OMRON



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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
2829457-8A1

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Introduction

Intended Use

Medical 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).

Intended User

This device should be used by a medical professional.

Patient Population

This device is intended for use on adults and children of age 3-years and older.

Environment

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

Service life

5 years (only when appropriate inspection is performed)

Measurement Parameter

- Non-Invasive Blood Pressure
- Pulse rate

Precautions for Use

Warnings and cautions described in the instruction manual should be observed at all times.

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Exemptions

OMRON will not bear any responsibilities on the following matters.

1. When a problem or damage occurs caused by the maintenance and/or repair conducted by a person other than OMRON or the dealer specified by OMRON
2. The problem or damage of OMRON product caused by the product of other manufacturer not delivered by OMRON
3. The problem and damage caused by the maintenance and/or repair using the repair parts not specified by OMRON
4. The problem and damage caused by the results not observing the Notes on Safety or the operational method mentioned in this Instruction Manual
5. Under the circumstances not within the operating conditions of this unit including the power source or the setting environment mentioned in this Instruction Manual
6. The problem and damage caused by the result(s) of remodeling or improper repair of this product
7. The problem and damage caused by act of god such as fire, earthquake, flood, or lightning

1. The contents of this Instruction Manual may be changed without prior notice.
2. We have thoroughly reviewed the contents of this Instruction Manual. However, if an inadequate description or error is found, please let us know.
3. It is prohibited to copy a part of or the entire Instruction Manual without getting OMRON's permission. Unless this Instruction Manual is used by an individual (company), it cannot be used without getting OMRON's permission from the standpoint of the Copyright Law.

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Notes on Safety

The warning signs and symbol examples indicated below are intended to ensure safe use of the product and prevent damage and injury to you and others. The signs and symbols are explained below.

Safety Symbols used in this Instruction Manual	
⚠ Warning	Indicates the matters in which death or severe bodily damage may arise as a result of incorrect handling.
⚠ Caution	Indicates the matters in which bodily harm or material damage may arise as a result of incorrect handling.

General Information
Note: Indicates general information to keep in mind when using the unit and other useful information.

Storage/Setup

⚠ Warning

- 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 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.

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⚠ Caution

- 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

⚠ Warning

- The unit complies with the EMC (Electro Magnetic Compatibility) standard (EN60601-1-2). 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.

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⚠ 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)
  - 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 SpO_2 sensor or other monitoring equipment attached. The pulse may disappear when the cuff pressurizes, causing a temporary loss of monitoring function.

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Cleaning

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⚠ 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. This may damage on the surface of the device.
- Clean the unit regularly.

Maintenance and inspection

Warning

- 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

Warning

- 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.

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Caution

- 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 (NIBP) measurement

Warning

- 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 SpO_2 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.

⚠ Caution

- 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.

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Note:

Setup

- Read and understand the manual for each optional accessory. This manual does not contain cautionary information for optional accessories.
- Exercise caution with the cables and arrange so that the patient does not become entangled or bound.

Before use / during use

- Check the following after turning on the power:
  - No smoke, abnormal odor, or abnormal noise is emitted.
  - Press each button and verify that it operates.
  - For functions that cause icons to light or flash, verify that the icons light or flash (page 12).
  - Measurement can be performed normally, and measurement error is within the tolerance value.
- If the screen is not displayed normally, do not use the unit.
- When recycling or disposing of parts (including batteries) of the unit, follow local government rules and regulations.

Cleaning

- For cleaning, see page 22.

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Non-Invasive Blood Pressure (NIBP) measurement

- If the patient has acute inflammation, a pyogenic ailment, or an external wound at the location where the cuff is to be wrapped, follow the instructions of the doctor.
- Non-Invasive Blood Pressure measurement (NIBP) is performed by compressing the upper arm.Some people may experience intense pain, or transient spotting caused by subcutaneous hemorrhaging (bruising) may appear. The spotting will disappear with time; however, it may be appropriate to inform patients for whom this may be a concern that spotting sometimes occurs, and if necessary, refrain from measurement.
- Clinical evaluation of the unit was carried out in a resting position (feet on floor without crossing legs, back supported by backrest, arm supported such that cuff is attached at same height as heart) in accordance with ISO81060-2:2013. Measurement in a position other than the resting position may result in differences in measurement results.
- As the patient's posture or physiological condition influences blood pressure, it easily fluctuates. Recommend the followings to take a more accurate measurement:
  - Make the patient relaxed.
  - Do not talk to the patient.
  - Let the patient rest for at least 5 minutes before the measurement.

