

NEW PRODUCT INFORMATION SHEETS-

Specifications subject to change
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Sales Name: **RS6**
Item Number: **HEM-6221-E**

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General Information:

Product Description	Wrist Blood Pressure Monitor
Sales Name	RS6
Item number	HEM-6221-E
Model Category	Wrist Type Blood Pressure Monitor
Legal Manufacturer	 OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN
Production Facilities	OMRON (DALIAN) Co., LTD. Dalian, China
Photo of Product	
Packaging Content	Main unit, soft fan-shaped cuff, battery pack (2 x AAA), Instruction manual, Storage case, Guarantee card, blood pressure pass
EAN Code	4015672107274

Packaging Information:

Carton	Qty	Approx Weight	Approx dimensions W x D x H mm
Main unit without batteries	1	85g	87 x 14 x 64
Sales Package	1	306g	90 x 90 x 110
Master Carton	20	6.7kg	470 x 196 x 237

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

Particularities

RS6 (HEM-6221-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
- Soft fan-shaped easy to fit cuff
- Irregular heartbeat detection
- Blood pressure level indicator
- Advanced Positioning Sensor
- Silent Measurement
- Body Movement Detector
- Hypertension indicator
- Average of past 3 readings
- 90 x memories

Packaging




Expanded View – Front Panel



Expanded View – Back Panel

<p>EN - RS6 Wrist blood pressure monitor. Clinically validated • Cuff wrapping guide • Irregular Heartbeat Detector • For wrist circumferences 13,5-21,5 cm • Hardcase • Batteries Included</p> <p>NL - RS6 Pols bloeddrukmeter. Klinisch gevalideerd • Plaatsingsindicator manchet • Detectiesysteem voor onregelmatige hartslag • Voor polsometrek van 13,5-21,5 cm • Opbergdoos • Incl. batterijen</p> <p>ES - RS6 Monitor de presión arterial de muñeca. Clínicamente validado • Guía para el ajuste correcto del manguito • Detección de arritmias • Para un perímetro de muñeca de 13,5-21,5 cm • Estuche protector rígido • Pilas incluidas</p> <p>FR - RS6 Tensiomètre au poignet. Validation clinique • Guide d'enroulement du brassard • Détection des pulsations cardiaques irrégulières • Périmètre de poignet de 13,5-21,5 cm • Boîte de rangement • Piles fournies</p>	<p>IT - RS6 Misuratore di pressione a polso. Validato clinicamente • Sensore posizionamento bracciale • Rilevamento battito irregolare • Per circonferenza del polso da 13,5-21,5 cm • Custodia rigida • Batterie incluse</p> <p>DE - RS6 Handgelenk-Blutdruckmessgerät. Klinisch validiert • Manschettensitzkontrolle • Erkennung unregelmäßiger Herzschläge • Für Handgelenkumfang 13,5-21,5 cm • Aufbewahrungsbox • Batterien im Lieferumfang enthalten</p> <p>RU - RS6 измеритель артериального давления на запястье. Клинически апробирован • Индикатор правильной фиксации манжеты • Индикатор аритмии • Для запястий окружностью 13,5-21,5 см • Жесткий футляр • Элементы питания входят в комплект</p> <p>RS6-AR جهاز قياس ضغط الدم المعصمي لم التحقق منه سريرياً • دليل ربط المشريط الحافظة • اكتشاف نبضات القلب غير المنتظمة • حجم المعصم من 13.5 إلى 21.5 سم الصلبة كيس • بطاريات في الداخل</p>
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Expanded View - Side Panel 1



Expanded View – Side Panel 2



Instruction Manual Design



Wrist Blood Pressure Monitor
Model B6C
Instruction Manual



Thank you for purchasing the OMRON Wrist Blood Pressure Monitor.

The OMRON B6C is a compact and easy-to-use blood pressure monitor, operating on the oscillometric principle. It measures your blood pressure at the wrist with accuracy and stability. For comfortable, controlled inflation without the need of pressure pre-inflation or oscillation, the device uses an advanced "intelligent" technology.

Intended Use
This product is designed to measure the blood pressure and pulse rate of people within the range of the designated cuff. Following the instructions in this instruction manual, it is easily changed for general household use. Please read the important safety information in this instruction manual before using the unit.

⚠ Warning
Please read this instruction manual thoroughly before using the unit.
Please keep for future reference.
For specific information about your wrist blood pressure, CONSULT YOUR DOCTOR.

Important Safety Information
Consult your doctor prior to using a program or if diagnosed with arrhythmia or abnormal pulse.
Please read the section carefully before using the unit.

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

General Usage
• Always consult your doctor. Self diagnosis of measurement results and self treatment are dangerous.
• People with abnormal blood pressure, or blood disorders, should consult a doctor before using the unit, as cuff inflation can cause arterial blockage.
Display Usage
• Wearing feet should gain your eyes, immediately raise with plenty of clearance. Consult a doctor if there is any.

⚠ Caution
• Includes 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 Precautions
• Do not leave the unit unattended with infants or persons who cannot express their concern.
• Do not use the unit for any purpose other than measuring blood pressure.
• 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 the unit or wrist cuff.
• Do not operate the unit in a wetting condition (see warnings).

Display Usage
• Wearing feet should gain your eyes or clothing, immediately raise with plenty of clearance.
• Do not use two "AAA" alkaline batteries with this unit. Do not use other types of batteries.
• Do not insert the battery with their positive polarity aligned.
• Replace old batteries with new ones immediately. Replace both batteries at the same time.
• Recharge the batteries if the unit will not be used for three months or more.
• Do not use new and used batteries together.

