New Product Information Sheet

Specifications subject to change

Model (code): HBP-1120

(HBP-1120-E)

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All for Healthcare

PM-1794-01-06/2018

Product description: ***Automatic Upper Arm Blood Pressure Monitor***
Product category: ***Electronic Sphygmomanometers***
Model (code): ***HBP-1120 (HBP-1120-E)***

LEGAL MANUFACTURER
OMRON HEALTHCARE Co., Ltd
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PRODUCION FACILITY
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EU REPRESENTATIVE
OMRON HEALTHCARE EUROPE B.V.
Scorpius 33, 2132 LR Hoofddorp,
THE NETHERLANDS

Included accessories / optional accessories

Included:

Product description	*Model*	*Product code*
Upper Arm Cuff	GS CUFF2 M	HXA-GCFM-PBE
AC Adapter	HHP-CM01	HHP-CM01-E
AC Adapter UK	HHP-BFH01	HHP-BFH01-E

Optional:

Product description	*Model*	*Product code*
Upper Arm Cuff	GS CUFF2 SS	HXA-GCFSS-PBE
Upper Arm Cuff	GS CUFF2 S	HXA-GCFS-PBE
Upper Arm Cuff	GS CUFF2 M	HXA-GCFM-PBE
Upper Arm Cuff	GS CUFF2 L	HXA-GCFL-PBE
Upper Arm Cuff	GS CUFF2 XL	HXA-GCFXL-PBE
AC Adapter	HHP-CM01	HHP-CM01-E
AC Adapter UK	HHP-BFH01	HHP-BFH01-E

General description

OMRON's HBP-1120 (HBP-1120-E) blood pressure monitor is a professional medical device meant for measurement of blood pressure on the basis of the oscillometric principle**.**

Packaging content

The manufacturer produces the HBP-1120 with the applicable accessories included, necessary for the application of its intended purpose.

1. Main unit
2. GS CUFF2 M (HXA-GCFM-PBE) (22-32 cm)
3. AC Adapter HHP-CM01 (or HHP-BFH01)
4. Instruction manual
5. Guarantee card

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

Purpose

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

This product is intended for use in in physicians' offices, hospitals, clinics and other medical facilities.

Intended 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.

Indications for use

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

Measurement Parameter
■ Non-Invasive Blood Pressure
■ Pulse rate

Features (Particularities)

The blood pressure accuracy of the HBP-1120 is clinically proven. Easy to use, the HBP-1120 is intended for use by medical professionals.

Key features

- 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 icon - Helps identify changes in heart rate, rhythm, or pulse that may be caused by heart disease or other serious health problems.

Description of operating principle

How it works

Blood pressure monitor HBP-1120 measures blood pressure using oscillometric method. For detailed description of this method, consult the “Non-Invasive Blood Pressure (NIBP) Measurement” chapter of the instruction manual.

How to use the device

Main steps:

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

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

Technical Specifications

Main unit

Product Category	Electronic Sphygmomanometers
Product Description	Automatic Upper Arm Blood Pressure Monitor
Model (code)	HBP-1120 (HBP-1120-E)
Measurement Parameter	NIBP, PR
Dimension	Main unit: 130 × 175 × 120 (mm) 5.12 × 6.89 × 4.72 (inch) (W×H×D) AC adapter: 64.5 × 21 × 51 (mm) 2.53 × 0.83 × 2.01 (inch) (W×H×D)
Weight	Main unit: Approx. 510 g (not including accessories) AC adapter: Approx. 48 g
Display	7 segment LCD
Protection Class	Class II (AC Adapter)  Internal powered equipment (when operating with battery only)
Degree of Protection	Type BF (Applied part): Cuff

Operation Mode	Continuous operation
MDD Classification	Class II a
Packaging contents	Main unit, Arm cuff (M size), AC Adapter, Instruction Manual, Guarantee card

Power supply

AC adapter	Input voltage range: AC 100 V to 240 V Frequency: 50/60 Hz Output voltage range: DC 6 V ±0.5 V Rated Output Current: 0.7 A
Dry cell battery	Type: AA batteries, x4 Approx. 250 measurements • Measurement conditions - New batteries (AA high-performance manganese) - Ambient temperature of 23°C (73.4°F) - Using M-size cuff - SYS120 / DIA80 / PR60 - One 5-minute cycle consisting of “cuff measurement time + wait time”

