

New Product Information Sheet

Specifications subject to change
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Model (code): Complete (HEM-7530T-E3)



Versions	Remark	Date
1	Without DoC content + key visual	30/09/2020

Complete

2-in-1 home blood pressure and ECG monitoring

Product Name: Complete (HEM-7530T-E3)

Product Description: Automatic Upper Arm Blood Pressure Monitor + ECG

Product Category: Electronic Sphygmomanometers with ECG function


Features:

- ECG Recording
- Blood Pressure Measurement
- Afib indicator function
- Record measurements
- Intellisense technology
- Cuff Wrap Guide
- Clinically validated
- Omron connect

Packaging content:

- Monitor
- Arm Cuff (HEM-RML31-E)
- 4 "AA" alkaline batteries
- Storage Case
- Instruction Manual
- Setup Instructions
- Blood Pressure Diary

Logistic information

Package	Amount	Approximate weight	Approximate dimensions (wxdxh)
Main Unit	1	550g (w/o batteries)	232 mm x 123 mm x 98 mm
Single Package	1	1630 g	140 mm x 160 mm x 246 mm
Master Carton	6	10.7 kg	511 mm x 306 mm x 287 mm
UDI-ID (Unique Device Identifier) / EAN code	 4 015672 112865		

Storage & transport

Temperature: - 20 to +60°C

Humidity: 10% to 90%

Technical data

Product category	Electronic Sphygmomanometers with ECG function
Product description	Automatic Upper Arm Blood Pressure Monitor Single lead electrocardiogram
Model (code)	Complete (HEM-7530T-E3)
BP reading display	LCD digital display
Operation mode	Continuous operation
IP classification	IP 21
Rating	DC6 V 4 W
Power source	4 "AA" alkaline batteries 1.5 V
Battery life	Approximately 300 measurements (using new alkaline batteries)
Durable period / Service life	Monitor: 5 years Cuff: 5 years
Operating conditions	+10 °C to +40 °C / 15 to 90 % RH (non-condensing) / 800 to 1060 hPa
Storage / Transport conditions	-20 °C to +60 °C / 10 to 90 % RH (non-condensing)
Weight	Monitor: Approximately 550 g not including batteries Arm cuff: Approximately 170 g
Dimensions	Monitor: Approximately 232 mm (w) × 98 mm (h) × 123 mm (l) Arm cuff: Approximately 145 mm × 594 mm (air tube: 750 mm)
Applied part	Type BF (arm cuff), Type CF (electrodes)
Protection against electric shock	Internally powered ME equipment
Maximum temperature of the applied part	Lower than +48 °C
Contents	Monitor, arm cuff (HEM-RML31), storage case, 4 "AA" alkaline batteries, instruction manual, setup instructions, blood pressure diary

Blood pressure measurement:

Cuff pressure range	0 to 299 mmHg
Blood pressure measurement range	SYS: 60 to 260 mmHg DIA: 40 to 215 mmHg
Pulse measurement range	40 to 180 beats / min.
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % of display reading
Inflation	Automatic by electric pump
Deflation	Automatic pressure release valve
Measurement method	Oscillometric method
Transmission method	Bluetooth® Low Energy
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz) Modulation: GFSK Effective radiated power: <20 dBm
Cuff circumference applicable to the monitor	17 to 42 cm (included arm cuff: 22 to 42 cm)
Internal memory	Stores up to 90 blood pressure readings

ECG recording:

Performance characteristics	ECG channel: Single channel Input dynamic range: 10 mV Peak-to-Peak
Circuitry	Frequency response: 0.67 Hz to 40 Hz CMRR: > 60 dB Input Impedance: > 10 M Ω
Output	Modulation: Frequency modulated ultrasonic audio tone Center frequency: 19 kHz Modulation index: 200 Hz/mV
Accuracy of Afib algorithm	98% sensitivity and 97% specificity ¹ 1. Lau JK, Lowres N, Neubeck L, Brieger DB, Sy RW, Galloway CD, et al. Int J Cardiol. 2013;165(1):193-4

General description

Thank you for purchasing the OMRON Complete Automatic Upper Arm Blood Pressure Monitor + ECG.