General Precautions
• Do not apply strong shocks or vibrations to or drop the unit.
• Do not take measurement after bathing, drinking alcohol or caffeine, smoking, exercising or eating.
• Do not inflate the wrist cuff when it is not wrapped around your wrist.
• Read and follow the "Important Information Regarding Electric Magnetic Compatibility (EMC)" in the Technical Data Section.
• Read and follow the "Correct Operation of the Product" in the Technical Data Section when operating the device using your accessories or optional parts.

1. Overview

Main unit:



- A. Wrist cuff
- B. Battery compartment
- C. Display
- D. Inflation (P) button
- E. Operation setting (O) button
- F. START/STOP button

Display:



- 1. Inflation indicator
- 2. Inflation pressure
- 3. Deflation indicator
- 4. Heart rate indicator
- 5. Pulse width indicator
- 6. Inflation error indicator
- 7. Inflation error indicator
- 8. Inflation error indicator
- 9. Inflation error indicator
- 10. Inflation error indicator
- 11. Inflation error indicator
- 12. Inflation error indicator
- 13. Inflation error indicator
- 14. Inflation error indicator

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 symbol (P) 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 battery is re-installed.

Deposited measurements should be stored with accordance with the national regulations for the disposal of batteries.

2.2 Setting the Date and Time

1. Press the (O) button.

2. Set the monitor to the correct date and time before taking a measurement for the first time.



3. Press the START/STOP button to store the setting.

Notes:
• If the battery has been returned, the date and time setting will need to be reset.
• If the date setting area is not set, "1" appears during or after measurement.

3. Using the Unit

3.1 Applying the Wrist Cuff

Do not apply over clothing.

1. Put your arm through the cuff loop.

Your palm should face upward.



2. Wrap the wrist cuff around your wrist.

Wrap the wrist cuff securely around the wrist for a snug, accurate measurement.



Make sure that the wrist cuff does not cover the positioning part of the wrist loop (indicated by the white dot) on the outside of the wrist.



Notes:
• Do not cut into a measurement site or your wrist or right vein.
• The wrist cuff cannot be applied as shown in the figure.

3.2 How to Sit Correctly

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

- Sit in 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 mind and hand. Do not bend your wrist back, stretch your feet, or bend your neck forward.



3.3 Taking a Reading

Notes:
• To take an measurement, press the START/STOP button at any time during measurement.
• Please wait before taking a measurement.

1. Press the START/STOP button.

The monitor will power on. The monitor will power on. The monitor will power on.



After the Positioning indicator lights for more than 2 seconds, the wrist cuff starts to inflate automatically.



Cuff Wrapping Guide



A START A DELAY A INFLATE A COMPLETE

Cuff Wrapping Guide

The cuff wrapping guide is a unique feature that indicates if the cuff is not wrapped tightly enough around the wrist. When the (P) is displayed, a blood pressure reading will be taken.

Note: The reading is NOT available due to the incorrect wrapping of the cuff. Please wrap the cuff again, being sure to wrap it correctly all the time around the wrist. After the (P) 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 shuts off measurement to its memory. It will automatically turn off after five minutes.

Important:
• Please review it suggests that the library value can be used as a guide to high blood pressure for measurement before at home.

System Blood Pressure	Above 135 mmHg
Normal Blood Pressure	Above 95 mmHg

Notes:
• Your blood pressure monitor includes an integral treatment timer. In your treatment, we introduce the results of the measurement. The integral treatment algorithm automatically determines if the measurement is usable or needs to be repeated. If the measurement results are effective, the pulse treatment will be repeated. The result is shown together with the integral treatment symbol (P). If the integral treatment symbol (P) is shown, it means it shows. If the integral treatment symbol (P) is shown after you have taken a measurement, repeat the measurement. If the integral treatment symbol (P) is shown frequently, please consult your doctor soon if it.

⚠ Warning:
• If you are taking medication, the monitor will advise (P) on the display. Please ask your doctor about it.

Notes:
• Step 2: 2 minutes before taking another blood pressure measurement, making a measurement shows the white dot to return to the condition prior to taking the blood pressure measurement.
• The blood pressure can differ between the left and the right arms, 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:
• In a situation of stress and results are treated as dangerous. Please follow the instructions of your doctor.

Setting the Positioning Sensor


1. Press and hold the (P) button to reset the Positioning sensor.

The Positioning sensor is set "off" as default.



2. Press the START/STOP button to store the setting.

TECHNICAL PRODUCT INFORMATION

Product Description	Digital Automatic Wrist Blood Pressure Monitor
Model	OMRON RS6 (HEM-6221-E)
Display	LCD Digital Display
Measurement Method	Oscillometric method
Languages	EN, DE, FR, IT, ES, NL, RU, AR,
Measurement Range	Pressure: 0mmHg to 299mmHg Pulse: 40 to 180/min.
Memory	90 x memory
Applied Part	 = Type B
Protection Against Electric Shock	Internally powered ME equipment
Accuracy	Pressure: ± 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 85g 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, blood pressure pass

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 R3 (HEM-6052-E)	OMRON RS6 (HEM-6221-E)
Measurement Method	Oscillometric method	Same as Predecessor
Measurement Range	Pressure: 0mmHg to 299mmHg Pulse: 40 to 180/min	Same as Predecessor
Memory	2 x 90 memory	90 x memory
Accuracy	Pressure: ± 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	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
Start/Stop button	Acrylonitrile butadiene styrene	UMG EX-120 or Techno polymer 130
Memory button	Acrylonitrile butadiene styrene	UMG EX-120 or Techno polymer 130
Front Panel	Polymethyl methacrylate	Asahikasei DELPET80N
Outer Cloth	Polyvinyl chloride	PVC95F
Inner Cloth	Nylon	G6028-38C
Fastener Hook	Nylon	A9663Y
Fastener Loop	Polyvinyl chloride	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