heart sure

Automatic Blood Pressure Monitor

Model BP100 Instruction Manual



3723568-1F Issue Date: 2022-11-07

Introduction

Thank you for purchasing the BP100 Automatic Blood Pressure Monitor. The BP100 is a compact, fully automatic blood pressure monitor, operating on the oscillometric principle. It measures your blood pressure and pulse rate simply and quickly.

Intended Use

This product is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population who can understand this instruction manual with the arm circumference range printed on the arm cuff.

It is mainly designed for general household use.

Please follow this instruction manual thoroughly for your safety

Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR PHYSICIAN.

Important Safety Information

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

(General Usage)

- DO NOT adjust medication based on measurement results from this blood pressure monitor. Take medication as prescribed by your doctor. Only a doctor is qualified to diagnose and treat High Blood Pressure
- Consult your doctor before using this monitor for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases.

Note that PATIENT motion, trembling, shivering may affect the measurement

- Do not use this monitor on the injured arm or the arm under medical treatment.
- Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion • Consult your doctor before using this monitor on the arm with an arterio-venous
- (A-V) shunt.
- Do not use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading
- DO NOT use this monitor in an area where HF surgical equipment, MRI, or CT scanner exists, or in an oxygen rich environment. This may result in incorrect
- operation of the monitor and/or cause an inaccurate reading. • The air tube may cause accidental strangulation in infants.
- Contains small parts that may cause a choking hazard if swallowed by infants.
- Stop using this monitor and consult your doctor if you experience skin irritation or

⚠ Caution: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

(General Usage)

- · Always consult your doctor. Self-diagnosis of measurement results and self-treatment are dangerous.
- Consult your doctor before using this monitor for any of the following conditions:
- If you have had a mastectomy - People with severe blood flow problems or blood disorders as cuff inflation can
- cause bruising.
- Do not take measurements more than necessary. It may cause bruising due to blood flow interference.
- If there are any abnormalities during the measurement, remove the arm cuff. • Do not use this monitor on infants or persons who cannot express their intentions.
- Do not inflate the arm cuff more than necessary.
- Do not use this monitor for any purpose other than measuring blood pressure. • Use only the approved arm cuff for this monitor. Use of other arm cuffs may result
- in incorrect measurement results. • During measurement, make sure that no mobile phone or any other electrical
- devices that emit electromagnetic fields is within 30cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate reading. • Do not disassemble the monitor or arm cuff. This may cause an inaccurate
- Do not use in a location with moisture, or a location where water may splash on
- this monitor. This may damage this monitor.
- Do not use this monitor in a moving vehicle (car, airplane).

(Battery Usage)

- Do not insert the batteries with their polarities incorrectly aligned.
- Use only four "AA" alkaline or manganese batteries with this monitor. Do not use other types of batteries. Do not use new and used batteries together.
- Remove the batteries if this monitor will not be used for 3 months or more. • Use the battery within recommended period mentioned to it.

General Precautions

- Do not forcibly bend the arm cuff or bend the air tube excessively.
- Do not fold or kink the air tube while taking a measurement. This may cause harmful injury by interrupting blood flow.
- To unplug the air plug, pull on the air plug at the connection with the monitor, not the tube itself.
- Do not apply strong shocks and vibrations to or drop the monitor and arm cuff.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Read and follow the "Important information regarding Electromagnetic
- Compatibility (EMC)" in the "6. Specifications".
- Read and follow the "Correct Disposal of This Product" in the Technical Data Section when disposing of this monitor and any used accessories or optional parts. • Do not use this monitor outside the specified environment. It may cause an
- Dispose of this monitor, components and optional accessories according to
- applicable local regulations. Unlawful disposal may cause environmental pollution. • Please check (for example, by observation of the limb concerned) if this monitor is
- not causing a prolonged impairment of PATIENT blood circulation.

recommend waiting for approx. 2 hours before using the monitor.

