

New Product Information Sheet

Specifications subject to change
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Model (code):

M3 Comfort (HEM-7155-E(C))



Versions	Remark	Date
1	Complete NPIS	17.11.2021

Intelli Wrap Cuff
THE **EASY**
WAY TO GET
ACCURATE
RESULTS

So you can get
on with the things
you love to do.

Intelli Wrap Cuff
Accurate results in
any position around
the upper arm¹

Irregular heartbeat
detection
Alerts you during
your reading

Cuff wrap guide
To let you know the cuff
is wrapped correctly



TAKE TIME
FOR YOUR HEART



M3 Comfort

Automatic Upper Arm Blood Pressure Monitor

1. Bilo G, Sala O, Perego C, et al. Impact of cuff positioning on blood pressure measurement accuracy: may a specially designed cuff make a difference? Hypertens Res. 2017;40(6):573-580. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5506235/>. Last accessed July 2019.

GOING
FOR **ZERO**

Intelli Wrap Cuff

The easy way to get accurate results

Product Name: M3 Comfort (HEM-7155-E(C))

Product Description: Automatic upper arm blood pressure monitor

Product Category: Electric Sphygmomanometers

Features

- Intelli Wrap Cuff (HEM-FL31)
- Irregular Heartbeat Detection
- 2 Users, 60 memories & Guest mode
- Clinically validated in general populations, and for people who are pregnant or have diabetes
- Cuff Wrap Guide

Packaging content

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

Logistic information

Package	Amount	Approximate weight	Approximate dimensions
Main Unit	1	340g (w/o batteries)	105 mm (w) x 152 mm (d) x 85 mm (h)
Single Package	1	800g	187 (w) mm x 113 mm (d) x 175 mm (h)
Master Carton	10	9.1kg	598 mm (w) x 400 mm (d) x 215 (h)
EAN code	401567211348 0		

Storage & transport

Temperature: - 20 to +60°C

Humidity: 10% to 90%

Technical data

Product description	Automatic Upper Arm Blood Pressure Monitor
Product Category	Electronic Sphygmomanometers
Model (code)	M3 Comfort (HEM-7155-E(C))
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)
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	Internally powered ME equipment (when using only

electric shock	batteries) Class II ME equipment (optional AC adapter)
Memory	Stores up to 60 readings per user
Warranty	Monitor: 3 years / Optional parts: 1 year
Weight	Monitor: approximately 340 g (not including batteries) / Arm cuff: approximately 163 g
Dimensions (approximate value)	Monitor: 105 mm (W)× 85 mm (H)× 152 mm (L), Arm cuff: 145 mm × 532 mm (air tube: 750 mm)
Contents	Monitor, Intelli Wrap Cuff (HEM-FL31), 4 "AA" batteries, storage case, Instruction Manual 1 and 2
Optional accessories	AC adapter (HHP-CM01), AC Adapter UK version (HHP- BFH01)

General description

Thank you for purchasing the OMRON Automatic Upper Arm Blood Pressure Monitor. This blood pressure monitor uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

Purpose

This 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.

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 Precautions and Warnings' section of the instruction manual. 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 M3 Comfort Automatic Upper Arm Blood Pressure Monitor is a clinically validated device.

Key features:

- Irregular Heartbeat Detection
- 2 users x 60 memories, + guest mode
- Cuff Wrap 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.
7. Take the measurement by pressing the START/STOP button.
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
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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

OMRON

Automatic Upper Arm Blood Pressure Monitor

M3 Comfort (HEM-7155-E(C))

X3 Comfort (HEM-7155-EO(C))

EN

FR

DE

IT

ES

NL

RU

TR

AR

Symbols

Read Instruction manual ① and ② before use.

FR Lire le mode d'emploi ① et ② avant l'utilisation.

DE Lesen Sie vor der Verwendung die Gebrauchsanweisung ① und ②.

IT Leggere il manuale di istruzioni ① e ② prima dell'uso.

ES Lea el manual de instrucciones ① y ② antes del uso.

NL Lees de gebruiksaanwijzing ① en ② voor gebruik.

RU Прочтите руководство по эксплуатации ① и ② перед использованием.

TR Kullanmadan önce, kullanım kılavuzu ① ve ②'yi okuyun.

AR اقرأ دليل الإرشادات ① و ② قبل الاستخدام.

