

## NEW PRODUCT INFORMATION SHEETS-

Specifications subject to change  
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Sales Name: **RS2**  
Item Number: **HEM-6121-E**

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## General Information:

Product Description	Wrist Blood Pressure Monitor
Sales Name	RS2
Item number	HEM-6121-E
Model Category	Wrist Type Blood Pressure Monitor
Legal Manufacturer	 <b>OMRON HEALTHCARE Co., Ltd.</b> 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN
Production Facilities	OMRON (DALIAN) Co., LTD. Dalian, China
Photo of Product	
Packaging Content	Main unit, pre-formed cuff, battery pack (2 x AAA), Instruction manual, Storage case, Guarantee card
EAN Code	4015672107304

## Packaging Information:

Carton	Qty	Approx Weight	Approx dimensions W x D x H mm
Main unit without batteries	1	101g	78 x 21 x 60 (without the wrist cuff)
Sales Package	1	300g	100 x 110 x 110
Master Carton	20	6.87kg	578 x 224 x 267

## List of Harmonized EN Standards

### Directives

General applicable directives: Medical Device Directive (MDD) 93/42/EEC

Standards:

EN 980:2008  
EN 1041:2008  
EN 1060-1:1995+A2:2009  
EN 1060-3:1997+A2:2009  
EN60601-1:1990+A1:1993+A2:1995  
EN 60601-1-2:2007  
EN60601-1-4:1996+A1:1999  
EN ISO 14971:2007  
EN ISO 10993-1:2009  
EN ISO 10993-5:2009  
EN ISO 10993-10:2009  
EN 62304:2006  
EN 62366:2008

## Intended Use

### Medical Purpose

This product is intended for use to measure and/or monitor patients to record their blood pressure levels.

### 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.

### Intended Patients

This product should not be used by patients, who are unconscious or are not breathing spontaneously, unattended children or persons who cannot express their intent.

### Environment

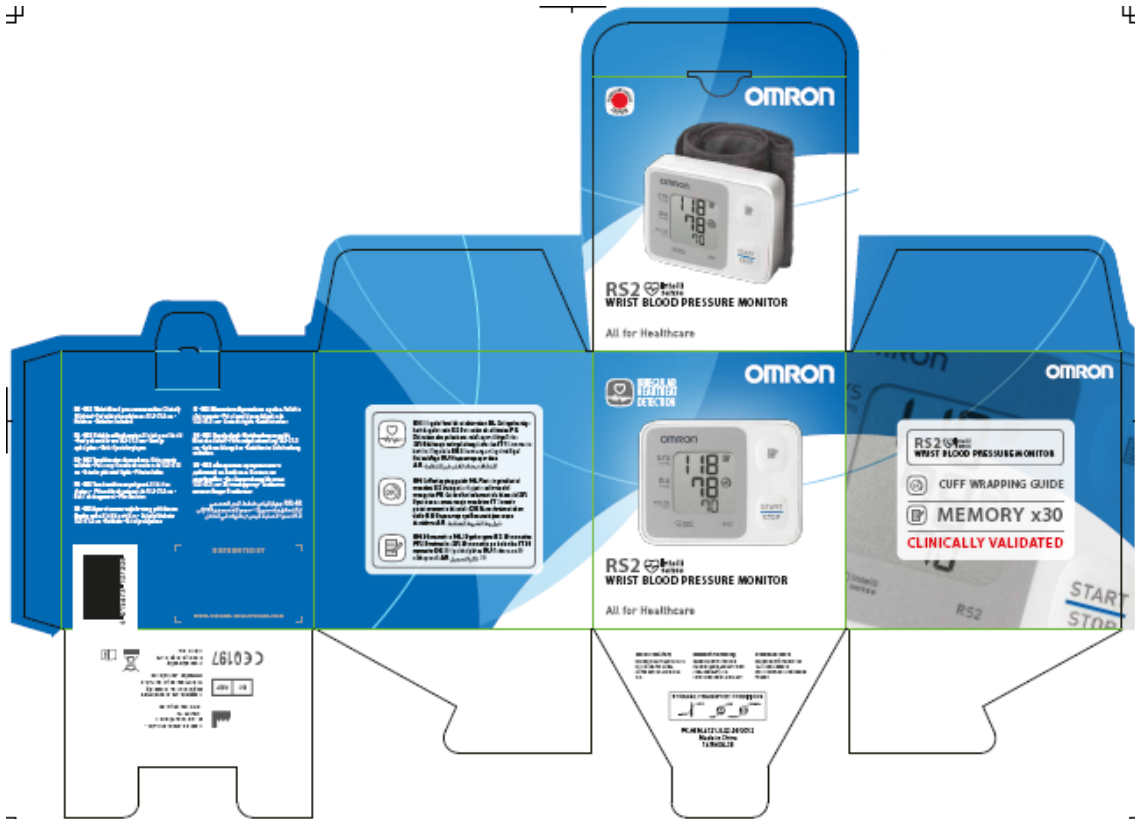
This product is intended for use in a medical facility, clinic and doctor's office, and in a room of general household.