Using the Unit

Components of the Product

Before using the unit, make sure that no accessories are missing and that the unit and accessories are not damaged. If an accessory is missing or there is damage, please contact your OMRON retail dealer or distributor.

Main unit



Standard Medical Accessories

- **AC adapter [HHP-CM01]***
  ***[HHP-BFH01]**
- **GS CUFF2 M [HXA-GCFM-PBE] (22-32 cm)**

Others

- **Instruction Manual (This paper)**
- **Guarantee Card**

Options

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

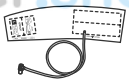
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AC adapter
HHP-CM01
(9546045-8)

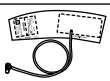


GS CUFF2 XL (1 m)
HXA-GCFXL-PBE
(9546010-5)



GS CUFF2 L (1 m)
HXA-GCFL-PBE
(9546009-1)

* UK 3-pin plug AC Adapter
AC Adapter UK
HHP-BFH01
(9546044-0)



GS CUFF2 M (1 m)
HXA-GCFM-PBE
(9546008-3)



GS CUFF2 S (1 m)
HXA-GCFS-PBE
(9546007-5)



GS CUFF2 SS (1 m)
HXA-GCFSS-PBE
(9546021-0)

⚠ Caution

- Only an OMRON GS CUFF2 can be used with this device. The use of any other cuff may result in incorrect measurement.

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Features of the Product

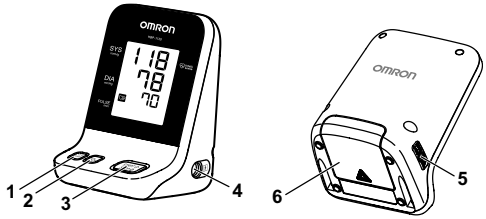
The blood pressure accuracy of the HBP-1120 is clinically proven. Easy to use, the HBP-1120 is intended for use by medical professionals.

- Zero indicator function (page 17): Before each measurement, this device indicates that “zero setting” was successful.
- Auscultation Mode
- 5 cuffs available - (XL: 42 to 50 cm, L: 32 to 42 cm, M: 22 to 32 cm, S: 17 to 22 cm, SS: 12 to 18 cm)
- 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, this device stops deflation for 5 seconds.
- Irregular pulse icon: Helps identify changes in heart rate, rhythm, and pulse that may be caused by heart disease or other serious health problems.

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Features / Functions of Unit

Front and bottom of unit



1	POWER	[Power ON/OFF] button	Turns the power ON/OFF.
2		[Auscultation] button	Press to enter “Auscultation Mode” (page 19).
3	START / STOP	[START/STOP] button	Press to start blood pressure measurement. While the cuff is inflating, hold down to continuously inflate (page 18).
4		NIBP connector	Connects the cuff tube.
5		Power connector	Connects the AC adapter.
6		Battery cover	Open to install or replace the batteries.

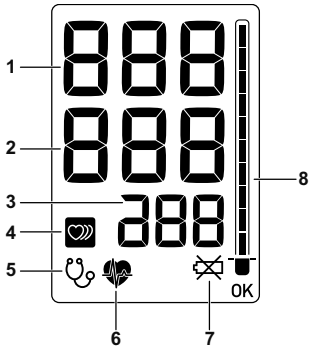
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Other symbols

Please refer to page 33 what the symbols on the units mean.

LCD Display



1	SYS	Displays systolic blood pressure.
2	DIA	Displays diastolic blood pressure.
3	PULSE	Displays the pulse rate.
4	Irregular pulse wave icon	Lights up in the measurement result display if the pulse wave interval was irregular or there was body movement during measurement.
5	Auscultation icon	Lights up when “Auscultation Mode” is ON.
6	Pulse synchronization icon	Flashes in synchronization with the pulse during measurement.
7	Battery replacement icon*	When this icon lights up, an E40 error also appears. Replace the batteries. (page 13)
8	Zero indicator icon	Lights up when “zero setting” is being performed prior to blood pressure measurement. When “zero setting” finishes, OK appears.