This monitor has 2 main features: a blood pressure measurement and an electrocardiogram (ECG or EKG) recording.

There are 3 ways to use this monitor: measuring blood pressure only; ECG only; blood pressure and ECG simultaneously.

Visit the "Help" section in the "OMRON connect" app for additional information about using the app.

Packaging content

The manufacturer produces Complete with the applicable accessories included, necessary for the application of its intended purpose.

1. Monitor
2. Arm cuff (HEM-RML31)
3. 4 "AA" batteries
4. Storage case
5. Instruction Manual
6. Setup instructions
7. Blood pressure diary

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

Purpose

The device is intended to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously.

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.

The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms.

The device in combination with a smartphone, displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm.

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Application field

It is designed for general household use.

Intended User

The device is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious individuals in a general household situation. The device has not been tested and it is not intended for pediatric use.

Indications for use

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population. The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms.

Features (Particularities)

The Complete Automatic Upper Arm Blood Pressure Monitor and Single Lead Electrocardiogram is a clinically validated device.

Key features:

- ECG Recording
- Blood Pressure Measurement
- Afib indicator function
- Record measurements
- Omron connect
- Intellisense technology
- Cuff Wrap Guide
- Clinically validated

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.

The device in combination with a smartphone, displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm.

How to use the device

Main steps:

Preparations:

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. Download and install the "OMRON connect" App
3. Install the batteries.
4. Pair your monitor with your smartphone. When the monitor is successfully connected, the OK symbol flashes. Bluetooth must be enabled!
5. Set the date and time.

Taking a Blood Pressure measurement and Recording an ECG:

6. Apply the arm cuff on the left arm. (If using the right arm instead, consult Chapter 3.3.3 of the IM). Attach the arm cuff to the monitor.
7. Sit correctly and place your arm at your heart's level. Remain still and don't talk.
8. Open the OMRON connect app on your smartphone
9. Follow the instructions to start an ECG recording on your smartphone and place the phone on the smartphone stand of your monitor
10. Press the BP (START/STOP) button to take a blood pressure measurement
11. Put your thumbs on the top electrodes and 2 or more fingers on each of the side electrodes. Once all 4 electrodes are covered, the ECG recording will automatically start
12. Remain still and don't talk until the measurement and recording process is over

Blood Pressure Measurement: the blood pressure and pulse rate are first displayed on the monitor, then the readings transfer to your phone.

ECG Recording: The app starts a 30-second countdown and shows the ECG wave on your smartphone. After completion of the recording, an ECG analysis result appears. It may show: Possible Afib, Bradycardia, Tachycardia, Normal, Unreadable, Unclassified or other messages. The blood pressure reading will also appear on the phone screen.

13. Release the electrodes and remove the arm cuff.
14. Press the BP (START/STOP) button to turn the monitor off.

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

Optional medical accessories

<i>Product Description</i>	<i>Model</i>
Upper Arm Blood Pressure Monitor Cuff	HEM-RML31
Upper Arm Blood Pressure Monitor Cuff	HEM-CS24

Materials used in main device

Item	Parts	Material
Package	Package	Coated board + E/F
	Soft case	PU (polyurethane)
	Instruction manual	Wood free paper
	Setup instructions	Wood free paper
	BP Diary	Wood free paper
Main unit	Front housing	ABS (acrylonitrile butadiene styrene)
	Ground housing	ABS
	Power switch	ABS
	Communication switch	ABS
	LCD panel	PC (Polycarbonate)
	Rubber plate	TPU (thermoplastic polyurethane)
	Electrode plate	SUS304
	Earth electrode	SUS304
	Battery cover	ABS
	Rubber foot	PU
	Air connector cap	ABS

