

Automatic Upper Arm Blood Pressure Monitor

EVOLV (HEM-7600T-E) Instruction Manual



OMRON

Introduction

Thank you for purchasing the OMRON EVOLV Automatic Upper Arm Blood Pressure Monitor.

Your new automatic upper arm blood pressure monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood movement through your brachial artery and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope so the monitor is simple to use.

Intended Use

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. It is mainly designed for general household use

Important Safety Information

Please read the Important Safety Information in this instruction manual before using the unit. Please follow this instruction manual thoroughly for your safety.

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

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

· DO NOT adjust medication based on measurement results 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 wear the arm cuff on your arm while on an intravenous drip or blood transfusion
- · DO NOT apply or inflate the arm cuff around any body parts other than your upper arm
- DO NOT use this monitor in areas containing high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, computerized
- tomography (CT) scanners or in oxygen rich environments. • DO NOT use this monitor on infants, toddlers, children or persons who cannot express themselves
- · Consult 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.
- Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous
- · Contains small parts that may cause a choking hazard if swallowed by children, toddlers or infants
- · Keep the BATTERY out of the reach of children, toddlers and infants. • 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.

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the **▲**Caution user or patient or damage to the equipment or other property.

 Stop using this monitor and consult your physician if you experience skin irritation or discomfort.

- · Consult your physician before using this monitor on an arm with an
- arterio-venous (A-V) shunt. • Note that PATIENT motion, trembling, shivering may affect the measurement reading
- · Consult your physician before using this monitor if you have had a mastectomy. Consult your physician before using the 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. · Remove the arm cuff if it does not start deflating during the measurement.
- Do not use this monitor for any purpose other than measuring blood pressure. Do not use a mobile phone or other electrical devices that emit electromagnetic
- fields near this monitor except when transferring your readings to your smart device. This may result in incorrect operation of this monitor. • Do not disassemble or attempt to repair the monitor or components. This may
- cause an inaccurate reading. · Do not use in a location where there is moisture or a risk of water splashing the
- monitor. This may damage the monitor. · Do not use this monitor in a moving vehicle such as in a car or on an airplane.
- 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 atures. See the "6. Specifications" section of the
- · Please check, by observation of the arm being used, that the monitor is not
- causing any impairment of patient blood circulation. · Do not use this monitor in high-use environments such as medical clinics or physician offices.
- · Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking the measurement. · Remove tight-fitting or thick clothing from your arm while taking a
- measurement. · Remain still and do not talk while taking a measurement.
- Read and follow the "Important information regarding Electro Magnetic
- Compatibility (EMC)" in the "6. Specifications". · Read and follow the "Correct Disposal of This Product" in "6. Specifications" when disposing of the device and any used accessories or optional parts.

Data Transmission

- Do not replace the battery while your reading is being transferred to your smart device. This may result in the incorrect operation of your monitor and failure to transfer your blood pressure data
- Do not place integrated circuit cards, magnets, metal objects, or other devices that emit electromagnetic fields near this monitor while your reading is being transferred to your smart device. This may result in the incorrect operation of your monitor and failure to transfer your blood pressure data

Battery Handling and Usage

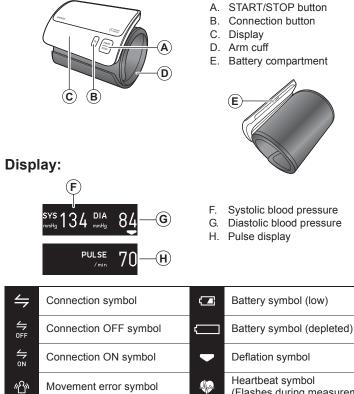
- Do not insert the batteries with their polarities incorrectly aligned.
- . Use only 4 "AAA" alkaline batteries with this monitor. Do not use other types of batteries. Do not use new and used batteries together.
- Remove the batteries if the monitor will not be used for a long period of time.