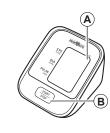
• If this monitor is stored at the maximum or minimum storage and transport temperature and is moved to an environment with a temperature of 20°C, we

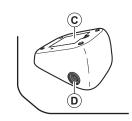
1. Know Your Monitor

Contents:

Monitor, arm cuff, instruction manual, battery set

Monitor:

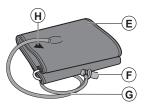




A. Display B. START/STOP button

|C. Battery compartment D. Air jack

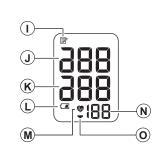
Arm cuff:



E. Arm cuff

- (Arm circumference 22 32 cm) F. Air plug
- G. Air tube H. Marker

Display:



- Memory symbol
- J. Systolic blood pressure K. Diastolic blood pressure
- Battery symbol (low/depleted) M. Heartbeat symbol
- IN. Pulse display O. Deflation symbol

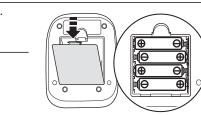
(Flashes during measurement.) **Before Taking a Measurement**

- To help ensure an accurate reading, follow these directions:
- 1. Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for 30 minutes before taking a measurement.
- 2. Rest for at least 5 minutes before taking the measurement.
- 3. Stress raises blood pressure. Avoid taking measurements during stressful times.
- 4. Measurements should be taken in a quiet place. 5. Remove tight-fitting clothing from your arm.

2. Preparation

2.1 Battery Installation

1. Remove the battery cover.



2. Insert 4 "AA" batteries as indicated in the battery compartment.

3. Replace the battery cover.

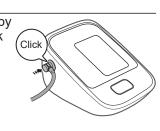
- When the depleted battery symbol (□) appears on the display, turn the monitor off and remove all the batteries. Replace with 4 new batteries at the same time. Long life alkaline batteries are recommended.
- The measurement values continue to be stored in memory even after the batteries are replaced.
- The supplied batteries may have a shorter life.
- ⚠ Disposal of used batteries should be carried out in accordance with the national/local regulations for the disposal of batteries.

3. Using the Monitor

3.1 Applying the Arm Cuff

Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Do not place the arm cuff over thick clothes.

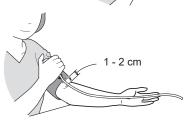
1. Plug the arm cuff into your monitor by inserting the air plug into the air jack securely until it clicks.



2. Wrap the arm cuff firmly in place around your left upper



The bottom edge of the arm cuff should be 1 to 2 cm above the elbow. Air tube is on the inside of your arm and aligned with your middle finger.



3. Secure closed with the fabric fastener.



- When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the
- The blood pressure can differ between the right arm and the left arm, also the measured blood pressure values can be different. Recommend to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician which arm to use for your measurements.

3.2 How to Sit Correctly

the same level as your heart.

To take a measurement, you need to be relaxed and comfortably seated at comfortable room temperature.

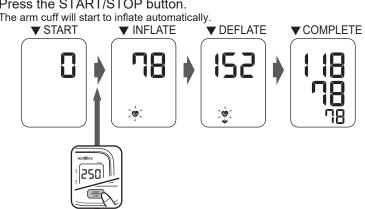
- Sit on a chair with your legs uncrossed and your feet flat on the floor.
- Sit with your back and arm being supported. • The arm cuff should be placed on your arm at



3.3 Taking a Measurement

- To stop a measurement, press the START/STOP button once to release the air in the arm cuff.
- · Remain still and do not talk while taking a measurement.

1. Press the START/STOP button.



If your systolic pressure is more than 210 mmHg After the arm cuff starts to inflate, press and hold the START/STOP button until the monitor inflates 30 to 40 mmHg higher than your expected systolic pressure.

Notes:

• The monitor will not inflate above 299 mmHg. • Do not apply more pressure than necessary.

