



New Product Information Sheet

Specifications subject to change
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Model (code):
M3 Comfort (HEM-7134-E)

Product description: *Automatic Upper Arm Blood Pressure Monitor*

Product category: *Electronic Sphygmomanometers*

Model (code): *M3 Comfort (HEM-7134-E)*



LEGAL MANUFACTURER

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THE NETHERLANDS

Included accessories / optional accessories

Included:

1. Product category: Electronic Sphygmomanometers
Model (code): **HEM-FL31** "Intelli Wrap Cuff" (HEM-FL31-E)

Optional:

2. Product category: Electronic Sphygmomanometers
Model (code): **AC ADAPTER-S** (60240HW5SW)
3. Product category: Electronic Sphygmomanometers
Model (code): **AC ADAPTER-UK** (60240H7000SW)

Optional Medical Accessories

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

Arm cuff
Arm circumference
22 - 42 cm



HEM-FL31

AC adapter



AC ADAPTER-S
(60240HW5SW)



AC ADAPTER-UK
(60240H7000SW)

General description

The OMRON M3 Comfort is a compact, fully automatic upper arm blood pressure monitor, operating on the oscillometric principle. It measures your blood pressure and pulse rate simply and quickly. For comfortable controlled inflation without the need of pressure pre-setting or re-inflation the device uses its advanced "IntelliSense" technology.

Packaging content

The manufacturer produces M3 Comfort with the applicable accessories included, necessary for the application of its intended purpose.

1. Monitor
2. Arm cuff

3. Instruction manual
4. Storage case
5. Battery set
6. Blood Pressure Pass

The complete set of the medical device is specified in the Instruction Manual in the Technical Data section.

Purpose (intended use)

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population who can understand this instruction manual with the arm circumference range printed on the arm cuff. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with the measurement result.

Application field

This product is intended for use in medical environment as well as general household.

Intended user

Intended users are adults who are capable of understanding general operation of the device and the content of instruction manual.

Indications for use

This product is intended to be used for measuring blood pressure and pulse rate.

Features (Particularities)

OMRON is introducing the M3 Comfort as a new amendment to its blood pressure monitor portfolio. This product operates with OMRON's unique, pre-formed Intelli Wrap Cuff. Thanks to the innovative design, the measurement zone of the cuff covers full 360 degrees, ensuring therefore accurate readings in any position around the upper arm.

Key features

- 360° accuracy thanks to the innovative Intelli Wrap Cuff
- Easy High Blood Pressure Colour Indicator
- Irregular Heartbeat Detection
- Cuff Wrap Guide
- 2 User Memory (60 readings each)
- Body Movement Detection

Description of operating principle

The device operates on the oscillometric principle. Due to the advanced IntelliSense sensing technology the inflation is controlled without the need for pressure pre-setting or re-inflation

How to use the device


Main steps:

1. Insert the air plug into the air jack
2. Apply the arm cuff to your left arm. Note that the bottom edge of the arm cuff should be 1 to 2 cm above the elbow. Cuff should be positioned on the upper arm with the air tube pointing towards your hand.
3. Secure closed with the fabric fastener

Review the Instruction Manual for the full details on the application of this product.

Technical data

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: $\pm 5\%$ 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)
Operating temperature / humidity / air pressure	+10°C to +40°C / 30% to 85%RH / 700 to 1060 hPa
Storage and transport Temperature / humidity / air pressure	-20°C to +60°C / 10% to 95%RH / 700 - 1060hPa
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
EAN code	401567210983 4

Materials used in main device and all accessories

Monitor:

Item	Material	Grade
Housing	ABS (acrylonitrile butadiene styrene)	BASF GP22
Battery Cover	ABS (acrylonitrile butadiene styrene)	BASF GP22
Front Panel	PC (polycarbonate)	TO.5
Button	ABS (acrylonitrile butadiene styrene)	UMG EX-120
Cuff	Nylon and Polyester	PVC115F/CM1770TF

Tube	PVC (polyvinyl chloride)	BCL9948N/MES2019B
Package	Cardboard	Duplex 300 gsm (Hansol paper, brightness > 76%) + E flux carton
Instruction Manual	Paper	Wood free paper (60 gsm)

Cuff:

Item	Material
Bias Tape	Polyester
Cloth covering	Polyester
Air Tube	Polyvinyl Chloride (PVC)
Hook and Loop fastener	Hook: Polyvinyl Chloride (PVC) Loop: Nylon
Air plugs to device	Acrylonitrile butadiene styrene (ABS)
Air plug to cuff	Polyvinyl Chloride (PVC)