Symbols / Symbole / Simboli / Símbolos /
Symbolen / Cimbboni / Semboller / الرمز

All for Healthcare

CE0197

Instruction Manual

2

OMRON

Automatic Upper Arm
Blood Pressure Monitor

M3 Comfort (HEM-7155-E(C))

X3 Comfort (HEM-7155-EO(C))



All for Healthcare



IM2-HEM-7155-E(C)-01-09/2021
3292459-4A

Read Instruction manual ① and ② before use.

FR Lire le mode d'emploi ① et ② avant l'utilisation.

DE Lesen Sie vor der Verwendung die Gebrauchsanweisung ① und ②.

IT Leggere il manuale di istruzioni ① e ② prima dell'uso.

ES Lea el manual de instrucciones ① y ② antes del uso.

NL Lees de gebruiksaanwijzing ① en ② voor gebruik.

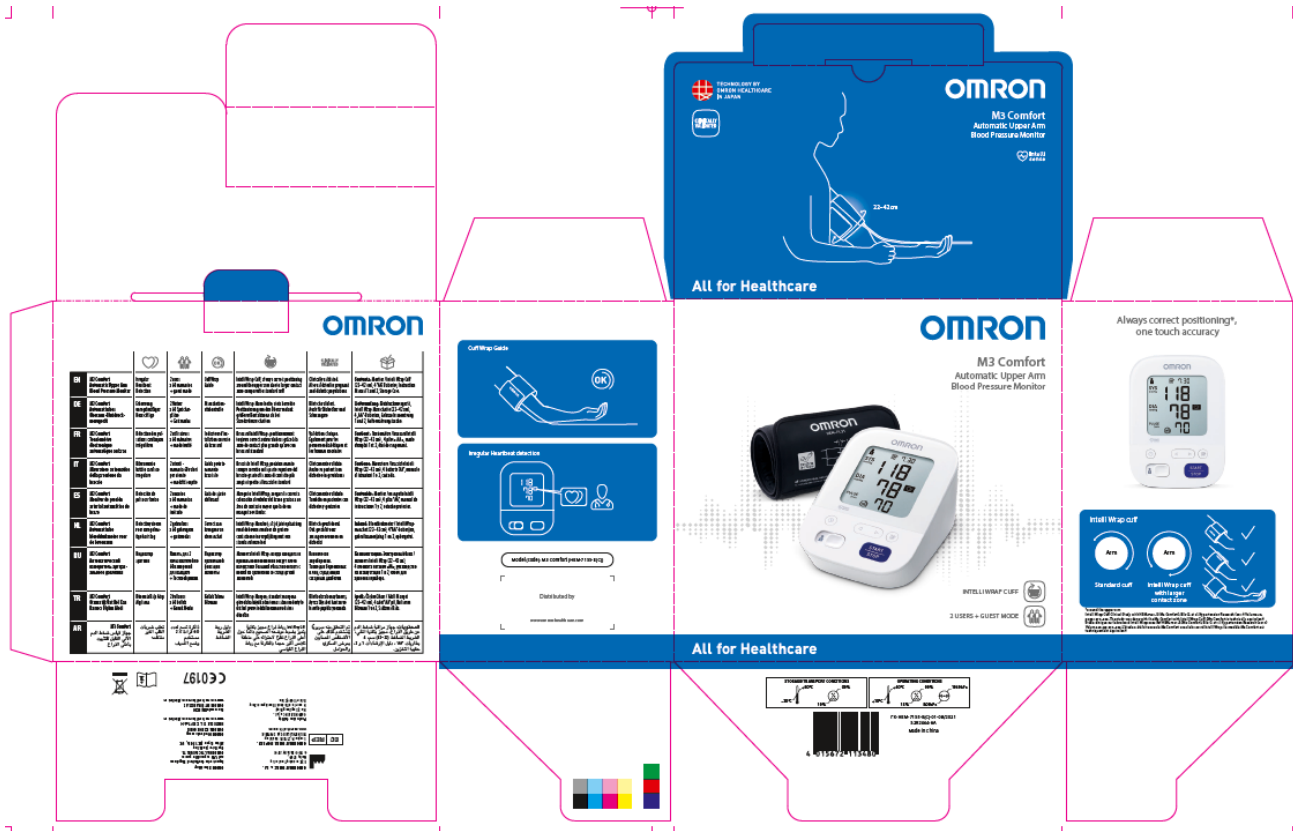
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AR اقرأ دليل الإرشادات ① و ② قبل الاستخدام.

