New Product Information Sheet

Specifications subject to change

Sales Name: HBP-1100
Item Number: HBP-1100-E

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OMRON HEALTHCARE EUROPE B.V.
Scorpius 33 2132 LR Hoofddorp The Netherlands
P.O. Box 2050 2130 GL Hoofddorp The Netherlands
Phone: +31 (0)23 55 44 700 fax +31 (0)23 55 44 701
www.omron.healthcare.com

BANKERS BANK OF TOKYO-MITUSBISHI (HOLLAND) N.V.
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Professional Blood Pressure Monitor
OMRON HBP-1100 (HBP-1100-E)

LEGAL MANUFACTURER
Address:
OMRON HEALTHCARE Co., Ltd
53, Kunotsubo, Terado-cho, Muko, Kyoto
617-0002 Japan
Phone/Fax: +31 23 5544700 / +31 23 5544 701
e-mail: info@omronhealthcare@eu.omron.com

PRODUCION FACILITIES
Address: OMRON DALIAN CO., LTD.
Economic & Technical Development Zone
Dalian 116600, China
Phone/Fax: +31 23 5544700 / +31 23 5544 701
e-mail: info@omronhealthcare@eu.omron.com

Blood pressure monitor OMRON HBP-1100 (HBP-1100-E) is a professional medical device meant for measurement of blood pressure on the basis of the oscillometric principle.

The manufacturer produces **blood pressure monitor OMRON HBP-1100 (HBP-1100-E)** and with applicable accessories included, necessary for the application for its intended purpose:

1. Main unit
2. GS CUFF M (22- 32 cm)
3. AC Adapter
4. Instruction Manual
5. Guarantee Card

The complete set of the medical device is specified in the Instruction Manual in Using the Unit section.

The above-mentioned medical device belongs to 2a potential risk class.

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

EN980:2008
EN1041:2008
EN1060-1:1995 + A2:2009
EN1060-3:1997 + A2:2009
EN60601-1:1990 + A1:1993 + A2:1995
EN60601-1-2:2007
EN60601-1-4:1996 + A1:1999
EN60601-1-6:2010
EN ISO 13971:2012
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN62304:2006
EN62366:2008
EN60601-1-8:2007

Intended Use

Medical product's intended use as determined by the manufacturer.

The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult and pediatric patient population with arm circumference ranging from 12 cm to 50 cm (from 5 inches to 20 inches).

Application field:

The unit is designed for use in physicians' offices, hospitals, clinics and other medical facilities.

User:

This device should be used by a medical professional. This device is intended for use on adults and children of age 3 years and older.

Intended Use of Cuff Accessories

Medical product's intended use as determined by the manufacturer.

This product is an upper arm cuff for OMRON non-invasive blood pressure monitors.

Application field:

The instrument is designed for use in physicians' offices, hospitals, clinics and other medical facilities.

User:

This product is to be used by doctors, nurses, technicians, or other medical professionals. This device is intended for use on adults and children.

Intended Use of AC Adapter Accessory

Medical product's intended use as determined by the manufacturer.

The AC adapter accessory is intended ONLY to be used with the Omron HBP-1100 monitor. It has no purpose on its own and functions as a key part of the HBP-1100.

Application field

The AC adapter is designed for use in all facilities where the HBP-1100 is used.

User:

The adapter should only be used with the qualified staff who are competent to use the HBP-1100 blood pressure monitor.

Particularities of OMRON HBP-1100 (HBP-1100-E):

- Zero indicator function - Before each measurement, this device indicates that "zero setting" was successful)
- Auscultation Mode
- 5 cuffs available - SS: 12 to 18 cm, S: 17 to 22 cm, M: 22 to 32 cm, L: 32 to 42 cm, XL: 42 to 50 cm (12 to 50 cm arm circumference range)
- This device and cuff can be cleaned with a soft cloth moistened with alcohol.
- Compact, can be stored in a drawer
- Motion stop function - When body movement is detected, the device stops deflation for 5 seconds.
- Irregular pulse Indicator - Helps identify changes in heart rate, rhythm, or pulse that may be caused by heart disease or other serious health problems.

How it works

Blood pressure monitor OMRON HBP-1100 measures blood pressure using oscillometric method.