Environmental Conditions

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

Non-Invasive Blood Pressure (NIBP)

Measurement technology	Oscillometric
Measurement method	Dynamic Linear Deflation method
Pressure display range	0 to 300 mmHg
Pressure display accuracy	Within ±3 mmHg
NIBP measurement range	SYS 60 to 250 mmHg DIA 40 to 200 mmHg PULSE 40 to 200 /min
NIBP accuracy*	Maximum mean error within ±5 mmHg Maximum standard deviation within 8 mmHg
Pulse rate accuracy	Within ±5 % of reading
Reference Standard	EN1060-1:1995+A2:2009 EN1060-3:1997+A2:2009 EN80601-2-30:2010+A1:2015 EN ISO 81060-2:2013

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

Materials used for main device

Item	Material
Housing	ABS (acrylonitrile butadiene styrene)
Battery Cover	ABS (acrylonitrile butadiene styrene)
Front Panel	PC (polycarbonate)
Cuff	Nylon / Polyester
Tube	PVC (polyvinyl chloride)
Package	Cardboard
Instruction Manual	Paper

Materials used for accessories

Cuff

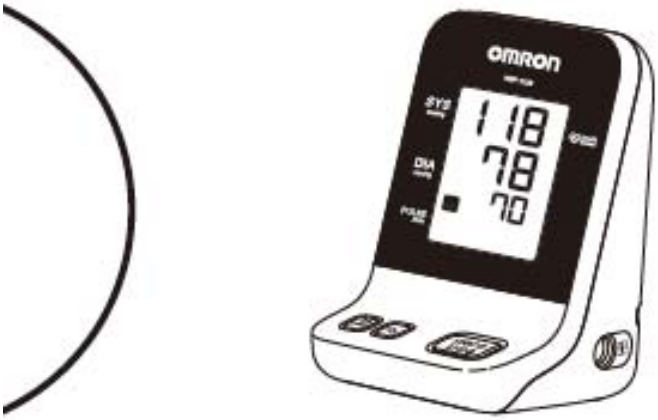
Item	Material
Outside cloth	Nylon / Polyester
Inner cloth	Polyester
Air bag	Flexible urethane sheet
Velcro tape hook	Nylon
Velcro tape loop	Nylon
Sewing cotton	Polyester
Air Tube	PU (polyurethane)
Air plug to device	PVC (polyvinyl chloride)
Air plug to cuff	PVC (polyvinyl chloride)

AC Adapter

Item	Material
Cable	PVC (polyvinyl chloride)
Adapter plug	Copper
Housing	PPE (polyphenylenether)

Title page of Instruction Manual

OMRON



Professional Blood Pressure Monitor

HBP-1120

- 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

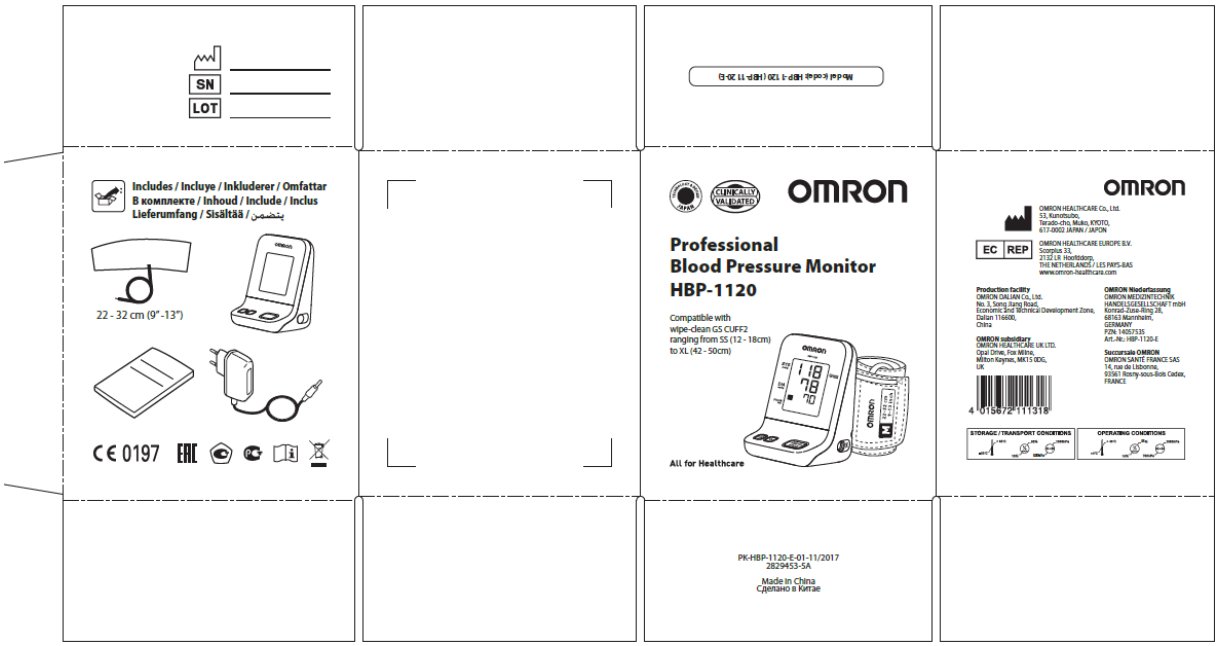
Thank you for purchasing this OMRON Professional Blood Pressure Monitor.
Please completely read this Instruction Manual before using the monitor for the first time.
Read this manual to ensure the safe and accurate use of the monitor.