## Particularities

**RS2 (HEM-6121-E) is an automatic wrist type blood pressure monitor that has the unique selling points as noted:**

- **Intellisense Technology**
- **Cuff wrapping guide**
- **Optimal speed and pressure for gentle inflation/deflation**
- **Pre-formed easy to fit cuff**
- **Irregular heartbeat detection**
- **Hypertension indicator**
- **30 x memories**

## Packaging



## Expanded View – Front Panel



### RS2 Intelli sense WRIST BLOOD PRESSURE MONITOR

All for Healthcare

## Expanded View – Back Panel

**EN • RS2 Wrist blood pressure monitor.** Clinically Validated • For wrist circumferences 13,5-21,5 cm • Hardcase • Batteries Included

**NL • RS2 Polsbloeddrukmeter.** Klinisch gevalideerd • Voor polsometrek van 13,5-21,5 cm • Stevige opbergdoos • Batterijen inbegrepen

**ES • RS2 Tensiómetro de muñeca.** Clínicamente validado • Para un perímetro de muñeca de 13,5-21,5 cm • Estuche protector rígido • Pilas incluidas

**FR • RS2 Tensiomètre au poignet.** Validation clinique • Périmètre de poignet de 13,5-21,5 cm • Boîte de rangement • Piles fournies

**SR • RS2 Aparat za merenje krvnog pritiska na članku ruke.** Klinički potvrđen • Za ručni kružnice 13,5-21,5 cm • Hardcase • Baterije uključene

**IT • RS2 Misuratore di pressione a polso.** Validato clinicamente • Per circonferenza del polso da 13,5-21,5 cm • Custodia rigida • Batterie incluse

**DE • RS2 Handgelenk-Blutdruckmessgerät.** Klinisch validiert • Für Handgelenkumfang 13,5-21,5 cm • Aufbewahrungsbox • Batterien im Lieferumfang enthalten

**RU • RS2 измеритель артериального давления на запястье.** Клинически апробирован • Для запястий окружностью 13,5-21,5 см • Жесткий футляр • Элементы питания входят в комплект