Title page of Instruction Manual



Automatic Upper Arm Blood Pressure Monitor

M3 Comfort (HEM-7134-E) Instruction Manual



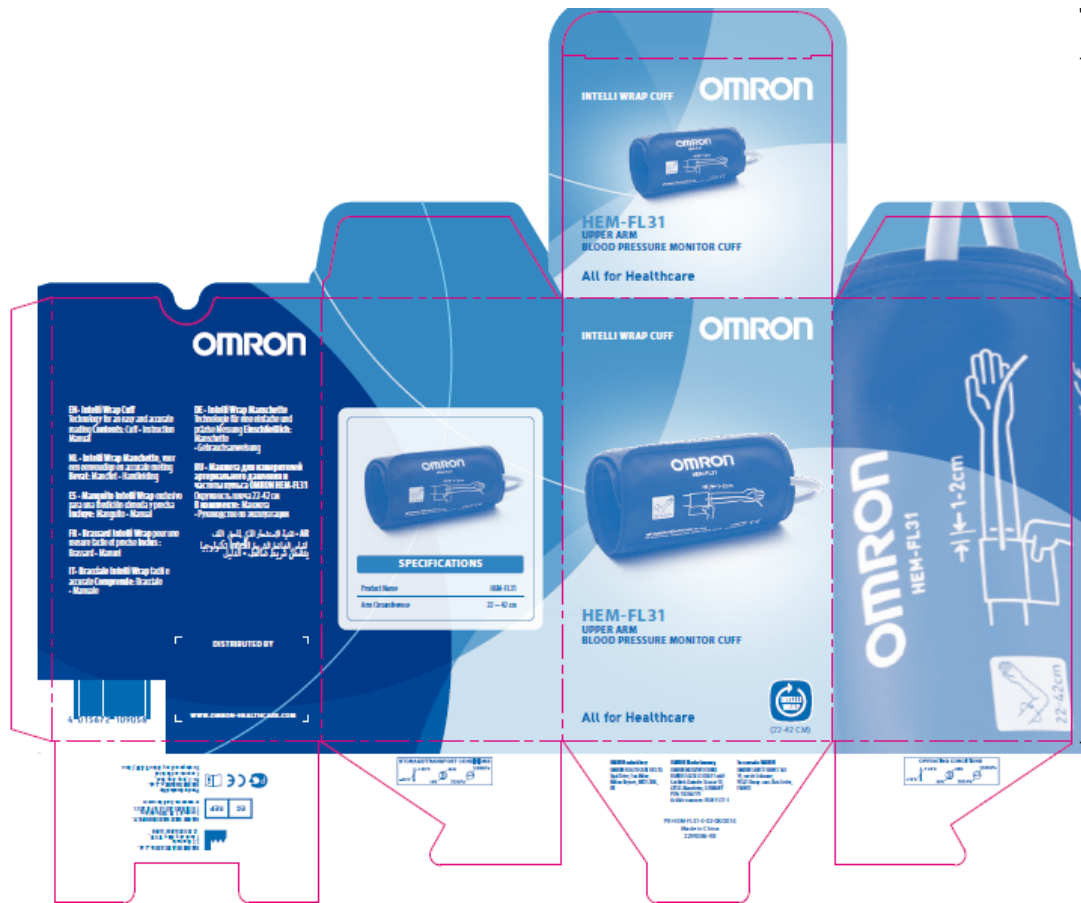
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Unfolded package design of main device and accessories

Main device:



Accessories:



Packaging specifications from Explanation Diagram

Package	Amount	Approx. weight (g)	Approx. dimensions W x D x H (mm)
Main Unit	1	300	107 x 141 x 79
Package	1	880	200 x 100 x 175
Master Carton	10	10kg	533 x 426 x 218

List of Harmonized EN Standards

The above mentioned medical device belongs to IIa (MDD Annex IX Rule 10) potential risk class.

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

EN 980: 2008
EN 1041: 2008
EN1060-1:1995+A2:2009
EN1060-3:1997+A2:2009
EN60601-1:2006
EN60601-1-2:2007
IEC60601-1-6:2010
EN ISO 14971: 2012
EN ISO 10993-1: 2009
EN ISO 10993-5: 2009
EN ISO 10993-10: 2010
EN62304: 2006
EN62366:2008
EN50581:2012

Operation and care

Cleaning of 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. Read the Manual for further instructions.

