

New Product Information Sheet

Specifications subject to change
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Model (code):
M6 Comfort (HEM-7360-E)
X6 Comfort (HEM-7360-EO)



| Versions | Remark | Date |
|----------|---|-------------------------------|
| 1 | Logistics and Harmonized Standards info not complete; | 31.07.2019 |
| 2 | Full NPIS | Expected date – end of August |

Intelli Wrap Cuff

The easy way to get accurate results

Product Name: M6 Comfort (HEM-7360-E), X6 Comfort (HEM-7360-EO)

Product Description: Automatic Upper Arm Blood Pressure Monitor

Product Category: Electronic Sphygmomanometers

Features

- Intelli wrap cuff
- Afib indicator function
- Clinically validated in general populations, and for people who are pregnant or have diabetes
- 2 Users, 100 memories, and Guest Mode
- 3x consecutive measurement functionality
- Cuff Wrap Guide

Packaging content

- Monitor
- Arm Cuff (HEM-FL31)
- 4 "AA" batteries
- Storage Case
- Instruction Manual 1 & 2
- Setup Instructions

Logistic information

| Package | Amount | Approximate weight | Approximate dimensions |
|-----------------------|---|----------------------|-------------------------------------|
| Main Unit | 1 | 460g (w/o batteries) | 191 mm (w) x 85 mm (h) x 120 mm (l) |
| Single Package | 1 | Xxxg | 157 mm x 120 mm x 223 mm |
| Master Carton | 10 | Xxxkg | 633 mm x 340 mm x 263 mm |
| EAN code | M6 Comfort : 401567211174 5 , X6 Comfort : 401567211215 5 | | |

Storage & transport

Temperature: - 20 to +60°C

Humidity: 10% to 90%

Technical data

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|---|--|
| Product description | Automatic Upper Arm Blood Pressure Monitor |
| Product Category | Electronic Sphygmomanometers |
| Model (code) | M6 Comfort (HEM-7360-E) X6 Comfort (HEM-7360-EO) |
| Measurement method | Oscillometric method |
| Display | LCD digital display |
| Cuff Pressure range | 0 to 299 mmHg |
| Pulse measurement range | 40 - 180 beats/min |
| Blood pressure measurement range | SYS 60 to 260 mmHG, DIA: 40 to 215 mmHG. |
| Accuracy | Pressure +- 3mmHg, Pulse +-5% of display reading |
| Inflation | Automatic by electric pump |
| Deflation | Automatic pressure release valve |
| Operating mode | Continuous operation |
| IP classification | Monitor: IP 20/ Optional AC adapter: IP21 |
| Rating | DC6 V 4.0 W |
| Applied part | Type BF (arm cuff) |
| Power Source | 4 "AA" batteries 1.5 V or optional AC adapter (input AC 100-240 V 50-60 Hz 0.12 -0.065 A) |
| Battery life | Approximately 1000 measurements (using new alkaline batteries) The number of times may decrease when using Afib mode because one Afib indication consists of 3 regular measurements. |
| Durable period (Service life) | Monitor: 5 years / Cuff: 5 years / Optional AC adapter: 5 years |

| | |
|---|---|
| Operating conditions | +10 to +40 °C / 15 to 90% RH (non-condensing)/ 800 to 1060 hPA |
| Storage / Transport conditions | -20 to +60 °C / 10 to 90% RH (non-condensing) |
| Protection against electric shock | Internally powered ME equipment (when using only batteries) Class II ME equipment (optional AC adapter) |
| Cuff circumference applicable to the monitor | 220 to 420 mm |
| Memory | Stores up to 100 readings per user |
| Warranty | 3 years |
| Weight | Monitor: approximately 460 g (not including batteries) / Arm cuff: approximately 163 g |
| Dimensions (approximate value) | Monitor: 191 mm (W)× 85 mm (H)× 120 mm (L), Arm cuff: 145 mm × 532 mm (air tube: 750 mm) |
| Contents | Monitor, arm cuff (HEM-FL31), 4 "AA" batteries, Instruction Manual 1 and 2, setup instructions, storage case. |
| Optional accessories | AC Adapter (HHP-CM01), AC Adapter UK version (HHP-BFH01), Arm cuff (HEM-FL31). |

General description

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. It is mainly designed for general household use. The device can detect an irregular pulse suggestive of Atrial Fibrillation (Afib).