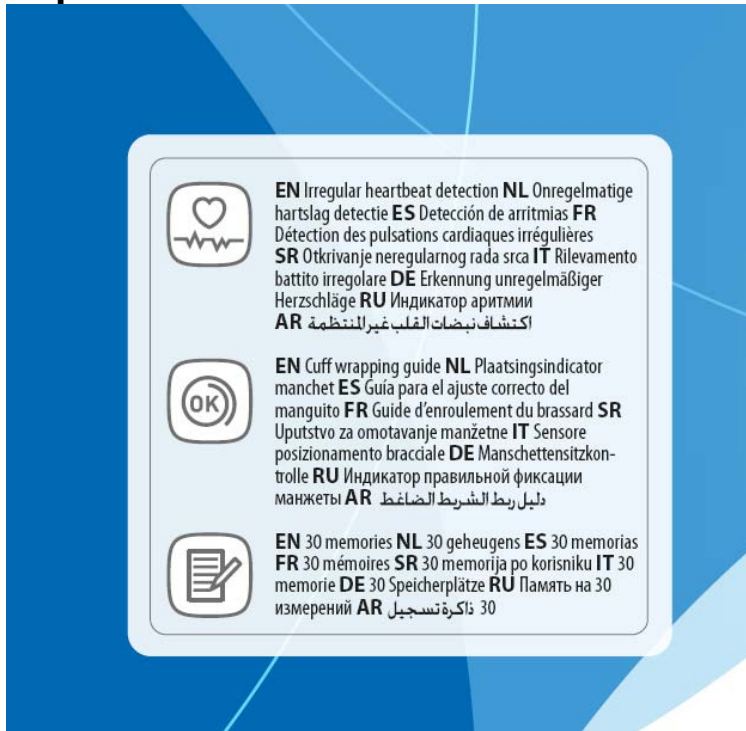
**RS2-AR** جهاز قياس ضغط الدم للعصوي تم التحقق منه سريريًا • حجم العصم من 13.5 إلى 21.5 سم • الصلبة كيس • بطاريات في الداخل



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## Expanded View - Side Panel 1

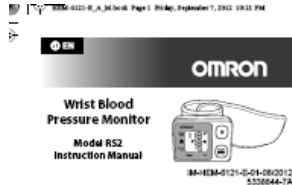


## Expanded View – Side Panel 2





## Instruction Manual Design



### Introduction

Thank you for purchasing the OMRON RS2 Wrist Blood Pressure Monitor.

The OMRON RS2 is a compact and easy-to-use blood pressure monitor, operating on the oscillometric principle. It measures your blood pressure and pulse rate simply and easily. For comfortable, controlled inflation without the need of pressure pre-setting or inflation, the device uses its advanced "HeartSense" technology.

**Intended Use**  
This product is designed to measure the blood pressure and pulse rate of people within the range of the designated wrist cuff, following the instructions in this instruction manual.

**Important Safety Information**  
Please read this section carefully before using the unit.

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

**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:**  
Do not use the unit for any purpose other than measuring blood pressure.

**Battery Usage:**  
If battery fluid should get on your eyes, immediately rinse with plenty of clean water. Consult a doctor immediately.

**Do not use:**  
Do not use the unit if it is damaged or if it is not wrapped around your wrist.

**Do not operate:**  
Do not operate the unit in a moving vehicle (car, airplane).

**Do not use:**  
Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.

**Do not disassemble:**  
Do not disassemble the unit or wrist cuff.

**Do not use:**  
Do not use the unit if the wrist cuff is not wrapped around your wrist.

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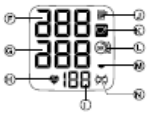
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### Display:



- F. Systolic blood pressure
- G. Diastolic blood pressure
- H. Heartbeat symbol
- I. Pulse display and Memory number
- J. Memory symbol
- K. Irregular heartbeat symbol
- L. Cuff wrapping guide
- M. Deflation symbol
- N. Battery low symbol

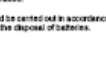
### 2. Preparation

#### 2.1 Installing/Replacing the Batteries

1. Remove the battery cover.



2. Insert two 1.5V "AAA" alkaline (LR03) batteries as indicated in the battery compartment and then replace the battery cover.



**Notes:**  
- If the battery low symbol (⊖) appears on the display, turn off the unit then replace both batteries at the same time.  
- The measurement values continue to be stored in memory even after the batteries are replaced.

Disposal of used batteries should be carried out in accordance with the national regulations for the disposal of batteries.

