

-NEW PRODUCT INFORMATION SHEETS-



Specifications subject to change
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Sales Name: **M6W**
Item Number: **HEM-7213-E(V)**

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General Information:

| | |
|-----------------------|---|
| Sales Name | M6W |
| Item number | HEM-7213-E(V) |
| Model Category | Blood Pressure Monitor |
| Legal Manufacturer |  OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN |
| Production Facilities | OMRON HEALTHCARE MANUFACTURING VIETNAM CO., LTD. No. 28 VSIP II, Street 2, Vietnam-Singapore Industrial Park II, Binh Duong Industry-Services-Urban Complex, Hoa Phu Ward, Thu Dau Mot Town, Binh Duong Province, VIETNAM |
| Photo of Product |  |
| Packaging Content | Main unit, wide range cuff (22-42 cm), instruction manual, storage case, battery set, guarantee card, blood pressure pass, quick guide |
| EAN Code | 4015672106000 |

Packaging Information:


| Carton | Qty | Approx Weight | Approx dimensions W x D x H mm |
|-----------------------------|-----|---------------|--------------------------------|
| Main unit without batteries | 1 | 380 g | 123 x 158 x 85 |
| Sales Package | 1 | 1150 g | 175 x 115 x 221 |
| Master Carton | 10 | 13.15 Kg | 612 x 375 x 262 |

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
- EN ISO 10993-1: 2009
- EN ISO 10993-5: 2009
- EN ISO 10993-10: 2009
- EN ISO 14971: 2009
- EN 60601-1:1990+A1:1993+A2:1995
- EN 60601-1-2: 2007
- EN 60601-1-4:1996+A1:1999
- 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

M6W (HEM-7213-E(V)) is an automatic blood pressure monitor that has the unique selling points as noted:

- Two users with memory
- 100 memories with date and time for each user (A and B)
- Optimal speed and pressure for gentle inflation/deflation
- Measurement quality confirmation by Dual Sensor
- Irregular heartbeat detection
- Wide range cuff – 22 – 42 cm
- Correct cuff wrapping guide
- Blood pressure level indicator bar
- Movement error symbol

Package Design

Packaging Information:



| Carton | QTY | Approx. Weight | Approx. Dimensions (W) x (D) x (H) |
|---------------|-----|----------------|---------------------------------------|
| Single unit | 1 | 340 g | 123 x 141 x 85 |
| Master carton | 10 | 9.5 Kg | 587 x 292 x 216 |

Instruction Manual Design

OMRON



Automatic Blood Pressure Monitor Model M6W Instruction Manual



All for Healthcare

English

Français

Deutsch

Italiano

Español




Nederlands

Русский

العربية

IM-HEM-7213-E(V)-01-08/2011
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Technical Specifications

| | |
|-----------------------------------|--|
| Product Description | Automatic Blood Pressure Monitor |
| Model | OMRON M6W (HEM-7213-E(V)) |
| 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 | 100 measurements with date and time for each user (A and B) |
| Accuracy | Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of display reading |
| Inflation | Fuzzy-logic controlled by electric pump |
| Deflation | Automatic pressure release valve |
| Rating | DC6V  4W |
| Power Source | 4 "AA" batteries 1.5V or optional AC Adapter (6V = 4W) |
| Battery life | Capacity of new alkaline batteries is approximately 1000 measurements |
| Applied Part |  = Type B |
| Protection Against Electric Shock | Internally powered ME equipment (When using only the batteries)  = Class II ME equipment (Optional AC adapter) |
| 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 / 700-1060hPa |
| Console Weight | Approximately 380g without batteries |
| Cuff Weight | Approximately 170g |
| Outer dimensions | Approximately 123 (w) mm x 85 (h) mm x 158 (l) mm |
| Cuff dimensions | Approximately 151 mm x 635 mm (Cuff: arm circumference 22 to 42 cm) |
| Cuff material | Nylon and polyester |
| Package Content | Main unit, cuff, instruction manual, storage case, battery set, guarantee card, blood pressure pass, quick guide |
| EAN code | 4015672106000 |

Note: Subject to technical modification without prior notice.