Unfolded package design of main device and accessories

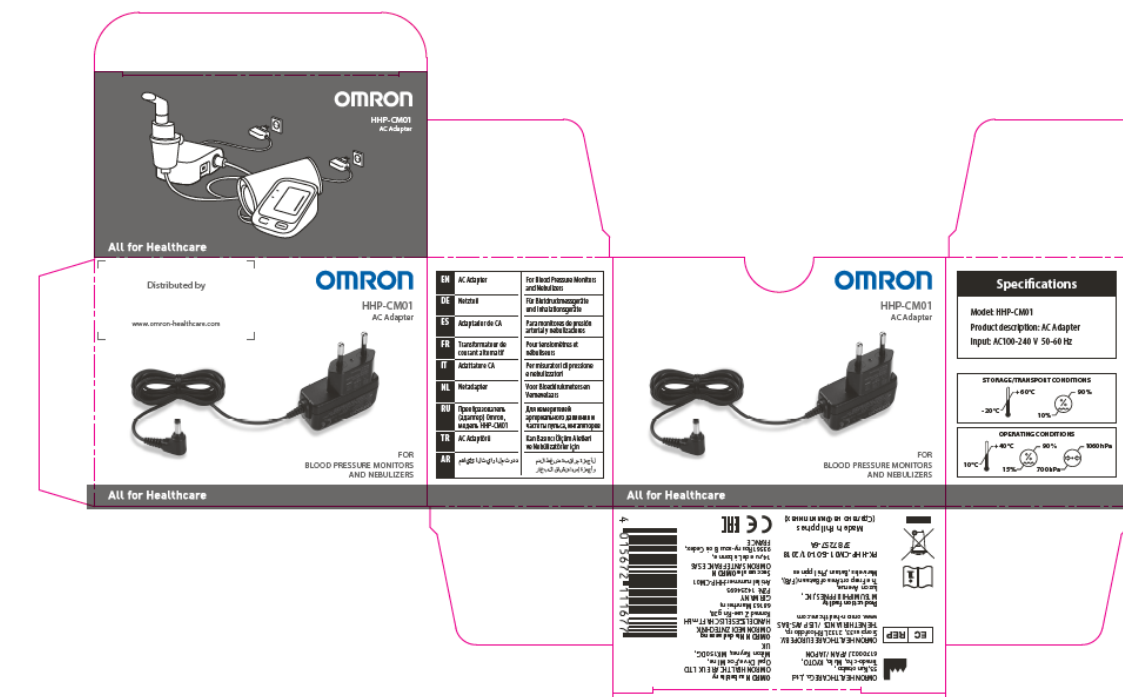
Main device:



Accessories: Arm Cuff (HEM-FL31)



AC Adapter (HHP-CM01)



AC Adapter (HHP-BFH01)



List of Harmonized EN Standards

The device is classified as a medical device, Class IIa (MDR Annex VIII Rule 10)
Applicable Directives:

Medical Device Regulation (EU) 2017/745

EN 1041:2008+A1:2013

EN 1060-1:1995+A2:2009

EN 1060-3:1997+A2=2009

EN 60601-1:2006+A1:2013+A12:2014

EN 60601-1-2:2015

EN 60601-1-6:2010+A1:2015

EN 60601-1-11:2015

EN 62304:2006+A1:2015

EN 62366-1:2015

EN 80601-2-30:2010+A1:2015

EN ISO 10993-1:2020

EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 13485:2016
EN ISO 14971:2019
EN ISO 15223-1:2016
EN ISO 81060-2:2014

RoHS Directive 2011/65/EU,
(EU)2015/863 and (EU)2017/2102
EN IEC 63000:2018

Operation and care

Cleaning of the device

The device should be cleaned with a soft dry cloth, or a soft cloth moistened with neutral soap to clean on the monitor and the arm cuff.

- 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 solvents to clean your monitor and arm cuff or other components.

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 where 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 authorised 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 authorised OMRON distributor. For the address refer to the product packaging / literature or to your specialised retailer. If you have difficulties in finding OMRON customer services, contact us for information: www.omron-healthcare.com.

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