2. Remove the arm cuff.

- 3. Press the START/STOP button to turn the monitor off. The monitor automatically stores the measurement result in its memory. It will automatically turn off after 2 minutes.
- Note: Wait 2-3 minutes before taking another measurement. Waiting between measurements allows the arteries to return to the condition prior to taking a measurement.
- ⚠ Always consult your physician. Self-diagnosis of measurement results and

3.4 Using the Memory Function

pressure and pulse rate).

To View the Measurement Values Stored in Memory

1. Press and hold the START/STOP button for more than 5 seconds. The last measurement value is displayed along with the memory symbol.



Note: If there are no measurements results stored in the memory, the screen to the right is displayed.

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2. Press the START/STOP button to turn the monitor off. It will automatically turn off after 2 minutes.

To Delete the Values Stored in Memory Press and hold the START/STOP button for

more than 15 seconds.



4. Error Messages and Troubleshooting

4.1 Error Messages

Error Display	Cause	Solution
(The batteries are low.	Recommend to replace the batteries with new ones ahead of time. Refer to section 2.1.
	The batteries are depleted.	Replace 4 batteries with new ones at once. Refer to section 2.1.
E۱	Air plug disconnected.	Insert the plug securely. Refer to section 3.1.
	Arm cuff is applied too loosely.	Apply the arm cuff tighter. Refer to section 3.1.
	Air is leaking from the arm cuff.	Replace the cuff with a new one. Refer to section 5.3.
E2	Movement during measurement and the arm cuff has not been inflated sufficiently.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
		If "E2" appears repeatedly, inflate the cuff manually until it is 30 to 40 mmHg above your previous measurement result. Refer to section 3.3.
E3	The arm cuff was inflated exceeding the maximum allowable pressure, and then deflated automatically.	Do not touch the arm cuff and/or bend the air tube while taking a measurement. Do not inflate the arm cuff more than necessary. Refer to section 3.3.
E٩	Movement during measurement.	Repeat measurement. Remain still and do not talk during measurement. Refer to section 3.3.
E5	Clothing is interfering with the arm cuff.	Remove any clothing interfering with the arm cuff. Refer to section 3.1.
Er	Device error.	Contact your local representative.

4.2 Troubleshooting

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

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



PRODUCT WARRANTY

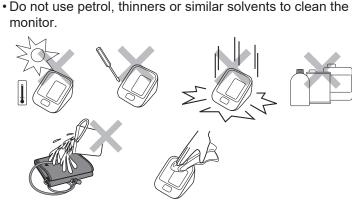
5. Maintenance and Storage

5.1 Maintenance

To protect your monitor from damage, please observe the following: • Store the monitor and the components in a clean, safe

location. Do not use any abrasive or volatile cleaners.

• Do not wash the monitor and any components or immerse them in water.



• Use a soft and dry cloth, or a soft and moistened cloth and

neutral soap to clean on the monitor and the arm cuff. Changes or modification not approved by the manufacturer will void the user warranty. Do not disassemble or attempt to repair the monitor or components. Consult your local representative.

Calibration and Service

• The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.

• It is generally recommended to have the device inspected every 2 years to ensure correct functioning and accuracy. Please consult your local representative.

5.2 Storage

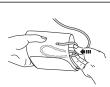
pulling out.

1. Remove the arm cuff from the monitor. The air plug is firmly connected not to come off accidentally. When removing the arm cuff from the monitor, pull the air plug in a straight way from the air jack. It clicks during



2. Gently fold the air tube into the arm cuff.

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



Do not store your monitor in the following situations:

• If your monitor and other components are wet.

• Locations exposed to extreme temperatures, humidity, direct sunlight, dust

or corrosive vapours such as bleach.

• Locations exposed to vibrations, shocks or where it will be at an angle.

5.3 Optional Parts





22 - 32 cm







Small Cuff HEM-CS24 Type B 17 - 22 cm

Note: Do not throw the air plug away. The air plug can be applicable to the optional cuff.