All for Healthcare

IM-HBP-1120-E-01-11/2017
2829457-8A

Unfolded package design of main device and accessories

Main device:



EN·Professional Blood Pressure Monitor · Compatible with wipe-clean GS CUFF2 ranging from SS (12 - 18cm) to XL (42 - 50cm) · Clinically validated.

ES·Monitor de presión arterial profesional · Compatible con GS CUFF2 de fácil limpieza de la talla SS súper-pequeña (12 - 18 cm) a la XL extra-grande (42 - 50 cm) · Clínicamente validado.

DA·Professionelt blodtryksapparat Kompatibel med GS CUFF2, der kan tørres af, fra størrelse SS (12-18 cm) til XL (42-50 cm) · Klinisk valideret.

SV·Blodtrycksmätare för yrkesmässig användning Kompatibel med avtorkningsbara GS CUFF2 från storlek SS (12-18 cm) till XL (42-50 cm) · Kliniskt validerad.

RU·Измеритель артериального давления и частоты пульса автоматический OMRON HBP-1120 · Подходят моющиеся GS CUFF2 разных размеров от SS (12 - 18 cm) до XL (42 - 50 cm) · Клинически апробирован.

NL·Professionele bloeddrukmeter Te gebruiken met nat afneembare GS CUFF2: SS (12-18 cm) tot XL (42-50 cm) · Klinisch gevalideerd.

IT·Misuratore professionale della pressione arteriosa · Compatibile con i lavabili GS CUFF2 delle misure da SS (12 - 18 cm) a XL (42 - 50 cm) · Clinicamente validato.

FR·Tensiomètre professionnel Compatible avec les GS CUFF2 faciles à nettoyer dont les tailles vont de SS (12 - 18 cm) à XL (42 - 50 cm) · Validation clinique.

DE·Professionelles Blutdruckmessgerät · Kompatibel mit abwischbaren GS CUFF2 von SS (12 - 18 cm) bis XL (42 - 50 cm) · Klinisch validiert.

FI·Ammattikäyttöön tarkoitettu verenpainemittari · Yhteensopiva puhtaaksi pyyhittävien GS CUFF2 kanssa koosta SS (12-18 cm) kokoon XL (42-50 cm) · Kliinisesti validoitu.

