

4. Error Messages and Troubleshooting

Error Display	Cause	Solution
	Irregular heartbeats are detected.	Remove the arm cuff. Wait 2 - 3 minutes and then take another measurement. Repeat the steps in section 3.3. If this error continues to appear, contact your physician.
	Movement during measurement.	Carefully read and repeat the steps in section 3.3.
	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	The batteries are low.	Recommend to replace the batteries with new ones ahead of time. Refer to section 2.1.
	The batteries are depleted.	Replace 4 batteries with new ones at once. Refer to section 2.1.
	Air plug disconnected.	Insert the plug securely. Refer to section 3.1.
	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the cuff with a new one. Refer to section 5.3.
	Movement during measurement and the arm cuff has not been inflated sufficiently.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
		If “E2” appears repeatedly, inflate the cuff manually until it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
	The arm cuff was inflated exceeding the maximum allowable pressure, and then deflated automatically.	Do not touch the arm cuff and/or bend the air tube while taking a measurement. Do not inflate the arm cuff more than necessary. Refer to section 3.3.
	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
	Movement during measurement.	
	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
	Device error.	Contact your OMRON retail outlet or distributor.

4.2 Troubleshooting

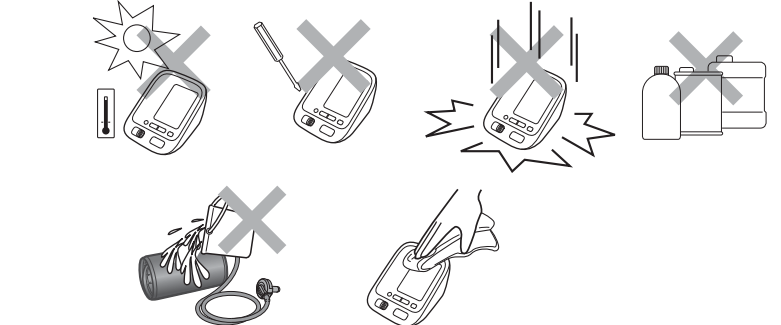
Problem	Cause	Solution
The measurement result is extremely high (or low).	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	Movement or talking during measurement.	Remain still and do not talk during measurement. Refer to section 3.3.
	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
Arm cuff pressure does not rise.	The air connector is not securely connected into the air jack.	Make sure that the air tube is connected securely. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the arm cuff with a new one. Refer to section 5.3.
Arm cuff deflates too soon.	The arm cuff is loose.	Apply the cuff correctly so that it is firmly wrapped around the arm. Refer to section 3.1.
Cannot measure or the results are too low or too high.	The arm cuff has not been inflated sufficiently.	Inflate the cuff so that it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
Nothing happens when you press the buttons.	The batteries are depleted.	Replace 4 batteries with new ones. Refer to section 2.1.
	The batteries have been inserted incorrectly.	Insert the batteries with the correct (+/-) polarity. Refer to section 2.1.
Other problems.	• Press the START/STOP button and repeat measurement. • Replace the batteries with new ones. If the problem continues, contact your OMRON retail outlet or distributor.	

5. Maintenance and Storage

5.1 Maintenance

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

- 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 petrol, thinners or similar solvents to clean the device.



- Use a soft and dry cloth, or a soft and moistened cloth and neutral soap to clean on the monitor and the arm cuff.
- Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the device or components. Consult your authorised OMRON retail outlet or distributor.

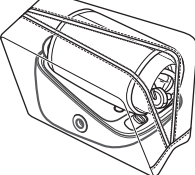
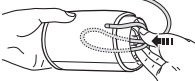
Calibration and Service

- 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 authorised OMRON retail outlet or distributor.

5.2 Storage

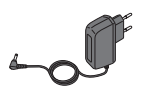
- Keep the device in its storage case when not in use.
1. Unplug the air plug from the air jack.
 2. Gently fold the air tube into the arm cuff.

Note: Do not bend or crease the air tube excessively.



- 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 vapours such as bleach.
 - Locations exposed to vibrations, shocks or where it will be at an angle.

5.3 Optional Medical Accessories (within the scope of EC Medical Device Directive 93/42/EEC)

Arm cuff Arm circumference 22 - 42 cm	AC adapter	
		
HEM-FL31	AC ADAPTER-S (60240HW5SW)	AC ADAPTER-UK (60240H7000SW)

- Using the Optional AC Adapter**
1. Insert the AC adapter plug into the AC adapter jack on the rear side of the monitor.
 2. Plug the AC adapter into an electrical outlet.

To disconnect the AC adapter, unplug the AC adapter from the electrical outlet first and then remove the AC adapter plug from the monitor.

6. Specifications

Product category	Electronic Sphygmomanometers
Product description	Automatic Upper Arm Blood Pressure Monitor
Model (code)	M3 Comfort (HEM-7134-E)
Display	LCD Digital Display
Measurement method	Oscillometric method
Measurement range	Pressure: 0 to 299 mmHg Pulse: 40 to 180 beats/min.
Accuracy	Pressure: ±3 mmHg Pulse: ±5% of display reading
Inflation	Fuzzy-logic controlled by electric pump
Deflation	Automatic pressure release valve
Memory	60 measurements with date and time for each user (1 and 2)
Rating	DC6V 4W
Power source	4 “AA” batteries 1.5V or optional AC adapter (AC ADAPTER-S, INPUT AC100-240V 50/60Hz 0.12A) (AC ADAPTER-UK, INPUT AC100-240V 50/60Hz 15VA)
Battery life	Approx. 1000 measurements (using new alkaline batteries)
Applied part	 = Type BF
Protection against electric shock	Internally powered ME equipment (When using only the batteries)  = Class II ME equipment (Optional AC adapter) +10 to +40°C / 30 to 85% RH / 700 to 1060 hPa

Operating temperature / humidity / air pressure	
Storage temperature / humidity / air pressure	-20 to +60°C / 10 to 95% RH / 700 to 1060 hPa
IP classification	IP 20
Weight	Monitor: Approx. 300 g without batteries Arm cuff: Approx. 163 g
Outer dimensions	Monitor: Approx. 107 (w) mm x 79 (h) mm x 141 (l) mm Arm cuff: Approx. 145 mm x 532 mm
Cuff circumference	22 to 42 cm
Cuff / Tube material	Nylon, polyester, polyvinyl chloride
Package contents	Monitor, arm cuff, instruction manual, storage case, battery set, blood pressure pass

- Notes:
- These specifications are subject to change without notice.
 - In the clinical validation study, the 5th phase was used on 85 subjects for determination of diastolic blood pressure.
 - This device is clinically investigated according to the requirements of ISO 81060-2:2013.
 - 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.

CE 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.
- 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.

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 www.omron-healthcare.com.

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 wastes for disposal.

7. 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.
 - h. Optional parts have a one (1) year warranty from date of purchase. Optional parts include, but are not limited to the following items: Cuff and Cuff Tube, AC Adapter.
- 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.

www.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.

8. Some Useful Information about Blood Pressure

What is Blood Pressure?

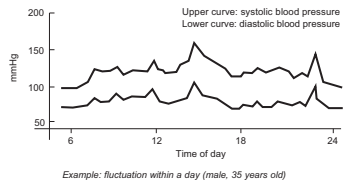
Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart's cycle. The highest pressure in the cycle is called the Systolic Blood Pressure; the lowest is the Diastolic Blood Pressure. Both 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 winter.



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.

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EC	REP		
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