* Only when the batteries are installed.

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Installing the Batteries

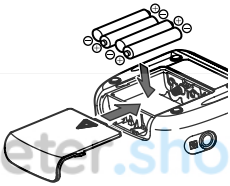
Warning

- 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.
- Do not attempt to disassemble or modify the battery.
- Do not use the AC adapter and battery at the same time.

Caution

- If battery fluid comes into contact with the skin or clothes, immediately rinse with water.

1. **Make sure the AC adapter has been disconnected.**
2. **Remove the battery cover from the bottom of the unit.**
3. **Insert the batteries in the correct orientation.**
4. **Replace the battery cover.**



Battery replacement icon

When this icon lights up, an E40 error also appears. Replace the batteries.

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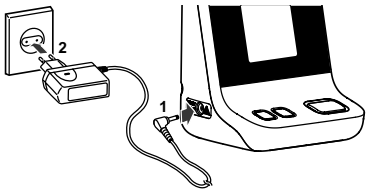
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Connecting the AC Adapter

AC power

Verify that the power outlet supplies the specified voltage and frequency (100 - 240 V AC, 50/60 Hz).

Connect the AC adapter to the power connector on the unit and the power outlet.



To disconnect the power outlet, unplug the AC adapter from the power outlet first and then remove the AC adapter plug from the unit.

Cuff Selection and Connection

⚠ Warning

- If a cuff is used on a patient with an infection, treat the cuff as medical waste, or disinfect before reuse.

⚠ Caution

- Do not use the cuff if it is damaged or has holes.
- Use the appropriate cuff size to ensure correct measurements. If a cuff that is too large is used, the measured blood pressure value tends to be lower than the actual blood pressure. If a cuff that is too small is used, the measured blood pressure value tends to be higher.

Note:

- Make sure that the connectors are tightly connected.

Selecting the cuff

Measure the circumference of the patient's arm and select the cuff size that is appropriate for the circumference.

It is important to use the correct sized cuff for a patient in order to get an accurate reading.

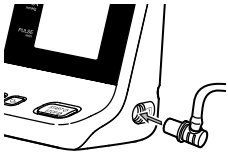
Select the cuff that is suitable for the patient from the cuffs below.

Cuff name	Arm circumference	
	(cm)	(inch)
GS CUFF2 XL*	42 - 50	17 - 20
GS CUFF2 L*	32 - 42	13 - 17
GS CUFF2 M	22 - 32	9 - 13
GS CUFF2 S*	17 - 22	7 - 9
GS CUFF2 SS*	12 - 18	5 - 7

*Available as an optional accessory.

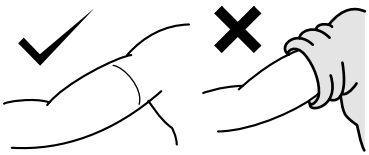
Connecting the cuff

Connect the cuff tube to the NIBP connector on the unit.

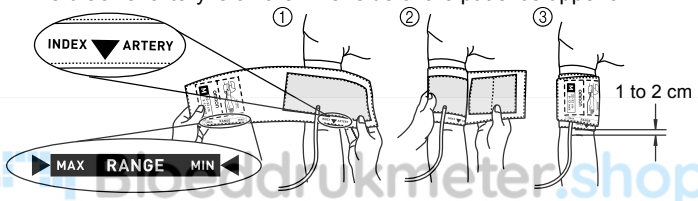


Applying the Cuff to the Patient

The device can be used on either the right or left arm.
Wrap the cuff on a bare arm or over thin clothing. Thick clothing or a rolled up sleeve will cause inaccurate blood pressure measurements.



1. **Make sure the cuff tube is not bent.**
   The cuff tube should be on the peripheral side.
2. **Wrap the cuff so that the INDEX ARTERY "▼" is directly over the brachial artery.**
   The brachial artery is on the inner side of the patient's upper arm.



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   Make sure that the INDEX ARTERY "▼" is within the range. If outside the ▶ MAX RANGE MIN ◀ range, there will be greater error in the blood pressure value. In this case, use the appropriate cuff size.
   * Attach the cuff so that the bottom edge is 1 to 2 cm from the inner side of the elbow joint.
   * The cuff should be wrapped to a tightness that roughly allows two fingers to be inserted under the cuff.
3. **During measurement, keep the brachial artery on which the cuff is wrapped at the same height as the right atrium of the heart.**

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⚠ Caution

- Make sure the cuff is wrapped in the correct arm position and is at the same height as the heart.