AR· جهاز قياس ضغط الدم المتخصص
متوافق مع GS CUFF2 القابلة للمسح والتنظيف،
وبمقاسات تتراوح ما بين مقاس SS (12 - 18 سم) إلى
مقاس XL (42 - 50 سم)•تم التحقق منه سريريًا

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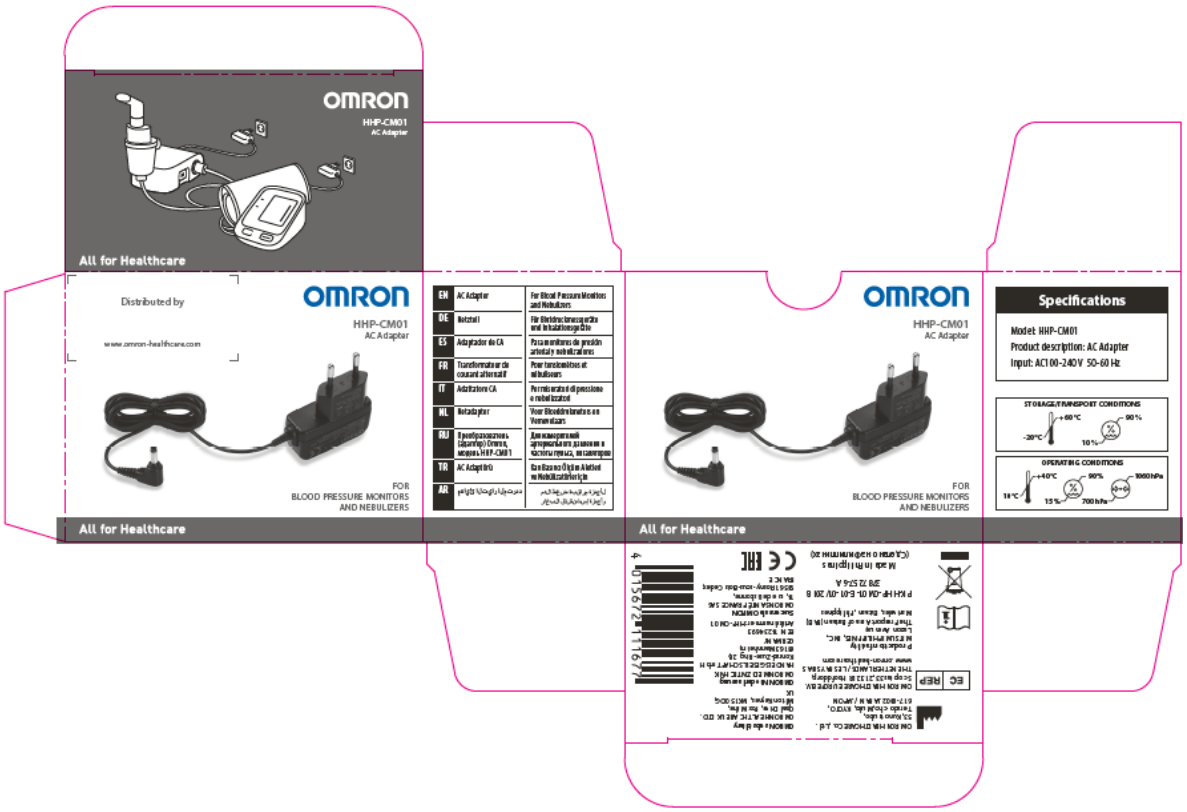
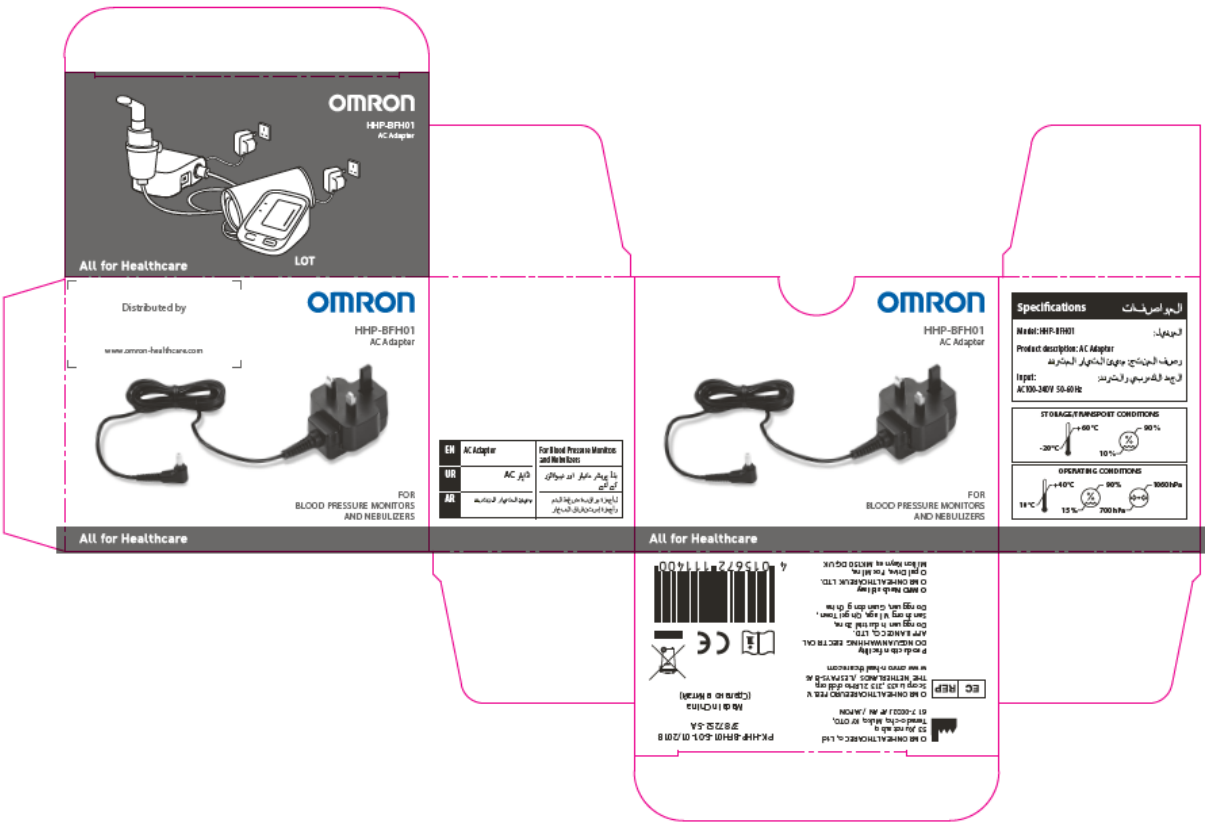
Information in white square on package artwork