#### 3. Using the Unit

##### 3.1 Applying the Wrist Cuff

1. Place the wrist cuff over your wrist.



Your palm should face upward.

2. Wrap the wrist cuff around your wrist.



Wrap the wrist cuff securely around the wrist for taking accurate measurements.

Make sure that the wrist cuff does not cover the protruding part of the wrist bone (ulna) on the outside of the wrist.



**Note:** You can take a measurement on either your left or right wrist.

### 3.2 How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated, under comfortable room temperature. No bathing, drinking alcohol or caffeine, smoking, exercising or eating 30 minutes before taking a measurement.



- Sit on a chair with your feet flat on the floor.
- Sit upright with your back straight.
- The cuff should be at the same level as your heart.
- Relax your wrist and hand. Do not bend your wrist back, stretch your feet, or bend your wrist forward.



### 3.3 Taking a Reading

**Notes:**  
- To cancel a measurement, press the START/STOP button at any time during measurement.  
- Remain still while taking a measurement.

1. Press the START/STOP button. All the symbols appear on the display, the wrist cuff will start to inflate automatically.



**Cuff Wrapping Guide**  
The Cuff Wrapping Guide is a unique feature that indicates if the cuff is not wrapped tightly enough around the wrist. Even when the ⊖ is displayed, a blood pressure reading will be taken.

**Note:** This reading is NOT reliable due to the incorrect wrapping of the cuff. Please wrap the cuff again, taking care to wrap it correctly and take the measurement again. When the ⊖ is displayed, the cuff is correctly wrapped tightly enough on the wrist and the reading is accurate and reliable.

2. Undo the wrist cuff and remove the unit.

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

The monitor automatically stores the measurement in its memory. It will automatically turn off after two minutes.

**Important:**  
If your systolic or diastolic pressure is outside the standard range, the heartbeat symbol will blink when the measurement result is displayed.



Recent research suggests that the following values can be used as a guide to high blood pressure for measurement taken at home.

Systolic Blood Pressure	Above 135 mmHg
Diastolic Blood Pressure	Above 85 mmHg

The criteria is for home blood pressure measurement.

Your blood pressure monitor includes an irregular heartbeat feature. Irregular heartbeats can influence the results of the measurement. The irregular heartbeat algorithm automatically determines if the measurement is stable or needs to be repeated. If the measurement results are affected by irregular heartbeats but the result is valid, the result is shown together with the irregular heartbeat symbol (⊖).




If the irregular heartbeats cause the measurement to be invalid, the result is shown. If the irregular heartbeat symbol (⊖) is shown after you have taken a measurement, repeat the measurement. If the irregular heartbeat symbol (⊖) is shown frequently, please make your doctor aware of it.

**Notes:**  
- Wait 2 - 3 minutes before taking another blood pressure measurement. Waiting between readings allows the arteries to return to the condition prior to taking the blood pressure measurement.

The blood pressure can differ between the right arm and the left arm, and therefore also the measured blood pressure values can be different. OMRON recommends to always use the same arm for measurement. If the values between the two arms differ substantially, please check with your physician which arm to use for your measurement.

**Warning:**  
Self-diagnosis of measured results and treatment are dangerous. Please follow the instructions of your doctor.