NOTE:

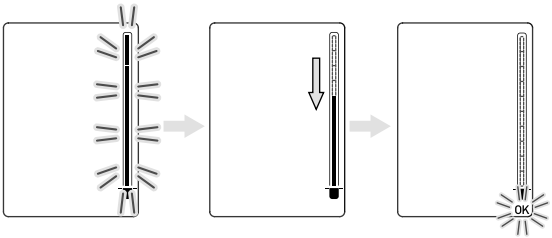
- If measurement is difficult due to arrhythmia, use a different blood pressure measurement method.
- If the patient has acute inflammation, a pyogenic ailment, or an external wound at the location where the cuff is to be wrapped, follow the instructions of the doctor.
- Non-Invasive Blood Pressure (NIBP) measurement is performed by compressing the upper arm. Some people may experience intense pain, or transient spotting caused by subcutaneous hemorrhaging may appear. The spotting will disappear over time, however, if it is possible that this will disturb the patient, try the following technique:
  - Wrap a thin towel or cloth (one layer) under the cuff.If the towel or cloth is too thick, there will be insufficient cuff compression and the blood pressure value will measure high.
- If the patient moves or the cuff is touched, this may be falsely detected as a pulse and over-inflation will occur.
- Do not inflate the cuff when it is not wrapped on the upper arm. This may damage the cuff.

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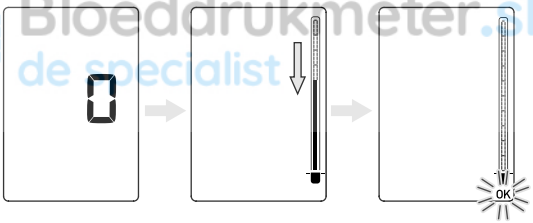
Zero Indicator Function

Before each measurement, this device indicates that “zero setting” was successful.

- When the power is turned on, the entire indicator blinks and then “zero setting” starts. When completed, OK appears.



- When the power is already on, measurement is started, then “zero setting” takes place from the ready screen (which shows “0”). When completed, OK appears.



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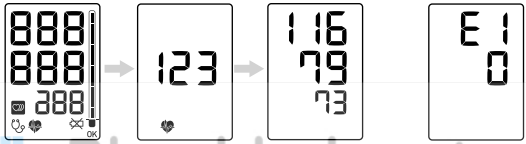
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Non-Invasive Blood Pressure (NIBP) Measurement

Measurement in “Normal Mode”

1. **Press the [START/STOP] button.**
   Blood pressure measurement is performed once.
2. **The measurement results are displayed.**
   If a measurement value is outside the corresponding range below, the value will flash.
   SYS: 59 mmHg or less, or 251 mmHg or higher.
   DIA: 39 mmHg or less, or 201 mmHg or higher.
   PULSE: 39 bpm or less, or 201 bpm or higher.

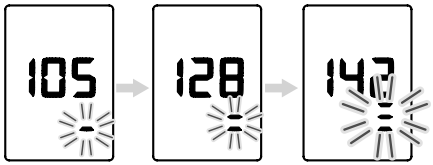
■ Normal measurement ■ Measurement error / failure



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Manual inflation in “Normal Mode”

If the cuff is not sufficiently inflated, it can be inflated manually. During inflation, hold down the [START/STOP] button to inflate continuously.
“-” appears below the value to indicate that manual inflation is in progress.



⚠ Caution

- The accuracy of a flashing measurement value that is outside the measurement range is not guaranteed. Always check the patient's condition before deciding what steps to take.

NOTE:

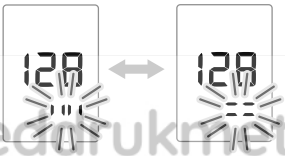
- If inflation is insufficient, inflation may restart automatically while measurement is in progress.

Irregular pulse wave detection function

If the pulse wave interval becomes irregular during measurement, the irregular pulse wave detection icon will light up.

Body movement detection function

If body movement is detected during measurement, deflation stops for 5 seconds and alternately below the value.



