAM CO., LTD.
No.28 VSIP II, Street2, Vietnam-Singapore Industrial Park II,
Binh Duong Industry-Services Urban Complex, Hoa Phu Ward,
Thu Dau Mot City, Binh Duong Province, Vietnam

EU REPRESENTATIVE

OMRON HEALTHCARE EUROPE B.V.
Scorpius 33, 2132 LR Hoofddorp,
THE NETHERLANDS

Included accessories / optional accessories

n/a

General description

The RS2 is an automatic wrist blood pressure monitor, operating on the oscillometric principle. This blood pressure monitor is to be worn on your wrist. When the cuff inflates, this monitor senses the pressure pulsations of the artery underneath the cuff.

Packaging content

The manufacturer produces the HEM-6161-E with the applicable accessories included, necessary for the application of its intended purpose.

1. Monitor
2. Storage case
3. 2 “AAA” alkaline batteries
4. Instruction Manual

Purpose

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 21.5 cm.

Application field

This monitor detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is mainly designed for general household use.

Intended user

- Legally certified medical experts, such as doctor, nurse and therapist, or healthcare personnel or patient under the guidance of qualified medical experts.

- The user should also be capable of understanding general operation of this device and the content of instruction manual.

Indications for use

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population.

Features (Particularities)

RS2 (HEM-6161-E) is an automatic wrist type blood pressure monitor that has the unique selling points as noted:

- Intellisense Technology
- Cuff wrapping guide
- Irregular heartbeat detection
- Pre-formed easy to fit cuff
- 30 memories

Description of operating principle

How it works

This 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.

How to use the device

Main steps:

1. Wrap the wrist cuff correctly on a bare arm.
2. Sit correctly
3. Press start
4. Remain still until the measurement process is completed
5. Press the stop button to turn off

Review the Instruction Manual for the full details on the application of this product.

Technical data

Product category	Electronic Sphygmomanometers
Product Description	Automatic Wrist Blood Pressure Monitor
Model (code)	RS2 (HEM-6161-E)
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	+10°C to +40°C / 15 to 90% RH (noncondensing) / 800 to 1060 hPa
Storage / Transport conditions	-20°C to +60°C / 10 to 90% RH (noncondensing)
Weight	Approximately 85 g not including batteries
Dimensions	Approximately 84 mm (w) × 62 mm (h) × 21 mm (l) (not including the wrist cuff)
Measurable wrist circumference	13.5 to 21.5 cm
Memory	Stores up to 30 readings
Contents	Monitor, storage case, 2 "AAA" alkaline batteries, instruction manual
Protection against electric shock	Internally powered ME equipment
Applied part	Type BF (wrist cuff)
Maximum temperature of the applied part	Lower than +48°C
EAN code	401567211111 0

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.

- 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.
- This device has not been validated for use on pregnant patients.

Materials used in main device and all accessories

Parts Name	Material
Front Housing	Acrylonitrile butadiene styrene
Ground Housing	Acrylonitrile butadiene styrene
Battery Cover	Acrylonitrile butadiene styrene
LCD	Glass
Front Panel	Polyethylene terephthalate
Outer Cloth	Polyester
Inner Cloth	Nylon
Collar	Polypropylene
Bladder	Polyvinyl chloride