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

| | New model | Predecessor |
|--|---|---|
| Model | M3W (HEM 7213-E(V)) | M6 (HEM 7211-E / E8) |
| Measurement Method | Oscillometric | Same as new model |
| Measurement range | Pressure: 0mmHg to 299mmHg Pulse: 40 to 180/min. | Same as new model |
| Memory | 100 measurements with date and time for each user (A and B) | 90 measurements with date and time for one user |
| Accuracy | Pressure: ± 3 mmHg Pulse: $\pm 5\%$ of display reading | Same as new model |
| Inflation | Fuzzy-logic controlled by electric pump | Same as new model |
| Deflation | Automatic pressure release valve | Same as new model |
| Power source | 4 "AA" batteries 1.5V or AC/DC adapter | Same as new model |
| Protection Against Electric Shock | Internally powered ME equipment (When using only the batteries) <input type="checkbox"/> = Class II ME equipment (Optional AC adapter) | Same as new model |
| Operating temperature/ Humidity | +10°C to +40°C Maximum: 30% to 85% RH | Same as new model |
| Storage temperature/ humidity | -20°C to +60°C Maximum: 10% to 95% RH / 700-1060hPa | Same as new model |

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 (Main unit)

| 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 |
| Start Button | Acrylonitrile butadiene styrene | UMG EX-120 or Techno polymer 130 |
| Memory Button | Acrylonitrile butadiene styrene | UMG EX-120 or Techno polymer 130 |
| Clock Button | Acrylonitrile butadiene styrene | UMG EX-120 or Techno polymer 130 |
| Arrow Button | Acrylonitrile butadiene styrene | UMG EX-120 or Techno polymer 130 |
| Slide Button | Acrylonitrile butadiene styrene | UMG EX-120 |
| Front Panel | Polycarbonate | — |
| Air Connector Cap | Acrylonitrile butadiene styrene | UMG EX-120 |
| Foot Rubber | Polyurethane | 3M SJ-5816 |
| Battery Contact | SWC-CU or CP wire | 15LSCD Ep-Fe/Ni or 15CP Ep-FE/Ni |

List of Materials (Medium Cuff)

| Item | Material | Grade |
|------------------------|--------------------------|---|
| Bias Tape | Polyester | #EX3001 |
| Cloth covering | Polyester | #P165T |
| Air Tube | PVC | DIC G-261 |
| Hook and Loop fastener | Hook: PVC Loop: Nylon | Hook: 1991# Loop: Pantone Cool Gray 7C |
| Metal Ring | SWRM | |
| Air plugs to device | ABS | |
| Air plug to cuff | PVC | DIC G-263 |

Maintenance and storage

Maintenance

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

- Do not subject the main unit and the cuff to extreme temperatures, humidity, moisture or direct sunlight.
- Do not fold the cuff or tubing tightly.
- Do not disassemble the unit.
- Do not subject the unit to strong shocks or vibrations (for example, dropping the unit on the floor).
- Do not use volatile liquids to clean the main unit.
- Do not wash the arm cuff or immerse it in water.
- Do not use petrol, thinners or similar solvents to clean the arm cuff.
- Do not carry out repairs of any kind yourself. If a defect occurs, consult your OMRON retail outlet or distributor as mentioned on the packaging.
- 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 authorised OMRON dealer or the OMRON Customer Service at the address given on the packaging or attached literature.

Storage

Keep the unit in its storage case when not in use.

1. Unplug the air plug from the air jack.

2. Gently fold the air tube into the arm cuff.

Note: Do not bend the air tube excessively.





3. Place the arm cuff and main unit in the storage case.

Do not store the unit in the following situations:

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

Optional Accessories

1. Cuffs

| Wide Range Arm Cuff | Medium Arm Cuff | Large Arm Cuff |
|---|---|---|
| Arm Circumference 22-42 cm | Arm Circumference 22-32 cm | Arm Circumference 32-42cm |
|  |  |  |
| Small Arm Cuff | | |
| Arm Circumference 17-22 cm | | |
|  | | |

2. AC Adapter S

Adapter S – 9515336-9