Materials for accessories

Item	Parts	Material
Cuff HEM- RML31*	Air plug	ABS
	Inner cloth	Polyester / PVC
	Outer cloth	Nylon / PVC
	Tube	PVC (polyvinyl chloride)
	Bias	Polyester / Cotton
	Hook Fastener	Polyester
	Nipple	PVC
	Ring	Steel
Cuff HEM- CS24	Air plug	ABS
	Inner cloth	Polyester / PVC
	Outer cloth	Nylon / PVC
	Tube	PVC
	Bias	Polyester / Cotton
	Hook Fastner	Polyester
	Nipple	PVC
	Ring	Steel

*Cuff provided with the main device

Title page of the Instruction Manual



OMRON



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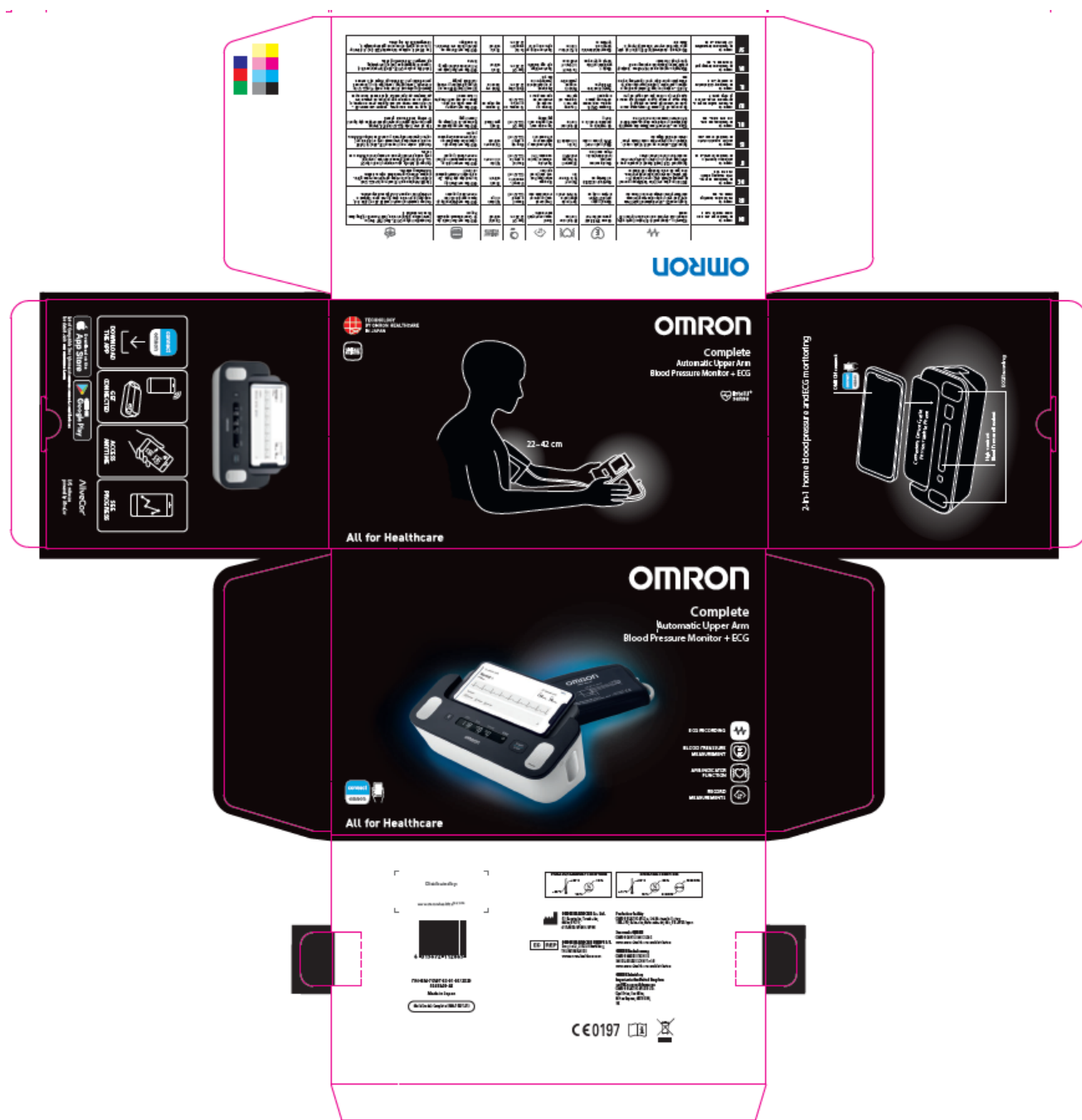
**Automatic Upper Arm Blood Pressure Monitor + ECG
Complete (HEM-7530T-E3)
Instruction Manual ①**