Please note that the device is not intended to diagnose Afib. A diagnosis of Afib can only be confirmed by an Electrocardiogram (ECG). If the Afib symbol appears, consult with your physician.

Packaging content

The manufacturer produces M6 Comfort / X6 Comfort with the applicable accessories included, necessary for the application of its intended purpose.

1. Monitor
2. Arm cuff (HEM-FL31)
3. 4 "AA" batteries
4. Instruction Manual 1 and 2
5. Setup instructions
6. Storage case

The complete set of the medical device is specified in the Instruction Manual 1 in the Specifications section.

Purpose

The device is intended for use in measuring blood pressure and pulse rate in adult patient population. It detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Application field

It is mainly designed for general household use.

Intended User

This unit is intended to be operated by adults who can understand this instruction manual.

Before using this device please refer to 'Important Safety Information' section of the Instruction Manual 1 and 2.

This device shouldn't be used by people mentioned in these sections.

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)

The M6 Comfort Automatic Upper Arm Blood Pressure Monitor is a clinically validated device.

Key features:

- Afib indicator function
- Intelli Wrap Cuff
- 2 users x 100 memories, + guest mode
- 3x consecutive measurement functionality
- CuffWrap Guide

Description of operating principle

The device operates on the oscillometric principle. It detects blood movement through the brachial artery and converts the movements into a digital reading.

How to use the device

Follow IM2 for detailed instructions!

Main steps:

1. Prepare for a measurement. 30 mins before it you shouldn't drink alcohol, smoke, have a hot shower, consume hot beverages, eat or exercise. 5 minutes before the measurement relax and rest.
2. Install the batteries.
3. Set the date and time.
4. Apply the arm cuff on the left arm. (On using the right arm instead, consult Chapter 2.3 of IM1).
5. Sit correctly and place your arm at your heart's level. Remain still and don't talk.
6. Select user ID (1 or 2).
7. Take the measurement by pressing the START/STOP button. In the Afib mode, your monitor automatically takes 3 consecutive readings at 30-second intervals and display the average.
8. Check the readings. Consult Section 9 of IM2 on the symbols that may appear.

9. After selecting your used ID, you can use the memory functions (readings stored, average of the latest 2-3 readings, clear memory).

Please, review Instruction Manual 1 and 2 for the full details on the application of this product.

Materials used in main device

| Parts Name | Material |
|--------------------|---------------------------------------|
| Housing | ABS (acrylonitrile butadiene styrene) |
| Battery Cover | ABS (acrylonitrile butadiene styrene) |
| Front Panel | ABS (acrylonitrile butadiene styrene) |
| Button | ABS (acrylonitrile butadiene styrene) |
| Package | Coated board |
| Instruction Manual | Paper |


Materials for accessories

| Parts name | Material | |
|------------|--------------------|---------------------------------------|
| Cuff | Cloth, fabric | Nylon, PVC (Polyvinyl Chloride) |
| | Air Tube | PVC (Polyvinyl Chloride) |
| | Air plug to device | ABS (acrylonitrile butadiene styrene) |
| | Air plug to cuff | PC (Polycarbonate) |
| AC Adapter | DC Cord | PVC (Polyvinyl Chloride) |
| | Print case | PPE (Polyphenylene Ether) |

Title page of Instruction Manuals

IM1:

Instruction Manual
1



Automatic Upper Arm Blood Pressure Monitor

M6 Comfort (HEM-7360-E)
X6 Comfort (HEM-7360-EO)

Read Instruction manual ① and ② before use.

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All for Healthcare

CE0197

IM2:

Instruction Manual
2



Automatic Upper Arm Blood Pressure Monitor

M6 Comfort (HEM-7360-E)
X6 Comfort (HEM-7360-EO)

Intellisense

All for Healthcare

Read Instruction manual ① and ② before use.