Title page of Instruction Manual

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OMRON

Automatic Wrist Blood Pressure Monitor

RS2 (HEM-6161-E)
Instruction Manual

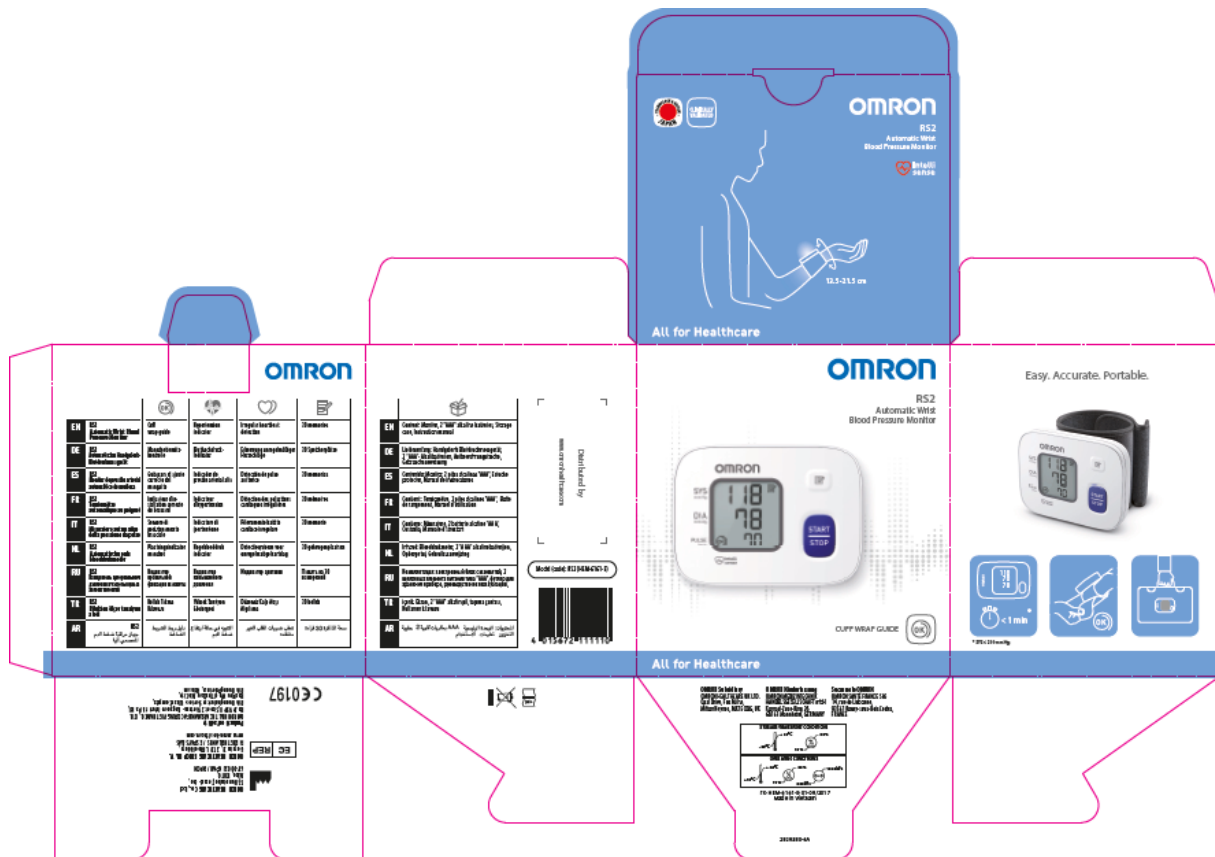


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All for Healthcare

Unfolded package design of main device and accessories

Main device:



Accessories:

n/a

Packaging specifications from Explanation Diagram

Package	Amount	Approx. weight	Approx. dimensions W x D x H, mm
Main Unit	1	85g	84 x 21 x 62 mm
Package	1	320g	109 x 94 x 115 mm
Master Carton	10	3.64kg	492 x 236 x 144 mm

List of Harmonized EN Standards

The device is classified as a medical device, Class IIa (MDD Annex IX Rule 10)

Applicable Medical Device Directive (93/42/EEC) standards:

EN ISO 15223-1:2016
EN 1041:2008
EN 1060-1:1995+A2:2009
EN 1060-3:1997+A2:2009
EN 60601-1:2006+A1:2013
EN 60601-1-2:2015
EN 60601-1-6:2010+A1:2015
EN 60601-1-11:2015
EN 80601-2-30:2010+A1:2015
EN 62304:2006+A1:2015
EN 62366:2008+A1:2015
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 14971:2012
EN ISO 81060-2:2014

Operation and care

Cleaning of the device

The device should be cleaned with a soft dry cloth, or a soft cloth moistened with neutral soap to clean on the monitor and the wrist cuff.

Warnings

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 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.

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 arteriovenous (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 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.
- DO NOT use this monitor in places with high or low humidity or high or low temperatures. Refer to chapter 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 chapter 8.
- DO NOT crease the wrist cuff excessively.
- Read and follow the “Correct Disposal of This Product” in chapter 10 when disposing of the device and any used accessories or optional parts.
- DO NOT use this monitor after the durable period has ended. Refer to chapter 8.

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.

Disposal

As there is a risk of environmental pollution, follow your applicable national and local legal regulations regarding disposal or recycling of this equipment and batteries. The main constituents of each part are listed in the table “Materials List”.

Transportation and storage conditions

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.

Storage and transportation:

Temperature range: -20 to +60°C

Humidity range: 10 to 90%RH

Warranty and lifetime

Warranty term for the blood pressure monitor – 3 years

Durable period (Service life) for the blood pressure monitor – 5 years

Repair

Do not disassemble or attempt to repair the device or components. Consult your OMRON retail outlet or distributor.

Servicing

It is generally recommended to have the device inspected every 2 years to ensure correct functioning and accuracy. Please consult your OMRON retail outlet or distributor.