Warnings

Read all the information in the instruction manual and any other literature included in the box before using the device.

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

(General Usage)

- 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.
- Consult your physician before using the device in pregnancy including pre-eclampsia, or if diagnosed with arrhythmia or arteriosclerosis.
- Do not use the device on the injured arm or the arm under medical treatment.

- Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion.
- Consult your physician before using the device on the arm with an arterio-venous (A-V) shunt.
- Do not use the device with other medical electrical (ME) equipment simultaneously.
- Do not use the device in the area the HF surgical equipment, MRI, or CT scanner exists, or in the oxygen rich environment.
- The air tube or the AC adapter cable may cause accidental strangulation in infants.
- Contained small parts that may cause a choking hazard if swallowed by infants.

(AC Adapter (optional) Usage)

- Do not use the AC adapter if the device or the power cord is damaged. Turn off the power and unplug the power cord immediately.
- Plug the AC adapter into the appropriate voltage outlet. Do not use in a multi-outlet plug.
- Never plug in or unplug the power cord from the electric outlet with wet hands.

Caution: Indicates 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.

(General Usage)

- Always consult your physician. Self-diagnosis of measurement results and self-treatment are dangerous.
- People with severe blood flow problems, or blood disorders, should consult a physician before using the device, as the arm cuff inflation can cause bruising.
- Remove the arm cuff if it does not start deflating during the measurement.
- Do not use this device on infants or persons who cannot express their intentions.
- Do not use the device for any purpose other than measuring blood pressure.
- Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement results.
- Do not use a mobile phone or other devices that emit electromagnetic fields, near the device. This may result in incorrect operation of the device.
- Do not disassemble the monitor or arm cuff. This may cause an inaccurate reading.
- Do not use in a location with moisture, or a location where water may splash on the device. This may damage the device.
- Do not use the device in a moving vehicle (car, airplane).
- Do not take measurements more than necessary. It may cause bruising due to blood flow interference.
- Consult your physician before using the device if you had a mastectomy.
- Read "If your systolic pressure is more than 210 mmHg" of this instruction manual, if your systolic pressure is known to be more than 210 mmHg. Inflating to a higher pressure than necessary may result in bruising where the cuff is applied.

(AC Adapter (optional) Usage)

- Fully insert the power plug into the outlet.
- When disconnecting the power plug from the outlet, do not pull the power cord.
- When handling the power cord, take care not to do the following:
Do not damage. Do not break it.
Do not tamper with it. Do not forcibly bend or pull.
Do not twist. Do not bundle during use.

- Do not pinch. Do not place under heavy objects.
- Wipe the dust off from the power plug.
- Unplug monitor when not in use.
- Disconnect the power plug before cleaning.
- Use only an OMRON AC adapter designed for this device. Use of unsupported adapters may damage and/or may be hazardous to the device.

(Battery Usage)

- Do not insert the batteries with their polarities incorrectly aligned.
- Use only 4 “AA” alkaline or manganese batteries with this device. Do not use other types of batteries. Do not use new and used batteries together.
- Remove the batteries if the device will not be used for three months or more.

General Precautions

- Do not forcibly crease the arm cuff or the air tube excessively.
- Do not press the air tube while taking a measurement.
- To unplug the air plug, pull on the air plug at the connection with the monitor, not the tube itself.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not use the device outside the specified environment. It may cause an inaccurate reading.
- 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.

Disposal

As there is a risk of environmental pollution, follow your applicable national and local legal regulations regarding disposal or recycling of this equipment and batteries. The main constituents of each part are listed in the table “Materials List”.

Transportation and storage conditions

Do not store the device in extreme hot or cold temperatures, high humidity or under direct sunlight.

Keep the device in its storage case when not in use.

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:
Temperature range: -20 to +60°C (-4 to 140°F)
Humidity range: 10 to 95%RH
Atmospheric pressure: 700 to 1060hPa

Warranty and lifetime

This device is guaranteed by OMRON for a period of 3 years after the date of purchase. Optional parts have a one (1) year warranty from date of purchase. Optional parts include the following items: Cuff and AC Adapters.

Repair

In case of malfunction of the device the user must turn to the OMRON retail outlet or distributor to test the device and repair the failure. The users shall not disassemble or attempt to repair the device by themselves.

Servicing

The device is not user serviceable. Return it to an authorized OMRON retail outlet or distributor in case of any problem listed in Troubleshooting chapter of the Instruction Manual.

Calibration:

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 authorized OMRON retail outlet or distributor.