## TECHNICAL PRODUCT INFORMATION

Product Description	Digital Automatic Wrist Blood Pressure Monitor
Model	OMRON RS2 (HEM-6121-E)
Display	LCD Digital Display
Measurement Method	Oscillometric method
Languages	EN, DE, FR, IT, ES, NL, RU, AR, TU, SR
Measurement Range	Pressure: 0mmHg to 299mmHg Pulse: 40 to 180/min.
Memory	30 x memory
Applied Part	 = Type B
Protection Against Electric Shock	Internally powered ME equipment
Accuracy	Pressure: $\pm 3$ mmHg Pulse: $\pm 5\%$ of display reading
Inflation	Automatic inflation by pump
Deflation	Automatic rapid deflation
Pressure Detection	Capacitive pressure sensor
Power Source	2 "AAA" alkaline (LR03) batteries 1.5V
Battery life	Approximately 300 measurements with new alkaline batteries at a room temperature of 23°C
Operating temperature / Humidity	+10°C to +40°C Maximum: 30% to 85% RH
Storage Temperature / humidity	-20°C to +60°C Maximum: 10% to 95% RH
Console Weight	Approximately 101g without batteries
Outer dimensions	Approximately 78 (w) mm x 60 (h) mm x 21 (d) mm (without the wrist cuff)
Measurable circumference of wrist	Approximately 13.5 to 21.5 cm
Cuff material	Nylon and polyester
Package Content	Main unit, battery set, instruction manual, guarantee card, carry case

### CE0197

This device fulfils the provisions of EC directive 93/42/EEC (Medical Device Directive).

- This blood pressure monitor is designed according to the European Standard EN1060, Noninvasive 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.

## Comparison Table

Product Description	Predecessor	New Model
Model	OMRON R2 HEM-6113-E	OMRON RS2 HEM-6121-E
Measurement Method	Oscillometric	Same as Predecessor
Measurement Range	Pressure: 0mmHg to 299mmHg Pulse: 40 to 180/min	Same as Predecessor
Memory	30 x memory	Same as Predecessor
Accuracy	Pressure: $\pm 3$ mmHg Pulse: $\pm 5\%$ of display reading	Same as Predecessor
Inflation	Automatic inflation by pump	Same as Predecessor
Deflation	Automatic rapid deflation	Same as Predecessor
Power Source	2 "AAA" alkaline (LR03) batteries 1.5V	Same as Predecessor
Protection against Electric Shock	Internally powered ME equipment (When using only the batteries)	Same as Predecessor
Operating temperature / Humidity	+10°C to +40°C Maximum: 30% to 85% RH	Same as Predecessor
Storage Temperature / humidity	-20°C to +60°C Maximum: 10% to 95% RH	Same as Predecessor

### Conclusion of Comparison

**The new model is a substantial equivalent of both of its predecessor in terms of Technology, Functionality, Safety, Reliability, Performance and general application.**

### List of Materials

Item	Material	Grade
Front Housing	Acrylonitrile butadiene styrene	UMG EX-120 or Techno polymer 130
Ground Housing	Acrylonitrile butadiene styrene	UMG EX-120 or Techno polymer 130
Battery Cover	Acrylonitrile butadiene styrene	UMG EX-120 or Techno polymer 130
LCD Holder	Acrylonitrile butadiene styrene	UMG EX-120 or Techno polymer 130
Hard Case	Polypropylene	PP6019
Front Panel	Polyethylene terephthalate	PET t=0.188mm
Outer Cloth	Polyester	P165T
Inner Cloth	Nylon	G4028FF-2C
Fastener hook	Nylon	A9663Y
Fastener Loop	Nylon & Polyester & PVC	PVC95F
Bias	Polyester	TC8864H(#1(CGR))

## Maintenance and storage

### Maintenance

To protect your unit from damage, please avoid the following:

- Subjecting your unit to extreme temperatures, humidity, moisture or direct sunlight.
- Washing the cuff or exposing the cuff or unit to water
- Disassembling the unit.
- Subjecting the unit to strong shocks or vibrations. Dropping the unit.
- Cleaning the unit with volatile liquids.
- The unit should be cleaned with a soft, dry cloth.
- Use a soft, moistened cloth and soap to clean the arm cuff.

### Calibration and Service

- The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorized OMRON dealer or the OMRON Customer Service at the address given on the packaging or attached literature.

### Storage

Do not store the unit in the following conditions:

- If the unit is wet.
- Locations exposed to extreme temperatures, humidity, direct sunlight, dust, chemicals or corrosive vapours.
- Locations exposed to vibrations, shocks or where it will be at an angle.

**Optional Accessories**

**Not applicable**