All for Healthcare



Unfolded package design of main device and accessories

Main device:



Accessories: Arm Cuff (HEM-RML31)



Accessories: Arm Cuff (HEM-CS24)



List of Harmonized EN Standards (tbc)

The device is classified as a medical device, Class IIa (MDD Article 9 Annex IX Rule 10)

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

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 the arm cuff and then wipe them with a dry cloth.
- When electrodes are dirty, use a soft cloth or cotton swab moistened with alcohol-based sanitizer to clean the electrodes.
- Do not use alcohol to clean any other parts, and use it only to clean electrodes.
- 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

To protect your monitor from damage, follow the directions below:

- Changes or modifications not approved by the manufacturer will void the user warranty.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate blood pressure readings and/or ECG recordings.

Storage

Keep your monitor and other components in the storage case when not in use.

- Store your monitor and other components in a clean, safe location.
 1. Remove the arm cuff from the monitor.
(Pull the air plug in a straight way from the air jack. It clicks during pulling out).

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

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

Do not store your monitor and other components:

- If the 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 and/or ECG recordings. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure and other heart related conditions.
- DO NOT use this monitor on an injured arm/fingers or an arm/fingers 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 blood pressure readings and/or ECG recordings.
- 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 blood pressure readings and/or ECG recordings.

- NEVER diagnose or treat yourself based on your blood pressure readings and/or ECG recordings. ALWAYS consult with your physician.
- Keep components out of the reach of infants, toddlers and children. This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers and children.
- DO NOT record an ECG with a cardiac pacemaker, Implantable Cardioverter Defibrillators, or other implanted electronic devices.

Data Transmission

- This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the **Bluetooth®** feature in this monitor, remove batteries when in RF restricted areas.

Battery Handling and Usage

- Keep batteries out of the reach of infants, toddlers and children.
- To help avoid strangulation, keep the air tube away from 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 arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which 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 blood pressure 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 blood pressure measurement.
- When the monitor malfunctions, it may get hot. DO NOT touch the monitor if it occurs.
- DO NOT use this monitor for any purpose other than measuring blood pressure and/or recording an ECG.
- During a blood pressure measurement and/or an ECG recording, make sure that no mobile device or any other electrical device that emits electromagnetic fields, other than the smartphone to be used with the monitor, is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause inaccurate blood pressure readings and/or ECG recordings.
- DO NOT disassemble or attempt to repair this monitor or other components. This may cause inaccurate blood pressure readings and/or ECG recordings.
- 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, on an aircraft or during physical activity.
- DO NOT drop or subject this monitor to strong shocks or vibrations.
- DO NOT use or store this monitor in places with high or low humidity, high or low temperatures or in bright and sunny environments. Refer to section 14.
- Ensure this monitor is not impairing blood circulation by observing the arm while blood pressure measurement is occurring.
- 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 devices and/or cause an inaccurate blood pressure readings and/or ECG recordings.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a blood pressure measurement.

