

NEW PRODUCT INFORMATION SHEETS-



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Sales Name: **RS3**
Item Number: **HEM-6130-E**

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General Information:

| | |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product Description | Wrist Blood Pressure Monitor |
| Sales Name | RS3 |
| Item number | HEM-6130-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, pre-formed cuff, battery pack (2 x AAA), Instruction manual, Storage case, Guarantee card |
| EAN Code | 4015672107342 |

Packaging Information:

| Carton | Qty | Approx Weight | Approx dimensions H x W x D (mm) |
|-----------------------------|-----|---------------|---------------------------------------|
| Main unit without batteries | 1 | 101g | 60 x 78 x 21 (without the wrist cuff) |
| Sales Package | 1 | 310g | 110 x 100 x 110 |
| Master Carton | 20 | 6.92kg | 267 x 578 x 224 |

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

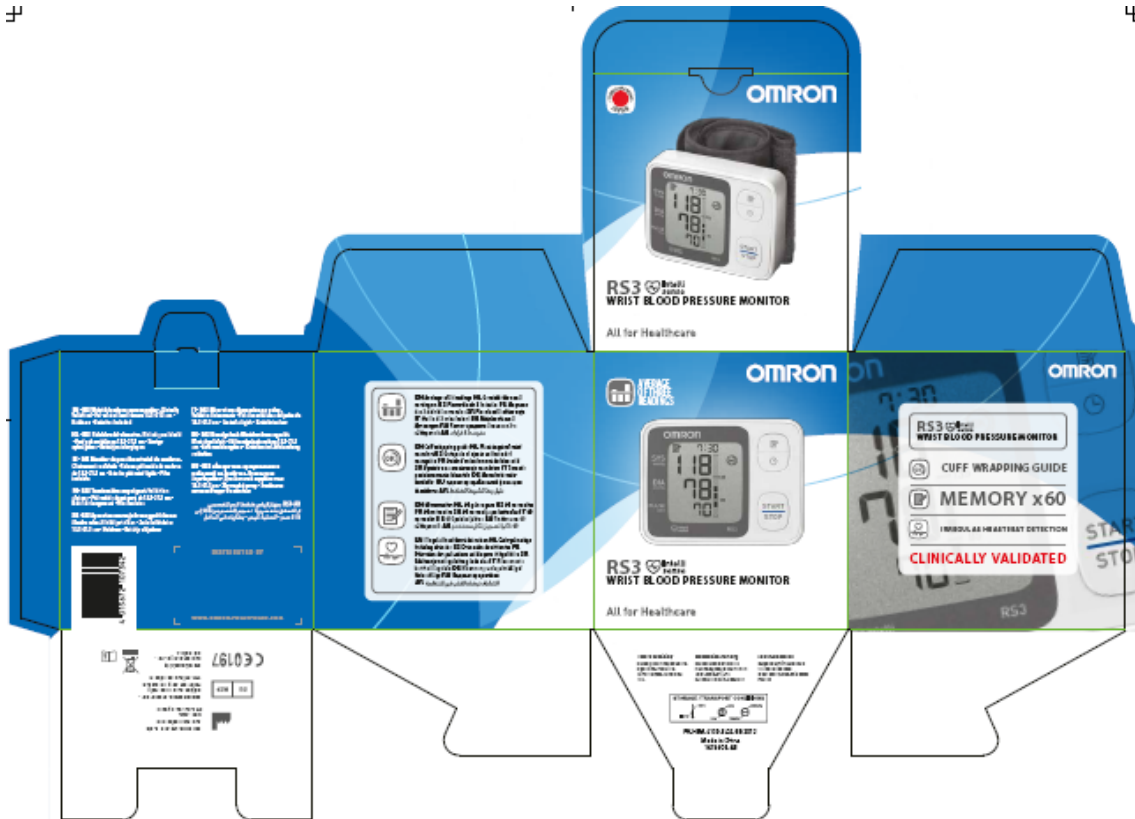
This product is intended for use in a medical facility, clinic and doctor's office, and in a room of general household.