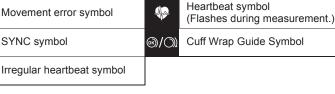
- · If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult a physician immediately.
- · If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult a physician. · Do not use batteries after their expiration date.
- Periodically check your batteries to ensure they are in good working condition. Only use batteries specified for this monitor. Use of unsupported batteries may damage and/or may be hazardous to the monitor.

1. Know Your Device

Contents:

Monitor, battery set, instruction manual, setup instructions, soft case Monitor:





1.1 Display symbols

 \bigcirc

Irregular Heartbeat Symbol () When the monitor detects an irregular rhythm

two or more times during the measurement, the

irregular heartbeat symbol will appear on the display with the measurement values.

measuring the systolic and diastolic blood

Blood pressure An irregular heartbeat rhythm is defined as a Irregular Heartbeat rhythm that is 25% less or 25% more than the average rhythm detected while the monitor is

Pulse Blood pressure

Normal Heartbea

Pulse

If the irregular heartbeat symbol displays with your measurement results, we recommend you consult your physician. Follow the directions of your physician

Movement Error Symbol ()

The movement error symbol is displayed if you move your body during the measurement. Please remove the arm cuff, and wait 2 - 3 minutes. Take another measurement and remain still during measurement.

Cuff Wrap Guide Symbol (/)

If the cuff was wrapped too loosely, it may cause unreliable results. If the wrapping of cuff is too loose, the cuff wrap guide symbol "O" appears. Otherwise "
"
"
appears. This is the function which is used as an aid in determining if the cuff is wrapped snugly enough.

SYNC Symbol (与)

pressure

• When the SYNC symbol appears on the display, make sure that your monitor has been pairing with the smart device or transfer the data.

· When the SYNC symbol appears on the display, transfer the data before the measurements are deleted. Maximum internal memory is for 100 measurements. The oldest value will be deleted when this is reached

before downloading. 2013 ESH/ESC Guidelines for the management of arterial hypertension

Definitions of hypertension by office and home blood pressure levels Office Home

	Systolic Blood Pressure	≥140 mmHg	≥135 mmHg	
	Diastolic Blood Pressure	≥90 mmHg	≥85 mmHg	
These are from statistical values for blood pressure				