AC adapter HHP-CM01:



AC Adapter with UK plug: HHP-BFH01



Packaging specifications from Explanation Diagram

Package	Amount	Approx. weight	Approx. dimensions W x D x H, mm
Main Unit	1	510 g	130 x 175 x 120 mm
Package	1	1050 g	149 x 142 x 178 mm
Master Carton	10	11.5 kg	735 x 315 x 211 mm
EAN code	4015672111318		

List of Harmonized EN Standards

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

Applicable Directives & Standards:

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

EN ISO 15223:1:2016
EN 1041:2008+A1:2013
EN 1060-1:1995+A2:2009
EN 1060-3:1997+A2:2009
EN 60601-1:2006+A1:2013
EN 60601-1-6:2010+A1 :2015
EN 80601-2-30 :2010+A1 :2015
EN 62304:2006+A1:2015
EN 62366:2008+A1:2015
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 14971:2012
EN ISO 81060-2 :2014
EN ISO 13485 :2016

2011/65/EU Restriction of Hazardous Substances (RoHS) : EN 50581 :2012

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.

Warnings

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

Storage / Setup

Warnings
• Install the unit in a location close to a power outlet where the AC adapter can be easily disconnected. If the power cannot be quickly disconnected when an abnormal condition occurs, an accident or fire may result.
• 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 contact your OMRON retail dealer or distributor.
• 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.
• During measurement, make sure that no mobile phone or any other electrical devices that emit electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.

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 in a location with noise-emitting equipment such as a room with MRI, CT, X-ray or HF surgical equipment or an operating room. Noise from the equipment may interfere with the operation of the unit.

Before use / during use

Warnings
• The unit complies with the EMC (Electro Magnetic Compatibility) 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. This may damage and/or may be hazardous to the device.
• 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.

Cautions
• 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)
- The patient has a mastectomy
- 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.
• Do not wrap the cuff on an arm with an SpO2 sensor or other monitoring equipment attached. The pulse may disappear when the cuff pressurizes, causing a temporary loss of monitoring function.

Cleaning

Warnings

• 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.

Cautions

• 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. This may damage the surface of the device.
• Clean the unit regularly.

Maintenance and inspection

Warnings

• To use the unit safely and correctly, always inspect the unit when starting work.
• Unauthorized modification is prohibited by law. Do not attempt to disassemble or modify the unit.