6. Specifications

Product description Automatic Blood Pressure Monitor

BP100 (HEM-7122-AU) LCD Digital Display Display Oscillometric method Measurement

Cuff pressure range 0 to 299 mmHg Blood pressure 20 to 280 mmHg

measurement range Pulse measurement 40 to 180 beats/min.

range Pressure: ±3 mmHg Accuracy Pulse: ±5 % of display reading

Inflation Fuzzy-logic controlled by electric pump Automatic pressure release valve Deflation Last Measurement

Rating DC6 V 4 W Operation mode Continuous operation 4 "AA" batteries 1.5 V Power source

Battery life Approx. 1000 measurements (using new alkaline batteries)

Durable Period Monitor: 5 years Cuff: 1 year Applied part Type BF (Cuff)

Protection against Internally powered ME equipment

electric shock

+10 to +40 °C / 15 to 90% RH (non-condensing) / Operating

conditions 700 to 1060 hPa

Storage/ -20 to +60 °C / 10 to 95 % RH (non-condensing) /

700 to 1060 hPa Transport

conditions IP 20 IP classification

Monitor: Approx. 250 g without batteries Weight Arm cuff: Approx. 130 g

Outer dimensions Monitor: Approx. 103 (w) mm x 80 (h) mm x 129 (l) mm

Arm cuff: Approx. 145 mm x 466 mm

Cuff circumference 22 to 32 cm Cuff/ Tube material Nylon, polyester, polyvinyl chloride

Package contents Monitor, arm cuff, instruction manual, battery set

• These specifications are subject to change without notice.

• In the clinical validation study, the 5th phase was used on 85 subjects for determination of diastolic blood pressure.

• This monitor is clinically investigated according to the requirements of EN ISO 81060-2:2014 and complies with EN ISO 81060-2:2014 and EN ISO 81060-2:2019+A1:2020.

• This monitor has not been validated for use on pregnant patients.

• IP classification is degrees of protection provided by enclosures in accordance with IEC 60529.

This monitor is protected against solid foreign objects of 12.5 mm diameter and greater such as a finger.

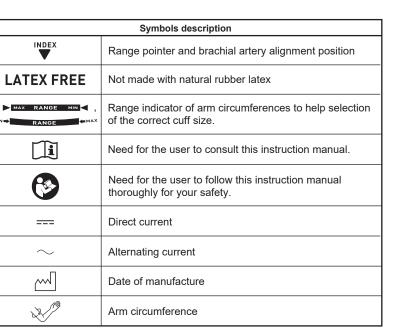
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• This blood pressure monitor is designed according to the European Standard EN1060, Non-invasive sphygmomanometers Part 1: General Requirements and Part 3: Supplementary requirements for electromechanical blood pressure measuring systems.

• Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device.

Symbols description

Symbols description		
*	Applied part - Type BF Degree of protection against electric shock (leakage current)	
	Class II equipment. Protection against electric shock	
CE	CE Marking	
SN	Serial number	
MD	Medical device	
LOT	LOT number	
	Temperature limitation	
<u></u>	Humidity limitation	
\$	Atmospheric pressure limitation	
○● ⊕ , ♦• ●	Indication of connector polarity	
	For indoor use only	
Intelli™ sense Intelli sense	OMRON's trademarked technology for blood pressure measurement	
	Identifier of cuffs compatible for the device	
A	Cuff positioning indicator for the left arm	
ART. O	Marker on the cuff to be positioned above the artery	



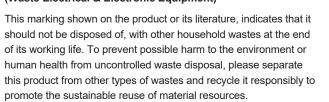
Depending on the product, some of the above symbols may not be applicable on

Important information regarding Electromagnetic Compatibility (EMC)

BP100 manufactured by OMRON HEALTHCARE Co., Ltd. conforms to EN60601-1-2:2015 Electromagnetic Compatibility (EMC) standard. Further documentation in accordance with this EMC standard is available at http://www.omronhealthcare-ap.com/emc-information. Refer to the EMC information for BP100 on the website.

Correct Disposal of This Product

(Waste Electrical & Electronic Equipment)



Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial

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Made in Vietnam