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After 5 seconds, measurement resumes, and an attempt is made to complete measurement in one cycle.

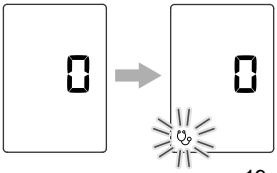
NOTE:

- When the body movement detection function has been activated, the irregular pulse wave icon appears in the measurement result.

Measurement in "Auscultation Mode"

In "Auscultation Mode", this device does not measure blood pressure. Measurement should be performed by a health care professional using a stethoscope.
The healthcare professional uses a stethoscope to determine SYS and DIA by means of the auscultation method.

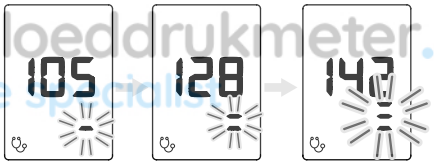
1. **Make sure the power is on.**
   "0" is displayed.
2. **Press the [Auscultation] button.**
   The auscultation icon appears and the device enters "Auscultation Mode".



3. **Press the [START/STOP] button.**
   Inflation starts. When the cuff is sufficiently inflated, deflation automatically starts.
4. **At the SYS point that you determine by auscultation, press the [Auscultation] button.**
   The first time you press the [Auscultation] button, the SYS value appears.
5. **At the DIA point that you determine by auscultation, press the [Auscultation] button.**
   The second time you press the [Auscultation] button, the DIA value appears and the cuff rapidly deflates.

Manual inflation in "Auscultation Mode"

If the cuff is not inflated sufficiently or you want to re-inflate, you can inflate the cuff manually.
Hold down the [START/STOP] button during inflation or deflation to inflate continuously.
"-" appears below the value to indicate that manual inflation is in progress.



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NOTE:
- The body movement detection function is disabled while "Auscultation Mode" is in use.
- In "Auscultation Mode", the pulse rate is not measured and does not appear.

Stopping the Measurement

To stop measurement while measurement is in progress, press [START/STOP] button.

Turning the Power OFF

To shut down the device, press the [Power ON/OFF] button.

Non-Invasive Pressure Measurement Principles

Oscillometric method

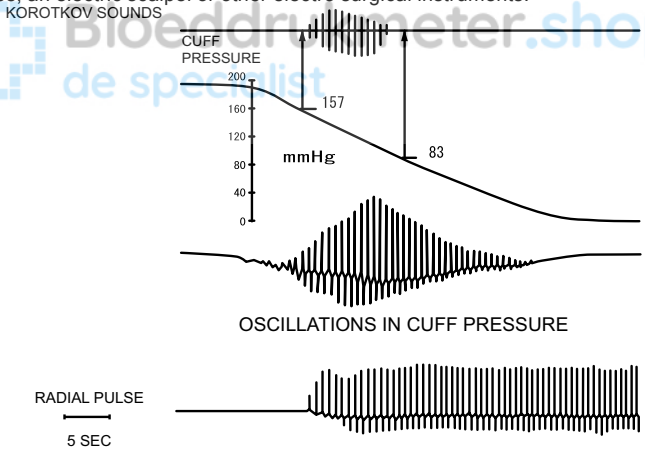
The beat in the pulsation generated by the contraction of the heart is captured as the pressure inside the cuff to measure the blood pressure. If the cuff wrapped around the upper arm is pressurized sufficiently, the blood flow stops, but the beat of the pulsation is present and the pressure inside the cuff receives this and oscillates. Next, as the pressure inside the cuff gradually decreases, the oscillation of the pressure within the cuff gradually increases and reaches a peak. As the pressure within the cuff decreases further, the oscillation decreases from its peak.

The pressure within the cuff and the relationship with the increase and decrease of the oscillation within the cuff in this series of processes are stored into memory, calculations are carried out, and the blood pressure value is determined.

The pressure within the cuff when the oscillation increases drastically is the systolic pressure and the pressure within the cuff when the oscillation decreases drastically is the diastolic pressure. Also, the pressure within the cuff when the oscillation peaks is taken as the average pulsation pressure.

The oscillometric method does not determine the blood pressure value instantly like a microphone type automatic blood pressure gauge with the auscultation method, but rather determines it from the series of change curves as explained above. Therefore, it is not easily affected by external noise, an electric scalpel or other electro surgical instruments.