Particularities

RS3 (HEM-6130-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**
- **Body Movement Detector**
- **Hypertension indicator**
- **Average of past 3 readings**
- **60 x memories**

Packaging



Expanded View – Front Panel




RS3  **Intelli sense**
WRIST BLOOD PRESSURE MONITOR

All for Healthcare

Expanded View – Back Panel

| | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>EN - RS3 Wrist blood pressure monitor. Clinically Validated • For wrist circumferences 13,5-21,5 cm • Hardcase • Batteries Included</p> <p>NL - RS3 Pols bloeddrukmeter. Klinisch gevalideerd • Voor polsomtrek van 13,5-21,5 cm • Stevige opbergdoos • Batterijen inbegrepen</p> <p>ES - RS3 Monitor de presión arterial de muñeca. Clínicamente validado • Para un perímetro de muñeca de 13,5-21,5 cm • Estuche protector rígido • Pilas incluidas</p> <p>FR - RS3 Tensiomètre au poignet. Validation clinique • Périmètre de poignet de 13,5-21,5 cm • Boîte de rangement • Piles fournies</p> <p>SR - RS3 Aparat za merenje krvnog pritiska na čanku ruke. Klinički potvrđen • Za nuci kružnice 13,5-21,5 cm • Hardcase • Baterije uključene</p> | <p>IT - RS3 Misuratore di pressione a polso. Validato clinicamente • Per circonferenza del polso da 13,5-21,5 cm • Custodia rigida • Batterie incluse</p> <p>DE - RS3 Handgelenk-Blutdruckmessgerät. Klinisch validiert • Für Handgelenkumfänge 13,5-21,5 cm • Aufbewahrungsbox • Batterien im Lieferumfang enthalten</p> <p>RU - RS3 измеритель артериального давления на запястье. Клинически апробирован • Для запястий окружностью 13,5-21,5 см • Жесткий футляр • Элементы питания входят в комплект</p> <p>RS3-AR جهاز قياس ضغط الدم للمعصم تم التحقق منه سريريًا • حجم المعصم من 13,5 إلى 21,5 سم • الصلبة كيس • بطاريات في الداخل</p> |
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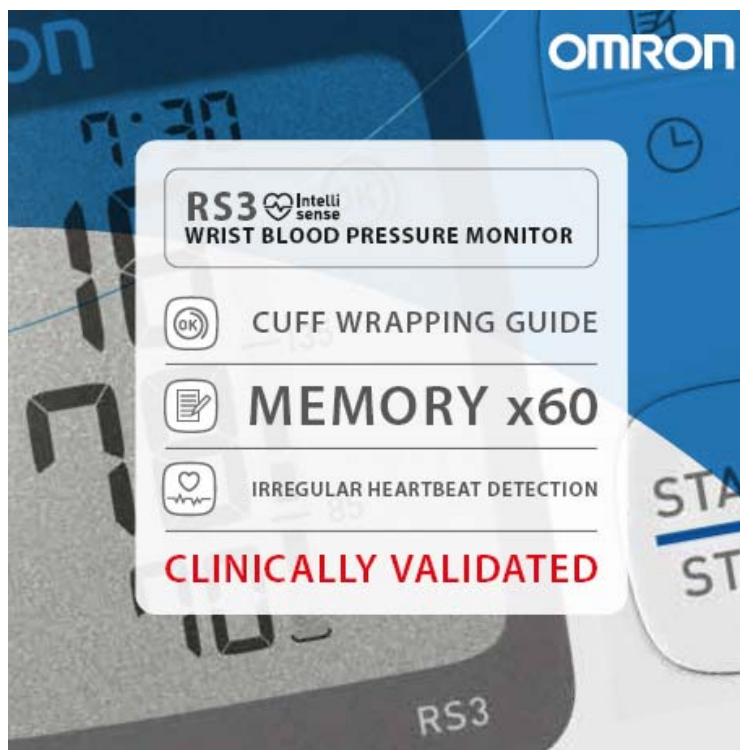
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Expanded View - Side Panel 1



Expanded View – Side Panel 2



Instruction Manual Design



Wrist Blood Pressure Monitor
Model R53
Instruction Manual

IM-H3M-0130-01-08/2012
533830-7A

Introduction

Thank you for purchasing the OMRON R53 Wrist Blood Pressure Monitor.

The OMRON R53 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 quickly. For comfortable controlled inflation without the need of pressure pre-setting or re-inflation the device uses its advanced "IntelliSense" 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.

It is mainly designed for general household use. Please read the important safety information in this instruction manual before using the unit.

⚠ Please read this instruction manual thoroughly before using the unit.

Please keep for future reference.
For specific information about your own blood pressure, CONSULT YOUR DOCTOR.

Important Safety Information

Consult your doctor prior to using in pregnancy or if diagnosed with arrhythmia or arteriosclerosis.

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.