Dry cell battery

Warnings

• If battery fluid comes in contact with the eye, immediately flush with copious amounts of water. Do not rub. Seek medical attention immediately.
• Do not throw into flame, disassemble, or heat.
• Always disconnect the AC adapter from the unit before removing or installing a battery.

• If the unit will not be used for a month or longer, remove the battery from the unit and store.
• Do not attempt to disassemble or modify the battery.
• Do not apply pressure to and deform the battery. Do not throw, pound, drop, bend, or hit the battery.
• The battery has positive/negative polarity. Do not insert batteries with their polarities reversed.
• Do not connect the positive and negative terminals of the battery with a wire or other metal object.
• Do not use the AC adapter and battery at the same time.
• Use only the specified type of battery.

Cautions
• If battery fluid comes into contact with the skin or clothes, immediately rinse with water.
• Do not use new and old batteries together, or use different types of batteries together.

Non-Invasive Blood Pressure (NBIP) measurement

Warnings
• If a cuff is used on some patients with an infection, treat the cuff as medical waste, or disinfect before reuse. Otherwise, an infection may result.
• If frequently performing NIBP measurement using a cuff over an extended period of time, periodically check the patient's circulation. In addition, wrap the cuff as indicated in the cautionary points in this manual.
• Do not connect the NIBP cuff or cuff joint to a luer lock adapter.
• Do not bend cuff tube during inflation and deflation, particularly after a change of body position.
• Do not wrap the cuff on the following parts:
- An upper arm on which intravenous drip or a blood transfusion is being performed.
- An upper arm on which SpO2 sensor, IBP catheter, or other instrument is attached.
- An upper arm with a shunt for hemodialysis.
- An injured upper arm.
• If measuring blood pressure with the cuff wrapped on the arm on the side of the body where a mastectomy was performed, check the patient's condition.

Cautions
• NIBP measurement should be performed on the upper arm.
• During NIBP measurement, stop excessive body movement by the patient and minimize trembling.
• If a doctor has indicated that the patient has hemorrhagic diathesis or hypercoagulability, check the condition of the arm after measurement.
• Use the appropriate cuff size to ensure correct measurements. If too large a cuff is used, the measured blood pressure value tends to be lower than the actual blood pressure. If too small a cuff is used, the measured blood pressure value tends to be higher.
• Before and during measurement, verify that none of the following apply to the patient:

- The part where the cuff is wrapped is at a different height than the heart. (A difference of 10 cm (4 inches) in height may cause a variation in the blood pressure value of up to 7 or 8 mmHg.)
- Body movement or conversing during measurement.
- Cuff wrapped over thick clothing.
- Pressure on the arm due to a rolled up sleeve.

• In the case of a cuff for adults, the cuff should be wrapped to a tightness that allows two fingers to be inserted in between the cuff and the arm.
• The accuracy of a flashing measurement value that is out of the measurement range cannot be guaranteed. Always check the patient's condition before deciding what steps to take.
• Do not use the cuff if it is damaged or has holes.
• Only an OMRON GS CUFF2 can be used with this device. The use of any other cuff may result in incorrect measurement.

Disposal

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

Consult also the "*Correct Disposal of This Product (Waste Electrical & Electronic Equipment*)" section of the Manual.

Transportation and storage conditions

Storage and transportation:
Temperature range: -20 to +60°C (-4 to 140°F)
Humidity range: 10 to 95%RH
Atmospheric pressure: 500 to 1060hPa

Warranty and lifetime

Warranty:
- blood pressure monitor: 3 years
- AC adapter: 1 years
- cuffs: this is considered a disposable item depending upon usage

Lifetime:
- blood pressure monitor: 5 years (only when appropriate inspection in performed)
- AC Adapter: 5 years
- tubes: no lifetime as these are considered disposable items

- cuffs: 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-1120.

Repair

If the unit has broken down, contact your OMRON retail dealer or distributor.

Servicing

The HBP-1120 must be maintained to ensure functionality and to secure the safety of patients and operators.
Daily checks and maintenance should be performed by the operator.
In addition, qualified personnel are necessary to maintain the performance and the safety, and to conduct periodic inspections. We recommend that the verification test be performed at least once a year.

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