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Comparison between the auscultatory, oscillometric and palpatory methods of measuring blood pressure.

L.A. Geddes,
"The Direct and Indirect Measurement of Blood Pressure", Year Book Medical Publishers, Inc. 1970

Maintenance

Maintenance Inspection and Safety Management

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.

Cleaning of the Device

Cleaning and disinfecting should be performed in accordance with your facility's infection control practice.
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.
Use a moistened cotton bud to remove dust that has accumulated on the vent ports.
The device requires no routine service other than cleaning, and visually checking the cuffs, tubing, etc.

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⚠ Caution

- 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.

Cuff Care

Wipe clean on the surface of the cuff with a cloth moistened with a 70 v/v% dilution of isopropyl alcohol, or a 80 v/v% or less dilution of disinfection ethanol (ethyl alcohol).
Do not allow any liquids inside the cuff. If a liquid gets in the cuff, dry the inside well.

Check before Use

Before turning on the power

Before turning on the power, check for the following

■ External appearance

- The device or accessories are not deformed due to falling or other impact.
- The device is not dirty.
- The device is not wet.

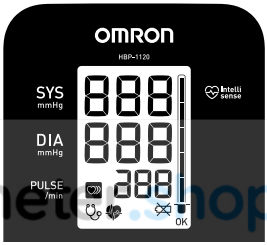
■ AC adapter

- The AC adapter is firmly connected to the connector on the device.
- There are no heavy objects lying on the AC adapter cable.
- The AC adapter cable is not damaged (core-wire exposure, breaks, etc.).

When turning on the power

When you turn on the power, check the LCD display.

- When the [START/STOP] or [Power ON/OFF] button is pressed to turn on the power, the right screen appears.



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After turning on the power

After turning on the power, check for the following

■ External appearance

- There is no smoke or odor coming from the device.
- The device is not making any unusual noises.

■ Buttons

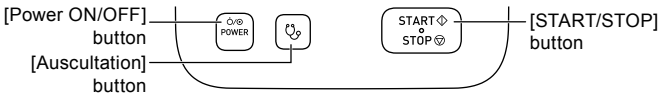
- Press each button and check that it works.

■ Non-invasive blood pressure (NIBP)

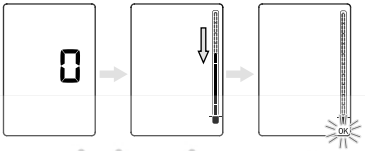
- Make sure that a suitable OMRON GS CUFF2 is attached (one that fits the circumference of the patient's arm).
- The cuff tube is firmly connected.
- The person checking the cuff should wrap the cuff around arm, perform cuff measurement and check to see that blood pressure is in the vicinity of normal measurements.
- While measurement is in progress, intentionally activate "Body movement detection function" to halt discharge by bending the relevant arm and move body and during this halt check that cuff pressure does not drop.

Checking Pressure Accuracy

You can check the pressure accuracy of the device.



1. **Make sure the power is on.**
2. **Hold down the [Auscultation] button for 3 seconds.**
   "Zero setting" is performed.
   When "zero setting" is finished, the pressure accuracy verification screen appears.



3. **Check the "0" display, and perform the pressure accuracy check.**
   Apply the external pressure.
   Compare with the displayed value and make sure there is no problem.



Example:

1. **Connect the blood pressure monitor, the calibrated reference pressure gauge, and the cuff and inflation bulb.**



2. **Check the pressure value of the blood pressure monitor and the pressure value of the calibrated reference pressure gauge.**

Note:

- Make sure that the blood pressure monitor reading is within ±3 mmHg compared to the calibrated reference pressure gauge.

4. **Turn off the power and exit.**

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Troubleshooting

In case of any of the below problems occur during use, first check that no other electrical device is within 30 cm. If the problem persists, please refer to the table below.

The power does not turn on	
Cause	Solution
If the unit is being powered by the batteries, the batteries are not installed or depleted.	Insert batteries or replace with new batteries (page 13).
The AC adapter is disconnected.	Connect the AC adapter (page 13).
If the power does not turn on and the above is not the cause, turn off the unit power, disconnect the AC adapter, remove the batteries, and contact your OMRON retail dealer or distributor.	