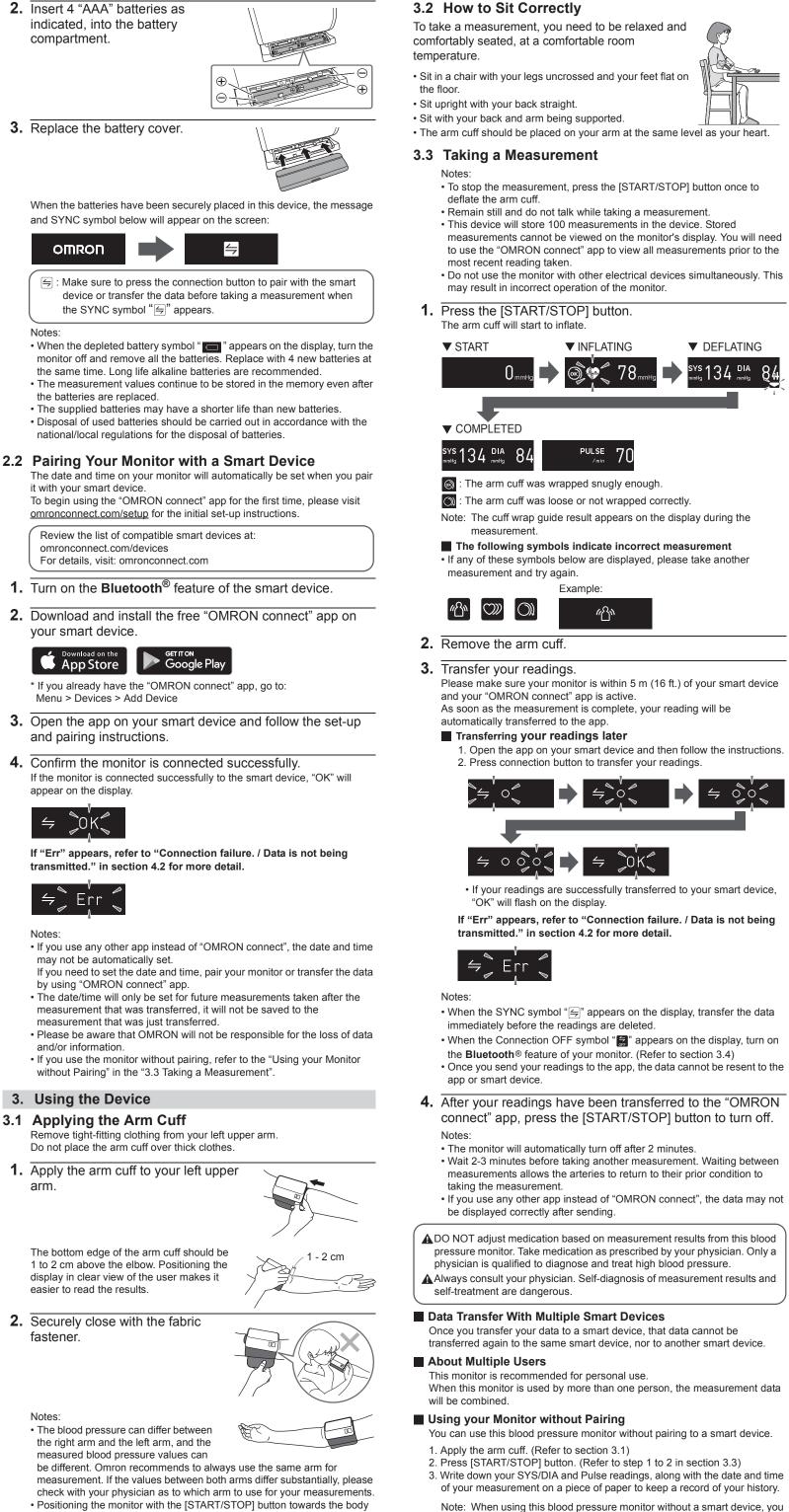
1.2 Before Taking a Measurement

- To help ensure an accurate reading, follow these directions: 1. Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for 30 minutes before taking a measurement.
- 2. Rest for at least 5 minutes before taking the measurement
- 3. Stress raises blood pressure. Avoid taking measurements during stressful times.
- 4. Measurements should be taken in a quiet place.
- 5. Remove tight-fitting clothing from your arm.
- 6. Keep 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. You need to take and record several readings over a period of time. Try to measure your blood pressure at the same time each day for consistency.

2. Preparation

2.1 Battery Installation

1. Remove the battery cover. Gently slip into the gap of the hook and pull downward.



- The supplied batteries may have a shorter life than new batteries.

2.2 Pairing Your Monitor with a Smart Device

it with your smart device.

- **1.** Turn on the **Bluetooth**[®] feature of the smart device
- **2.** Download and install the free "OMRON connect" app on your smart device.

makes it easier to use the device.

3. Open the app on your smart device and follow the set-up and pairing instructions.

> Note: When using this blood pressure monitor without a smart device, you will not be able to view your prior readings stored in the memory.

3.4 Turning "OFF" Bluetooth[®]

Turn off the $Bluetooth^{\ensuremath{\mathbb{R}}}$ in your monitor in the following areas where use of wireless equipment is prohibited.

• On aircraft • In hospitals • While abroad Your blood pressure monitor comes with the **Bluetooth**[®] already turned

- **1.** Turn your monitor power off if it is turned on.
- **2.** Press and hold the connection button for more than 10 seconds
- **3.** Release the connection button when " $\square \rightarrow \square$ " appears on the display.



4. Press the [START/STOP] button to turn the monitor off. Note: The monitor will automatically turn off after 2 minutes.

How to turn "ON" Bluetooth[®]

Operate the following step when the power has been off. Press and hold the connection button for more than 2 seconds and then release the connection button when " $\square \rightarrow \square$ " appears on the display.