- Rest for at least 5 minutes before taking a blood pressure measurement.
- Remove tight-fitting and thick clothing from your arm while taking a blood pressure measurement.
- Remain still and DO NOT talk while taking a blood pressure measurement.
- Remain still while recording an ECG.
- 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 blood pressure measurement and/or recording an ECG. Taking a blood pressure measurement and/or recording an ECG after an extreme temperature change could lead to an inaccurate blood pressure readings and/or ECG recordings. 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 of operating and storage/transport temperature, refer to section 14.
- DO NOT use this monitor after the durable period has ended. Refer to section 14.
- DO NOT crease the arm cuff or the air tube excessively.
- DO NOT fold or kink the air tube while taking a blood pressure 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 approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect blood pressure readings.
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied. NOTE: please refer to section 7 for taking a blood pressure measurement manually.
- ONLY use the arm cuff, batteries and accessories specified for this monitor. Use of unsupported arm cuffs and batteries may damage and/or may be hazardous to this monitor.
- The use of accessories and cables other than those specified or provided by OMRON could result in increased electromagnetic emission or decreased electromagnetic immunity of the monitor and result in improper operation.

- During a blood pressure measurement and/or an ECG recording, the use of the monitor adjacent to or stacked with another device, other than the smartphone to be used with the monitor, should be avoided because it could result in improper operation. In case such use is necessary, the monitor and the other device should be observed to verify that they are operating normally.
- OMRON makes no warranty for any data or information that is collected erroneously by the monitor, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the product as instructed.
- Interpretations made by this monitor are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.
- DO NOT use this monitor in the presence of flammable anesthetics or drugs.
- DO NOT expose this monitor to strong electromagnetic fields.
- DO NOT use this monitor while charging your smartphone.
- DO NOT record an ECG during cautery and external defibrillation procedures.
- DO NOT record an ECG in close vicinity to other equipment emitting acoustic sound.
- DO NOT record an ECG if the electrodes are dirty. Clean them first.
- After ECG analysis, the app may incorrectly identify ventricular flutter, ventricular bigeminy, and ventricular trigeminy heart conditions as unreadable. Consult with your physician.
- OMRON does not guarantee that you are not experiencing an arrhythmia or other health conditions when labeling an ECG as normal. You should notify your physician for possible changes in your health.
- If the "OMRON connect" app detects possible atrial fibrillation in an ECG, consult with your physician before making any medical decision, including altering your use of any drug or treatment.
- The atrial fibrillation detector evaluates for possible atrial fibrillation ONLY. It will NOT detect other potentially life threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present.
- The atrial fibrillation detector ONLY evaluates for possible atrial fibrillation after you have recorded an ECG. It does NOT continuously

monitor your heart and therefore cannot alert you if atrial fibrillation happens at any other time.

- Result of “Bradycardia” or “Tachycardia” are designations of heart rate, not a clinical diagnosis of an actual arrhythmia.

Consult with your physician.

- When your fingertips are dry, your ECG recording may not be successful. If dry, moisten your fingers with a wet towel, a water-based lotion, or something similar.
- DO NOT record an ECG with dirty hands.
- Make sure to place your smartphone on the smartphone stand of the monitor when recording an ECG. If it is not placed appropriately on the smartphone stand, there may be communication issues between the smartphone and the monitor, and your ECG may not be recorded successfully.
- The ECG electrodes should not touch any other conductive parts.
- If you wear hearing aids, turn them off.

Data Transmission

- DO NOT replace batteries while your blood pressure readings are being transferred to your smartphone. This may result in incorrect operation of this monitor and failure to transfer your blood pressure readings.

Battery Handling and Usage

- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 4 “AA” alkaline 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 3 months or more.
- 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.
- Make sure the battery compartment is securely closed with the battery cover when recording an ECG. If the battery cover is not in place,

recording an ECG may not be successful. If you have lost the battery cover, contact your OMRON retail outlet or distributor.

Disposal

This product should not be disposed of, with other household wastes at the end of its working life.

To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

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: 15 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 labor 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.

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.

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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