The unit display does not operate
Cause / solution
Stop using the unit and contact your OMRON retail dealer or distributor.

The unit becomes hot	
Cause	Solution
An object is on top of the unit or right next to the unit.	Keep the area around the unit free of objects.
If the unit becomes too hot to be touched, there may be a problem in the unit. Turn off the unit power, disconnect the AC adapter, remove the batteries, and contact your OMRON retail dealer or distributor.	

The cuff does not inflate when the [START/STOP] button is pressed	
Cause	Solution
Loose cuff tube connection.	Check the connection.
There is an air leak in the cuff.	Replace the cuff.
If pressure is displayed, the cuff tube is bent.	Make sure no part of the cuff tube is bent.

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Measurement was not possible
Cause / solution
Check the patient by palpation or other method. After checking the patient, check the error code and see “List of Error Codes” (page 28) for Non Invasive Blood Pressure (NIBP) measurement.

Abnormal measurement value
Cause / solution
The causes below are possible. Check the patient by palpation and then repeat measurement. • Body movement (chills or other trembling) • Arrhythmia. • Noise in the cuff - A nearby person touched the patient. - Cardiac massage was being performed.

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The measurement value is questionable	
Cause	Solution
Deflates quickly	Check for a loose cuff connection.
Incorrect cuff size used.	Measure circumference of patient's arm and ensure correct sized cuff is used.
Cuff wrapped over thick clothing.	Ensure cuff is applied to a bare arm, or very thin clothing.
Patient not seated properly.	Ensure patient is seated, feet flat on the floor, cuff at heart level.
Patient ate, drank, or exerted themselves recently.	Ensure before measurement taken, patient has not had food, caffeinated or alcohol beverages, or exerted/exercised in the last 30 minutes.
Simultaneously perform measurement with a stethoscope. Place the stethoscope and listen while viewing the pressure display of the manometer. 	
Blood pressure may vary widely due to physiological effects. The causes below are possible. • Emotional excitement or agitation • Pain due to cuff wrapping • White coat hypertension • Cuff size or wrapping method not correct • Cuff wrapping position on upper arm not at the same height as the heart • Patient's blood pressure not stable due to pulsus alternans, respiratory changes, or other reason	

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List of Error Codes

■ Example: E2



SYSTEM

Error code	Description	Points to check
E9	Internal hardware error	Contact your OMRON retail dealer or distributor.

Non-Invasive Blood Pressure (NIBP)

Error code	Description	Points to check
E1	The cuff tube is not connected	Firmly connect the cuff tube.
	Air is leaking from the cuff.	Replace with an OMRON GS CUFF2 that does not leak.
E2	Did not inflate properly because the arm or body moved during measurement.	Have the patient not move the arm or body, and repeat measurement.
	Moved body or arm during measurement, or talked.	Have the patient not talk or move, and repeat measurement.
	The cuff is not applied correctly.	Correctly apply the cuff.
	The sleeve is rolled up and is compressing the arm.	Remove the garment and re-wrap the cuff.
	Measurement time has exceeded specified time. Specified time: 165 seconds	The measurement time exceeds the expected time, so the measurement was ended in order to avoid patient discomfort. There is a possibility that measurement is being repeated over and over due to air leaking from the cuff.

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Other problems

Error code	Description	Points to check
E3	Cuff inflated to 300 mmHg or higher during manual inflation in “Auscultation Mode”	When inflating manually in “Auscultation Mode”, release the button when the pressure reaches the desired value.
	Over-inflation occurs	If this occurs during measurement, repeat measurement.If this occurs when not performing measurement, contact your OMRON retail dealer or distributor.
E40	The batteries are depleted.	Replace with new batteries. (page 13)

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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 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
	Bags	Polyethylene
Main unit	Enclosure	ABS (Acrylonitrile butadiene styrene), Polycarbonate, Silicone rubber
	Internal parts	General electronic components
Battery	AA battery	Battery (Commercially available)
Cuff / Cuff tube	Cuff	Nylon, Polyester, Polyurethane, Polyvinyl chloride
	Tube	Polyvinyl chloride
	Connector	PA, ABS
AC adapter	Enclosure	Polyphenylether
	Cord	Polyvinyl chloride
	Internal parts	General electronic components

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Specifications

Technical Specifications: HBP-1120

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

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”

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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”.