Efficiency of the medical product

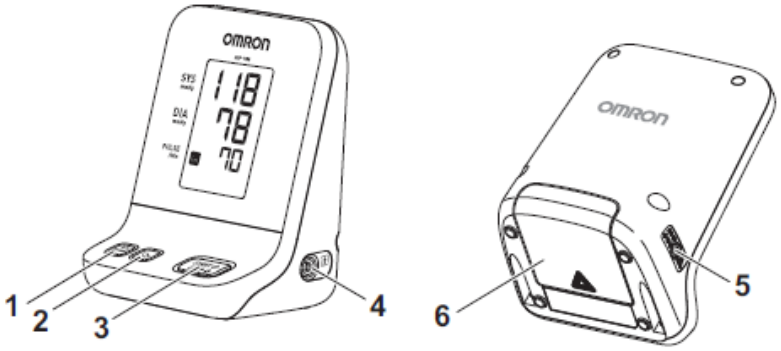
Efficient measurement of the blood pressure is the most important element of modern hypertension control. OMRON HBP-1100 blood pressure monitor's robustness and usability specially designed for medical professionals allows the care giver/medical professional to easily and accurately measure the patient's blood pressure.

The oscillometric method is used for detecting the blood pressuring using the OMRON HBP-1100 and is an accurate and reliable measurement method.

Description of the design and test procedure

OMRON HBP-1100 (HBP-1100-E)

Blood Pressure Monitor



1. Power ON/OFF button
2. Auscultation button
3. Start/Stop button
4. NIBP connector
5. Power connector
6. Battery cover

Application:

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

1. Select the right sized cuff for the patient.
2. Wrap the cuff correctly on a bare arm or over thin clothing.
3. Select the mode of application (Normal Mode, Auscultation Mode)
4. Press start
5. Note the blood pressure and pulse rate in the patients' documents

General Warnings

• Do not use the cuff or AC adapter to lift the unit, it can also cause the unit to malfunction.
• If the unit has broken down, contact OMRON HEALTHCARE.
• Do not use in combination with a hyperbaric oxygen therapy device, or in an environment where combustible gas may be generated.
• Do not use in combination with magnetic resonance imaging (MRI) equipment. If MRI is to be performed, remove cuff connected to the unit from the patient.
• Do not use with a defibrillator.
• Do not install the unit in the following locations:
- Locations subject to vibration such as ambulances and emergency helicopters.
- A location where there is gas or flame.
- A location where there is water or steam.
- A location where chemicals are stored.
• Do not use at extremely high temperature, high humidity, or high altitude. Use only within the required ambient conditions.
• Do not subject the unit to intense shock.
• Do not place heavy objects on the AC adapter cable, or allow the unit to sit on the cord.
• Clinical testing has not been conducted on newborn infants and pregnant women. Do not use on newborn infants and pregnant women.
• Do not plug in or unplug the AC adapter with wet hands.

General Cautions

• Do not install the unit in the following locations:
- Locations with dust, salt, or sulfur.
- Locations directly exposed to sunlight for extended periods of time (in particular, do not leave in direct sunlight or near a source of ultraviolet light for extended periods, as ultraviolet light will cause deterioration of the LCD).
- Locations subject to vibration or shock.
- Near heaters.
• Do not use the unit near large equipment that uses a switching relay for power ON/OFF.

Before use / during use Warnings

• The unit complies with the EMC standard (IEC60601-1-2). As such, it can be used simultaneously with multiple medical instruments. However, if instruments that generate noise such as an electric scalpel or a microwave therapy device are near the unit, check the operation of the unit during and after use of these instruments.
• If an error occurs or a measurement result is questionable, check the vital signs of the patient by auscultation or palpation. Avoid relying solely on the measurement results of the unit when judging the patient's condition.
• Only trained healthcare providers should use this device. Do not allow patients to operate this device.
• Properly connect the connectors and AC adapter cable.
• Do not place objects or liquids on top of this unit.
• Check the following before using the unit:
- Make sure the AC adapter cable is not damaged (wires are not exposed or broken), and the connections are firm.
• For the AC adapter connected to the unit, supplies, and optional devices, use only the standard accessories or OMRON-specified products.
• Do not use in a location with moisture, or a location where water may splash on the unit.

• This unit is intended for use in physicians' office, hospitals, clinics and other medical facilities.
• Do not use the unit if it emits smoke, an abnormal odor, or abnormal noise.
• Do not bring cellular telephones or transceivers into the room where the unit is installed or being used.
• Do not connect multiple monitors to the same patient.
• Do not connect the unit to a power outlet that is controlled by a wall switch.