- **3.5 Restoring Your Monitor to the Default Settings** To delete all the information stored in your monitor, follow the instructions below. Make sure that your monitor is turned off. It will be off when the screen is not showing numbers or symbols.
- **1.** While holding the connection button down, the Connection symbol " and "P" appear on the display, and then press the [START/STOP] button for more than 5 seconds.



2. When the "Clr" symbol appears on the display, release the connection button and [START/STOP] button. The "Clr" will appear on the display when your monitor settings have reverted back to their original.

Clr

- **3.** Press the [START/STOP] button to turn the monitor off. • The monitor will automatically turn off after 2 minutes.
- Reverting to initial settings of this monitor will not delete the information in the app

· When using this monitor again, please delete the registration of the monitor in the app first, and then pair your monitor.

4. Error Messages and Troubleshooting

4.1 Error Messages

higher.

Error Display	Cause	Solution		
\bigcirc	Irregular heartbeat is detected.	Remove the arm cuff. Wait 2 - 3 minutes and then take another measurement. Repeat the steps in section 3.1. If this error continues to appear, contact your physician.		
<i>"</i> ြိ"	Movement during measurement.	Carefully read and repeat the steps in section 3.3.		
Oì	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.		
	The batteries are low.	Recommend replacement of all 4 batteries with new ones. Refer to section 2.1.		
	The batteries are depleted or battery polarities are not properly aligned.	Immediately replace 4 batteries with new ones. Refer to section 2.1.		
		Confirm the batteries are properly inserted with polarities correctly aligned. Refer to section 2.1.		
⇔ Err	Connection failure. Data is not being transmitted.	Refer to "Connection failure. Data is not being transmitted." in section 4.2.		
E 1	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.		
E 3	The arm cuff was inflated exceeding the maximum allowable pressure, and then deflated automatically.	Do not touch the arm cuff while taking a measurement. Refer to section 3.3.		
E 4	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.		
E 5	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.		
Er XX * : "XX" will change to display an error number, 6 and bigber	Device error.	Contact your local OMRON representative.		

4.2 Troubleshooting

Problem	Cause and Solution
No power. No display appears on the monitor.	Replace all batteries with new ones. Check the battery installation for proper placement of the battery polarities. Refer to section 2.1.
Measurement values appear too high or too low.	Blood pressure varies constantly. Many factors including stress, time of day, and how you apply the arm cuff, may affect your blood pressure. Review the section, 3.2 and 3.3.
Connection failure. / Data is not being transmitted.	The blood pressure monitor might not be properly placed within the smart device's transmission range and is too far from the smart device. If there are no causes of data transmission interference found near the blood pressure monitor, move the blood pressure monitor within 5 m (16 ft.) of the smart device and try again.
	The Bluetooth [®] feature of the smart device is turned off. Turn on the Bluetooth [®] feature of the smart device and your monitor, and try sending the data again.
	The Bluetooth [®] feature of the blood pressure monitor is turned off. Refer to "To turn "ON" the Bluetooth [®] " in "3.4 Turning "OFF" the Bluetooth [®] ".
	The blood pressure monitor did not pair successfully to the smart device. Try to pair the devices again. Refer to "Pairing Your Monitor with a Smart Device" in section 2.2. For more detail, go to "Help" in the "OMRON connect" app.
	The application on the smart device is not ready. Check the application then try sending the data again. Refer to "Pairing Your Monitor with a Smart Device" in section 2.2. If the "Err" symbol still displays after checking the application, contact your OMRON retail outlet or distributor. Confirm your smart device compatibility with this monitor at omronconnect.com

5. Maintenance and Storage

5.1 Maintenance

- To protect your device from damage, please follow the directions below: • Store the device and the components in a clean, safe location. · Do not use any abrasive or volatile cleaners.
 - · Do not wash the device and any components or immerse them in water. • Do not use gasoline thinners or similar solvents to clean the device



• Use a soft dry cloth, or a soft cloth moistened with neutral soap to clean on the monitor and the arm cuff, and then wipe it with a dry cloth. · Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the device or components

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 device inspected every 2 years to ensure correct functioning and accuracy. Please consult your OMRON retail outlet or distributor.