(General Usage)

- Always consult your doctor. Self-diagnosis of measurement results and self-treatment are dangerous.
- People with severe blood flow problems, or blood disorders, should consult a doctor before using the unit, as cuff inflation can cause internal bleeding.

(Battery Usage)

- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult a doctor immediately.

⚠ 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 leave the unit unattended with infants or persons who cannot express their consent.
- 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 moisty vehicle (car, airplane).

(Battery Usage)

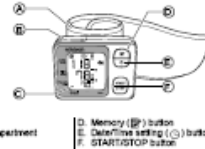
- If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.
- Use only two "AAA" alkaline (LR03) batteries with this unit.
- Do not insert the batteries with their polarities incorrectly aligned.
- Replace old batteries with new ones immediately. Replace both batteries at the same time.
- Remove 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 and vibrations to or drop the unit.
- Do not take measurements 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 Electro Magnetic Compatibility (EMC)" in the Technical Data Section.
- Read and follow the "Correct Disposal of This Product" in the Technical Data Section when disposing of the device and any used accessories or optional parts.

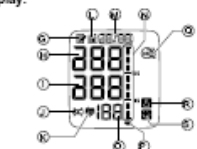
1. Overview

Main unit:



A. Wrist cuff
B. Battery compartment
C. Display
D. Memory (M) button
E. Date/Time setting (C) button
F. START/STOP button

Display:




G. Memory symbol
H. Systolic blood pressure
I. Diastolic blood pressure
J. Battery low symbol
K. Heartbeat symbol (flashes during measurement)
L. Average value symbol
M. Date/Time display
N. Blood pressure level indicator
O. Pulse display and Memory number
P. Definition symbol
Q. Cuff wrapping guide
R. Movement error symbol
S. Irregular heartbeat 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:

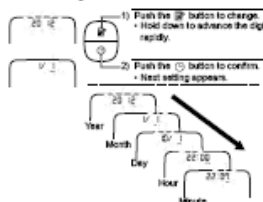
- If the battery low symbol (J) appears on the display, turn off the unit then replace both batteries at the same time.
- The measurement values continue to be stored in memory even after the batteries are replaced.

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

2.2 Setting the Date and Time

1. Press and hold the (C) button until the year flashes on the display.

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



1) Press the (M) button to change the unit then repeat both batteries at the same time.

2) Press the (C) button to confirm. Next setting appears.

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

Notes:


- If the batteries have been removed, the date and time setting will need to be reset.
- If the date and time are not set, "----" appears during or after measurement.

3. Using the Unit

3.1 Applying the Wrist Cuff


Do not apply over clothing.

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 (indicated 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 talking, 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, clench your fist, or bend your wrist forward.



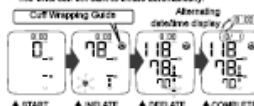
3.3 Taking a Reading

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.



Notes:

- START
- INFLATE
- DEFLATE
- 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. Even when the (Q) 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 (Q) 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.

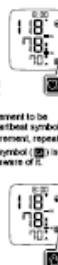
Important:

- 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 95 mmHg |

This 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 usable 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 (S).
- If the irregular heartbeat causes the measurement to be invalid, no result is shown. If the irregular heartbeat symbol (S) is shown after you have taken a measurement, repeat the measurement. If the irregular heartbeat symbol (S) is shown frequently, please make your doctor aware of it.
- If you move during measurement, the movement error symbol (R) will appear on the display. Keep still and repeat the measurement.




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 RS3(HEM-6130-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 | 60 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 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 | Predecessory | New Models |
|-----------------------------------|---------------------------------------------------------------|------------------------|
| Model | OMRON R3 (HEM-6200-E) | OMRON RS3 (HEM-6130-E) |
| Measurement Method | Oscillometric method | Same as Predecessor |
| Measurement Range | Pressure: 0mmHg to 299mmHg Pulse: 40 to 180/min | Same as Predecessor |
| Memory | 60 x memory | 60 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 | TORAY Toyolac2920 |
| Start/Stop button | Acrylonitrile butadiene styrene | TORAY Toyolac2920 |
| Memory button | Acrylonitrile butadiene styrene | TORAY Toyolac2920 |
| 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 |
| Outer Cloth | Polyvinyl chloride | PVC95F |
| Inner Cloth | Nylon | FTY140S |
| Fastener Hook | Nylon | A9663Y |
| Fastener Loop | Polyvinyl chloride | PVC95F |
| Bias | Polyester | #5000-25 |

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