Caution

• Before using the unit, verify that none of the following apply to the patient:
- Poor peripheral circulation, noticeably low blood pressure, or low body temperature (there will be low blood flow to the measurement position)
- The patient uses an artificial heart and lung (there will be no pulse)
- An SpO2 sensor and the cuff are attached to the same arm
- The patient has an aneurysm
- The patient has frequent arrhythmia
- Body motions such as convulsions, arterial pulsations, or trembling (cardiac massage in progress, minute continuous vibrations, rheumatism, etc.)
• Before use, visually inspect the unit to make sure there are no deformations due to falling, and that there is no dirt or moisture on the unit.
• When the unit has not been used for an extended period of time, always verify that it operates normally and safely before use.
• Do not use in a location where the unit may easily fall. In the event that the unit falls, verify that it operates normally and safely.

Cleaning:

Warning
• When cleaning the unit, turn off the power and disconnect the AC adapter from the unit.
• After cleaning the unit, make sure it is completely dry before connecting to a power outlet.
• Do not spray, pour, or spill liquids into or onto the unit, accessories, connectors, buttons, or openings in the housing.

Caution
• Do not use thinner, benzene, or other solvents to clean the unit.
• Do not sterilize by autoclave or gas sterilization (EOG, formaldehyde gas, high-concentration ozone, etc.).
• If using an antiseptic solution for cleaning, follow the instructions of the manufacturer.
• Clean the unit regularly.

Specifications of OMRON HBP-1100 (HBP-1100-E)

Name:	Blood pressure Monitor
Model:	OMRON HBP-1100 (HBP-1100-E)
Test/measurement technology/method	Oscillometric technology Dynamic Linear Deflation Method
Display	7 segment LCD
Pressure display range	0 to 300 mmHg
Pressure display accuracy	Within ±3mmHg
NIBP measurement range	SYS 60 to 250 mmHg DIA 40 to 200 mmHg Pulse rate 40 to 200 / min
NIBP accuracy*	Maximum mean error within ±5mmHg Maximum standard deviation with 8mmHg
Pulse rate accuracy	Within ±5% of reading
Protection Class	Class II (AC Adapter)  Internal powered equipment (when operating with battery only)
Degree of Protection	Type BF 
MDD Classification	Class II a
Operational temperature and humidity	Temperature range: 5 to 40 °C (41 to 104 °F) Humidity range: 15 to 85% RH (not condensed) Atmospheric pressure: 700 to 1060hPa
Storage and transportation Temperature Humidity	Temperature range: -20 to 60 °C (-4 to 140 °F) Humidity range: 10 to 95% RH (not condensed) Atmospheric pressure: 500 to 1060hPa
Dimensions	Main unit: 130 x 175 x 120 (mm) AC Adapter: 55 x 25 x 70 (mm)
Weight	Main unit: Approx. 0.51 kg (not including accessories) AC adapter: Approx. 0.04 kg
Power source	AC adapter: Input voltage range: AC 100V to 240V Frequency: 50/60Hz Output voltage range: DC 6V ±5% Rated Output Current: 0.5A
Packaging contents	Main unit, Medium cuff, AC Adapter, Instruction Manual, Guarantee card

* Comparison with auscultation method performed by a trained professional.
DIA determined by the auscultation method is “K5”.

Materials Used Main product

Item	Material
Front Housing	Acrylonitrile butadiene styrene
Ground Housing	Acrylonitrile butadiene styrene
Battery Cover	Acrylonitrile butadiene styrene
LCD Holder	Acrylonitrile butadiene styrene
Switches	Silicon
Front Panel	Polycarbonate

Materials Used Cuff

Item	Material
Outside cloth	Nylon ＋Polyester
Inner cloth	Polyester
Air bag	Polyvinyl Chloride (PVC)
Hook and Loop fastener	Hook：Nylon 66 Loop：Nylon 6
Sewing cotton	Polyester
Air Tube	PVC
Air plug to device	Brass + Nickel Chrome plating
Air plug to cuff	PolyvinylChloride (PVC)

Materials Used – AC Adapter

Item	Material
DC cord	Polyvinyl Chloride (PVC)
Pin Plug	Brass
Case (Housing)	Polyphenyleneether