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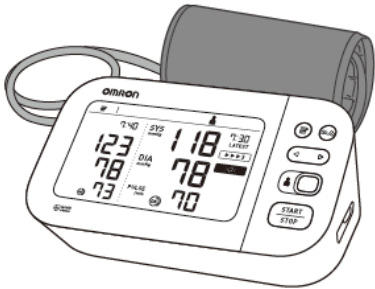
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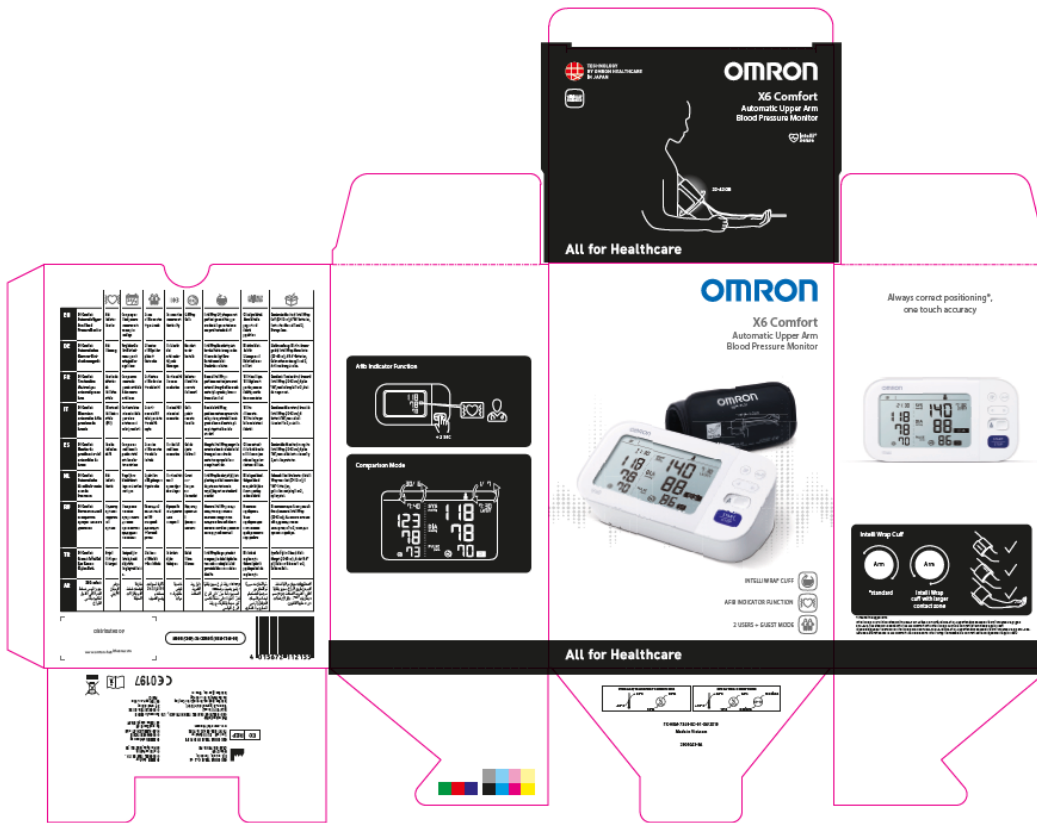
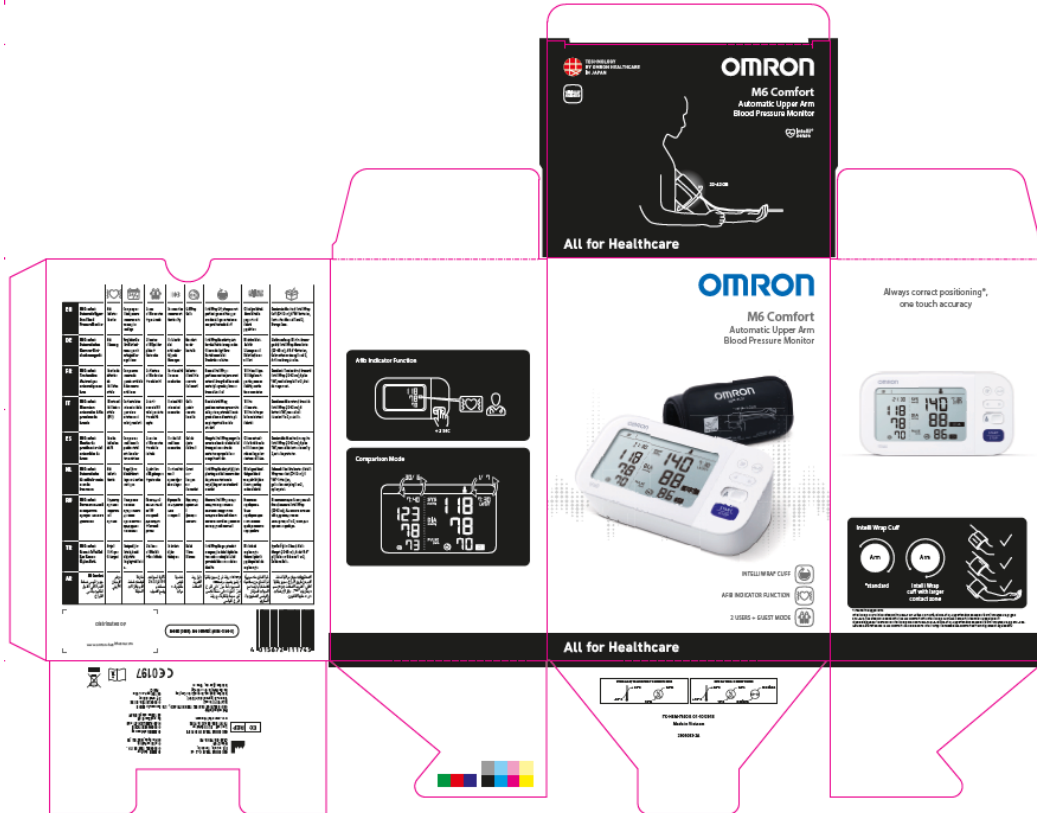
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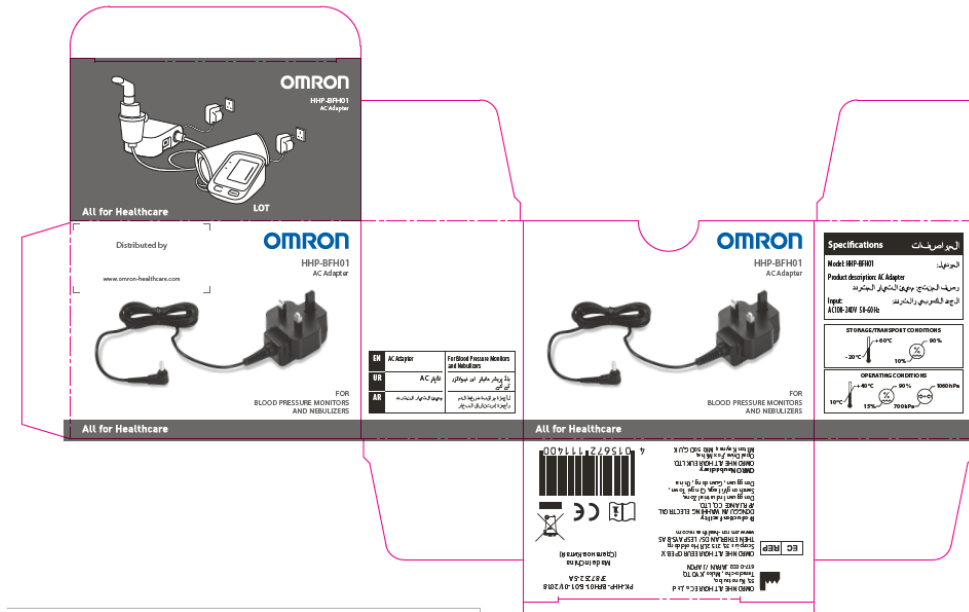