5.2 Storage

- 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

6. Specifications

0. Opechications	
Product category	Electronic Sphygmomanometers
Product description	Automatic Upper Arm Blood Pressure Monitor
•	EVOLV (HEM-7600T-E)
Model (code)	
Display Cuff pressure range	OLED display Pressure: 0 to 299 mmHg
Measurement range	Pressure: 40 to 260 mmHg
weasurement range	Pulse: 40 to 180 beats / min.
Accuracy	Pressure: ±3 mmHq
Accuracy	Pulse: ±5% of display reading
Inflation	Fuzzy-logic controlled by electric pump
Deflation	Automatic rapid deflation
Measurement method	Oscillometric method
Transmission method	Bluetooth [®] Smart
Wireless communication	Frequency range: 2.4 GHz (2400 - 2483.5 MHz)
	Modulation: GFSK
	Effective radiated power: <20 dBm
IP classification	IP 22
Power source	4 "AAA" batteries 1.5V
Battery life	Approximately 300 measurements
	(using new alkaline batteries)
Durable period (Service life)	Monitor: 5 years
Operating conditions	10°C to 40°C / 15 to 90% RH (non-condensing) / 800 to 1060 hPa
Storage / Transport	-20°C to 60°C / 10 to 90% RH (non-condensing)
conditions	Maritan Arganizately 040 r
Weight	Monitor: Approximately 240 g (not including batteries)
Dimensions	Monitor: Approximately 85 mm \times 120 mm \times 20 mm (not including the arm cuff)
Arm circumference	22 to 42 cm
Contents	Monitor, battery set, instruction manual, setup instructions,
	storage case
Applied part	Туре ВF
Protection against electric	Internally powered ME equipment
shock	

Notes:

- These specifications are subject to change without notice.
- In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure
- · This device is clinically investigated according to the requirements of ISO81060-2:2013.
- · This device has not been validated for use on pregnant patients.
- · IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This device is protected against solid foreign objects of 12 mm diameter and greater such as a finger, and against oblique falling water drops which may cause issues during a normal operation

C€0197

- 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, Non-invasive sphygmomanometers Part 1: General Requirements and Part 3: Supplementary requirements for electromechanical blood pressure measuring systems.
- · Hereby, OMRON HEALTHCARE Co., Ltd., declares that the radio equipment type EVOLV (HEM-7600T-E) is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.omron-healthcare.com
- 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.

Symbol descriptions				
	Please consult this instruction manual			
×	Applied part - Type BF Degree of protection against electric shock (leakag current)			
(((•)))	To indicate generally elevated, potentially hazardou levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentional apply RF electromagnetic energy for diagnosis or treatment.			
	Temperature limitation			
<u>~</u>	Humidity limitation			
\$. \$	Atmospheric pressure limitation			
ART. or O	Artery mark			

Product production date is integrated in a Serial or LOT number, which placed on the Rating Label and sales package: the first 2 digits mean year of production, the next 2 digits - month of production.

Important information regarding Electro Magnetic Compatibility (EMC) With the increased number of electronic devices such as PC's and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation

Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the EN60601-1-2:2007 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

This medical device manufactured by OMRON HEALTHCARE conforms to this EN60601-1-2:2007 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

• Do not use mobile (cellular) telephones and other devices, which generate strong electrical or electromagnetic fields, near the medical device. This may result in incorrect operation of the device and create a potentially unsafe situation. Recommendation is to keep a minimum distance of 7 m. Verify correct operation of the device in case the distance is shorter

Further documentation in accordance with EN60601-1-2:2007 is available at OMRON HEALTHCARE EUROPE at the address mentioned in this instruction manual

Documentation is also available at omron-healthcare.com.

About a wireless communication interference

This Product operates in the unlicensed ISM band at 2.4GHz. In case this Product is used around the other wireless devices including microwave and wireless LAN, which operate same frequency band of this Product, there is a v that interference occurs between this Product and such o devices. If such interference occurs, please stop the operation of other devices or relocate this Product before using this Product or do not use this Product around the other wireless devices.