Title page of Instruction Manual

(9 languages – English / French / German / Italian / Spanish / Dutch / Russian / Turkish / Arabic)

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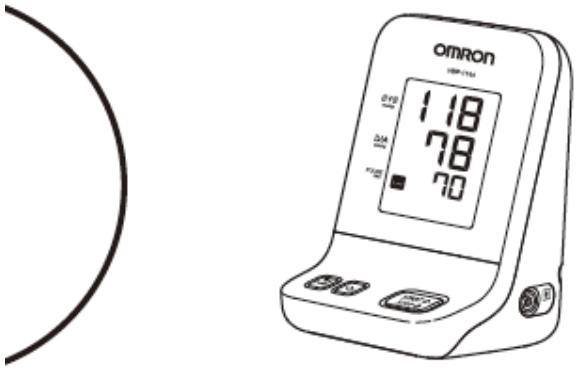


Professional Blood Pressure Monitor

HBP-1100

- Instruction Manual
- Mode d'emploi
- Gebrauchsanweisung
- Manuale di istruzioni
- Manual de instrucciones
- Gebruiksaanwijzing
- РУКОВОДСТВО ПО ЭКСПЛУАТАЦИИ
- Kullanım Kılavuzu
- كتيب الإرشادات

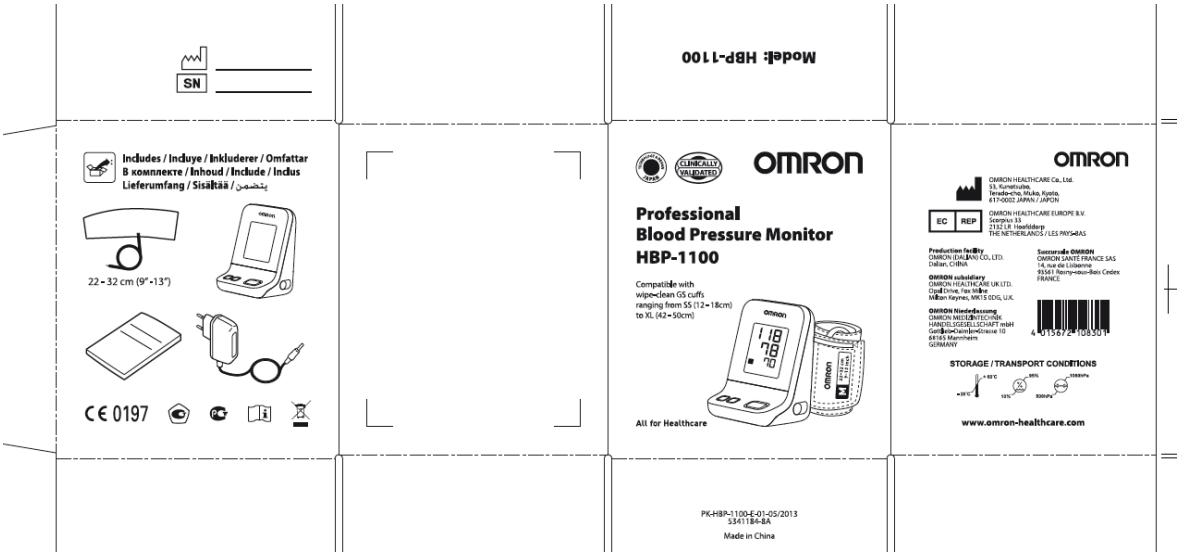
EN FR DE IT ES NL RU TR AR

Thank you for purchasing this OMRON Professional Blood Pressure Monitor.
Please completely read this Instruction Manual before using the monitor for the first time.
Read this manual to ensure the safe and accurate use of the monitor.

All for Healthcare

IM-HBP-1100-E-01-08/2013
2294509-7A

OMRON HBP-1100 (HBP-1100-E) Package Design:



Information in white square above

Package specifications:

Package	Amount	Approx. weight, g	Approx. dimensions W x D x H, mm
Main unit – not including accessories	1	510 g	130 x 175 x 120
Sales package	1	1050g	149 x 142 x 178
Master Carton	10	11.5kg	735 x 315 x 211

Operation and Care

Cleaning and disinfecting should be performed in accordance with your facility's infection control practice.

Cleaning of the device
Wipe with a cloth that has been moistened with isopropyl alcohol diluted to 50 v/v%, or ethyl alcohol (disinfection alcohol) diluted to 80 v/v% or less and wrung out.
Do not wipe the Power connector or allow it to become wet.