Unfolded package design of main device and accessories

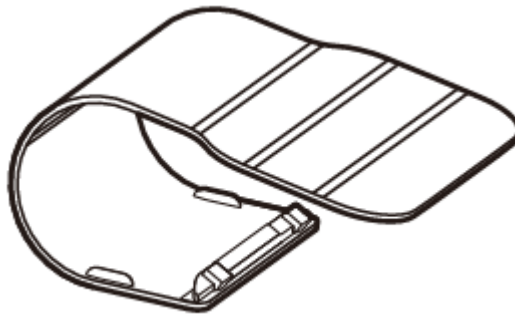
Main device:



AC Adapter (HHP-BFH01)



Other optional parts: Protective LCD Cover (HEM-CACO-734)



List of Harmonized EN Standards

Applicable Directives: Medical Device Directive (MDD) 93/42/EEC

Full list of Harmonized standards will be included in the next revision of the document.

Cleaning of the device

- Do not use any abrasive or volatile cleaners.

- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and arm cuff, and then wipe them with a dry cloth.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners or similar

Maintenance

This device does not require any regular maintenance.

Storage

Keep your monitor in the storage case when not in use.

1. Remove the arm cuff from the monitor.

Caution! To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.

2. Gently fold the air tube into the arm cuff. Note: Do not bend or crease the air tube excessively.

3. Place your monitor and other components in the storage case.

- Store your monitor and other components in a clean, safe location.

Do not store your monitor and other components:

- If your monitor and other components are wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.

Warnings

(Warning indicate a potentially hazardous situation which, if not avoided, could result in death or serious injury.)

It is important that you read all the warnings and precautions included in this instruction manual because they are intended to keep you safe, prevent injury and avoid a situation that could result in damage to the unit!

- 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 arm or an arm under medical treatment.
- DO NOT apply the arm cuff on your arm 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.
- To help avoid strangulation, keep the air tube and AC adapter cable away from infants, toddlers and children.
- This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children.

AC Adapter (optional accessory) Handling and Usage

- DO NOT use the AC adapter if this monitor or the AC adapter cable is damaged. If this monitor or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

Battery Handling and Usage

- Keep batteries out of the reach of infants, toddlers and children.

Cautions

(Cautions indicate 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.)

- 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 an arm where intravascular access or therapy, or an arteriovenous (A-V) shunt, is present because of temporary interference to blood flow and 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 arm cuff when it is applied on your upper arm.
- Remove the arm 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 emit 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 or on an aircraft.
- 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 section 6.
- During measurement, observe the arm to ensure that the monitor is not causing prolonged impairment to blood circulation.
- 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 or thick clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm 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 on operating and storage/transport temperature, refer to section 6.
- DO NOT use this monitor after the durable period has ended. Refer to section 6.
- DO NOT crease the arm cuff or the air tube excessively.
- DO NOT fold or kink the air tube while taking a measurement. This may cause an injury by interrupting blood flow.
- To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.
- ONLY use the AC adapter, arm cuff, batteries and accessories specified for this monitor. Use of unsupported AC adapters, arm cuffs and batteries may damage and /or may be hazardous to this monitor.

- ONLY use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- Inflating to a higher pressure than necessary may result in bruising of the arm here the cuff is applied. NOTE: refer to "If your systolic pressure is more than 210 mmHg" in section 11 of instruction manual 2 for additional information.
- Read and follow the "Correct Disposal of This Product" in section 7 when disposing of the device and any used accessories or optional parts.

AC Adapter (optional accessory) Handling and Usage

- Fully insert the AC adapter into the outlet.
- When unplugging the AC adapter from the outlet, be sure to safely pull from the AC adapter. DO NOT pull from the AC adapter cable.
- When handling the AC adapter cable:
Do not damage it. / Do not break it. / Do not tamper with it.
DO NOT pinch it. / Do not forcibly bend or pull it. / Do not twist it.
DO NOT use it if it is gathered in a bundle.
DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this monitor.

Battery Handling and Usage

- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 4 "AA" alkaline or manganese 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.

General precautions:

When you take a measurement on the right arm, the air tube should be at the side of your elbow. Be careful not to rest your arm on the air tube.

- Blood pressure may differ between the right and left arm and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.
- Remember to have a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. Please use the Blood Pressure Diary to keep records of several readings over a certain period of time. To download PDF files of the diary, visit www.omron-healthcare.com.

Disposal

Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Transportation and storage conditions

Do not store the device in the following situations:

- If the device is wet.
- Locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- Locations exposed to vibrations, shocks or where it will be at an angle.

Storage and transportation conditions:

1. Temperature range: -20 to +60°C
2. Humidity range: 10 to 90% RH

Warranty and lifetime

The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

| | Warranty | Lifetime (Service Life) |
|-------------|----------|-------------------------|
| Monitor: | 3 years | 5 years |
| Cuff: | 1 year | 5 year |
| AC Adapter: | 1 year | 5 years |

Repair

During the period of warranty OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts. Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.

Servicing

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.

Should warranty service be required please apply to the dealer whom the product was purchased from or an authorized OMRON distributor. For the address refer to the product packaging / literature or to your specialized retailer. If you have difficulties in finding OMRON customer services, contact us for information:

www.omron-healthcare.com.

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