NOTE:
- Specifications may be changed without prior notice.

CE 0197

This blood pressure monitor fulfils the requirements of the EC directive 93/42/EEC (Medical Device Directive). It also conforms to the European standard EN 1060, Non-invasive Sphygmomanometers Part 1: General Requirements and Part 3: Additional Requirements for Electromechanical Blood Pressure Measuring Systems.

Symbols description			
	Applied part - Type BF Degree of protection against electric shock (leakage current)		For indoor use only
	Class II equipment. Protection against electric shock		OMRON's trademarked technology for blood pressure measurement
	Alternating current		Range pointer and brachial artery alignment position
	CE Marking		Range indicator of arm circumferences to help selection of the correct cuff size.
	GOST-R symbol		Manufacturer's quality control mark
	Metrology symbol		Date of manufacture
	Symbol of Eurasian Conformity		Clinically validated
	Serial number		Technology and Design, JAPAN
	LOT number		OFF/ON for a part of equipment
	Temperature limitation		Direct current
	Humidity limitation		Need for the user to follow the instruction manual thoroughly for your safety
	Atmospheric pressure limitation		Need for the user to consult the instruction manual
	Indication of connector polarity		To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.

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Symbols description			
	Start; start of action To identify the start button.		Package content
	Stop To identify the control or the indicator to stop the active function.		Caution

Product production date is integrated in the serial number or LOT number, which is placed on the product and/or sales package: the first 4 digits mean year of production, the next 2 digits mean month of production.

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Important information regarding Electro Magnetic Compatibility (EMC)

HBP-1120 manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN60601-1-2:2015 Electro Magnetic Compatibility (EMC) standard. Nevertheless, special precautions need to be observed:

- The use of accessories and cables other than those specified or provided by OMRON could result in increased electromagnetic emission or decreased electromagnetic immunity of the monitor and result in improper operation.
- During measurement, the use of the monitor adjacent to or stacked with other device should be avoided because it could result in improper operation. In case such use is necessary, the monitor and other device should be observed to verify that they are operating normally.
- During measurement, portable RF communications device (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the monitor, including cables specified by OMRON. Otherwise, degradation of the performance of the monitor could result.
- Refer to further guidance below regarding the EMC environment in which the monitor should be used.

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 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 take 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.

This product does not contain any hazardous substances.

Disposal of used batteries should be carried out in accordance with the national regulations for the disposal of batteries.

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Manufacturer's Declaration

The HBP-1120 is intended for use in the electromagnetic environment specified below.
The customer or the user of the HBP-1120 should assure that it is used in such an environment.

Electromagnetic Emissions (EN60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The HBP-1120 uses RF energy only for internal functions. Therefore, this RF emission is extremely weak and there is little chance of it creating any kind of interference whatsoever with nearby electronic equipment.
RF emissions CISPR 11	Class B	The HBP-1120 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker IEC 61000-3-3	Complies	

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Electromagnetic Immunity (EN60601-1-2)

Immunity test	EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV normal mode ±2 kV common mode	±1 kV normal mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚	0 % U_T; 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HBP-1120 requires continued operation during power mains interruptions, it is recommended that the HBP-1120 be powered from an uninterruptible power supply or batteries.
	0 % U_T; 1 cycle 70 % U_T; 25/30 cycles single phase: at 0˚	0 % U_T; 1 cycle 70 % U_T; 25/30 cycles single phase: at 0˚	
	0 % U_T; 250/300 cycles	0 % U_T; 250/300 cycles	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (r.m.s) 50 Hz or 60 Hz	30 A/m (r.m.s) 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

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Immunity test	EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 80% AM (1 kHz)	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the HBP-1120, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommend separation distance** $d = 2\sqrt{P}$ 150 kHz - 80 MHz $d = 2\sqrt{P}$ 80 MHz - 2.7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to he transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM (1 kHz)	3 V/m	Field strengths from fixed RF transmitters as determined by an electromagnetic site survey*, should be less than the compliance level in each frequency range**. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

*Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HBP-1120 is used exceeds the applicable RF compliance level above, the HBP-1120 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HBP-1120.

**Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

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Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

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