Storage

Do not install the unit in the following locations:
- Locations with dust, salt, or sulfur.
- Locations directly exposed to sunlight for extended periods of time (in particular, do not leave in direct sunlight or near a source of ultraviolet light for extended periods, as ultraviolet light will cause deterioration of the LCD).
- Locations subject to vibration or shock.
- Near heaters.

Storage and transportation:
Temperature range: -20 to 60°C (-4 to 140°F)
Humidity range: 10 to 95%RH (not condensed)
Atmospheric pressure: 500 to 1060hPa

Servicing

The device requires no routine service other than cleaning, and visually checking the cuffs, tubing, etc.

Repair

In case of malfunction of the device the user must turn to the service center to test the device and repair the failure. The user shall not repair the device by themselves.

Disposal

Description
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 below. As there is a risk of infection, do not recycle patient attachments such as cuffs, but dispose of them as instructed by your facility's procedures and applicable regulations.

Item	Parts	Material
Package	Box	Cardboard
Package	Cushion	Cardboard
Package	Bag	PE
Main unit and accessories	Enclosure	ABS, PC, SR
Main unit and accessories	Internal parts	General electronic components
Battery	AA battery	Battery (Commercially available)

Warranty

Warranty term for the blood pressure monitor - 3 years.

Warranty term for the AC adapter- 2 years.

Warranty term for cuffs – this is considered a disposable item depending upon usage

Lifetime

Lifetime of the blood pressure monitor. 100,000 measurements

Lifetime of the AC Adapter: 3 years (under maximum load)

Life of the tubes: no lifetime as these are considered disposable items

Lifetime of the GS CUFF: no lifetime as these are considered disposable items

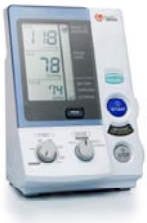
Warranty term, lifetime and addresses of service centers are specified in the warranty card inside the packaging of the HBP-1100.

Comparison with Previous Product

Blood pressure monitor OMRON HBP-1100 (HBP-1100-E), manufactured by OMRON HEALTHCARE Co., Ltd at the production location of 53, Kunotsubo, Terado-cho, Muko, Kyoto, 617-0002 Japan, is an equivalent of a similar device HBP-1300-E.

The device under registration is equivalent to the earlier registered equivalent device in the context of its intended use, field of application, technology, quality, reliability, main specifications, lifetime, operating and storage conditions, safety, functional peculiarities, efficiency and other parameters.

Comparative table of the product with the Previous Model

	Medical device under registration	Earlier registered analogue
Pictures of the devices		
Name	Blood Pressure Monitor	Blood Pressure Monitor
Model	OMRON HBP-1100 (HBP-1100-E)	OMRON HEM-907 (HEM-907-E7)
Manufacturer	OMRON HEALTHCARE Co., Ltd 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan	OMRON HEALTHCARE Co., Ltd 53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 Japan
Manufacturing plants	OMRON DALIAN CO., LTD. Dalian, China	OMRON HEALTHCARE Co., Ltd. Mie, JAPAN
Delivery set	Main unit (device), Medium Cuff, AC Adapter, Instruction Manual, guarantee card	Main unit, medium cuff, AC adapter, instruction manual, guarantee card
Measurement method	Oscillometric method	Oscillometric method
Measurement range	SYS 60 to 250 mmHg DIA 40 to 200 mmHg Pulse rate 40 to 200 beats / min	Pressure: 0 – 299 mmHg Pulse: 30 to 199 beats/min
Memory	No memory	No memory

Operating temperature	from 5 to 40 °C	from 10 °C to 40 °C
Operating relative humidity	15 to 85%RH (not condensed)	from 30–85%
Dimensions	130 x 175 x 120 (mm)	139 x 203 x 131 (mm)
Weight of main unit	510 g	910 g
Power source	AC adapter (100 to 240 V, 50/60 Hz) OR AA dry cell battery x 4	AC adapter (230 VAC, 50 Hz, 20 VA) OR battery pack (4.8 VDC, 6W)

On the basis of protocol of tests for conformity to standards requirements, technical specifications of medical devices and the comparative table above we can make a conclusion that the functional peculiarities, safety, efficiency and quality of the new device are equivalent to the previous device.