Use this monitor only in the member countries of EU or the country you purchased it in. If you use it elsewhere, you may violate the radio laws or regulations of that country.

Correct Disposal of This Product

(Waste Electrical & Electronic Equipment) This marking shown on the product or its literature, indicates that it 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.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

ge us.

ally



7. Trademarks



The $\textbf{Bluetooth}^{\texttt{®}}$ Smart word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of Bluetooth such marks by OMRON HEALTHCARE Co., Ltd. is under license. Other trademarks and trade names are those of their respective owners

Apple and the Apple logo are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc. Android, the Google Play logo are trademarks of Google Inc.

8. Limited Warranty

Thank you for buying an OMRON product. This product is constructed of high quality materials and great care has been taken in its manufacturing. It is designed to give you every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.

This product is guaranteed by OMRON for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product is guaranteed by OMRON. During this period of guarantee OMRON will, without charge for labour or parts, repair or replace the defect product or any defective parts

The guarantee does not cover any of the following: a. Transport costs and risks of transport.

- b. Costs for repairs and / or defects resulting from repairs done by unauthorised persons
- c. Periodic check-ups and maintenance.
- d. Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly guaranteed above.
- e. Costs arising due to non-acceptance of a claim (those will be charged for). f. Damages of any kind including personal caused accidentally or from misuse. g. Calibration service is not included within the guarantee.

Should guarantee 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

omron-healthcare.com

Repair or replacement under the guarantee does not give rise to any extension or renewal of the guarantee period.

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

9. Some Useful Information about Blood Pressure What is Blood Pressure?

Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart's cycle.

The highest pressure in the cycle is called the Systolic Blood Pressure; the lowest is the Diastolic Blood Pressure. Both pressures, the Systolic and Diastolic, are necessary to enable a physician to evaluate the status of a patient's blood pressure

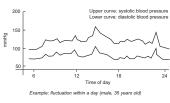
What is Arrhythmia?

Arrhythmia is a condition where the heartbeat rhythm is abnormal due to flaws in the bio-electrical system that drives the heartbeat. Typical symptoms are skipped heartbeats, premature contraction, an abnormally rapid (tachycardia) or slow (bradycardia) pulse.

Why is it a Good Thing to measure Blood Pressure at Home?

Many factors such as physical activity, anxiety, or the time of day, can influence your blood pressure. A single measurement may not be sufficient for an

accurate diagnosis Thus it is best to try and measure your blood pressure at the same time each



day, to get an accurate indication of any changes in blood pressure. Blood pressure is typically low in the morning and increases from afternoon to evening. It is lower in the summer and higher in the

How is Hypertension related to Stroke?

Hypertension (high blood pressure) is the key risk factor for Stroke. It is estimated that amongst hypertensive patients, effective treatment would prevent 1 in 4 haemorrhagic strokes (bleeding around the brain). Hypertension guidelines have endorsed the use of Home Blood Pressure Monitoring in addition to the measurements in physicians' offices to help manage hypertension effectively.

References to above medical claims are available upon request.

Manufacturer	OMRON HEALTHCARE Co., Ltd. 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN
EU-representative	OMRON HEALTHCARE EUROPE B.V. Scorpius 33, 2132 LR Hoofddorp, THE NETHERLANDS www.omron-healthcare.com
Production facility	OMRON HEALTHCARE Co., Ltd. Matsusaka Factory 1855-370, Kubo-cho, Matsusaka-shi, Mie, 515-8503 Japan
Subsidiaries	OMRON HEALTHCARE UK LTD. Opal Drive, Fox Milne, Milton Keynes, MK15 0DG, UK www.omron-healthcare.com
	OMRON MEDIZINTECHNIK HANDELSGESELLSCHAFT mbH Gottlieb-Daimler-Strasse 10, 68165 Mannheim, GERMANY www.omron-healthcare.com
	OMRON SANTÉ FRANCE SAS 14, rue de Lisbonne, 93561 Rosny-sous-Bois Cedex, FRANCE www.omron-healthcare.com