

OMRON

GS CUFF2

- SS (HXA-GCFSS-PBAP)
- S (HXA-GCFS-PBAP)
- M (HXA-GCFM-PBAP)
- L (HXA-GCFL-PBAP)
- XL (HXA-GCFXL-PBAP)

Manufacturer
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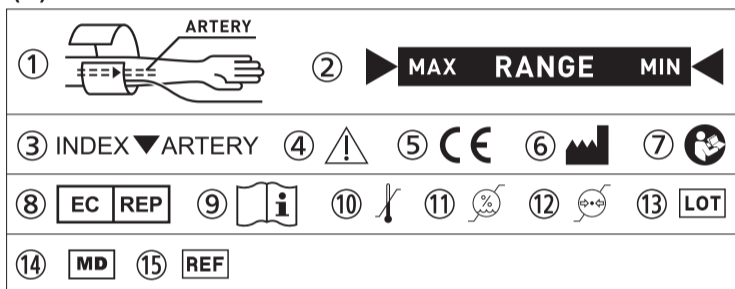
Production facility
OMRON DALIAN Co., Ltd.
 Dalian 116600, China



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 4616743-5D

Made in China

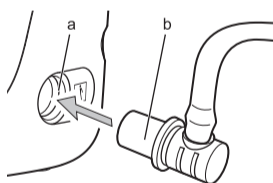
(A)



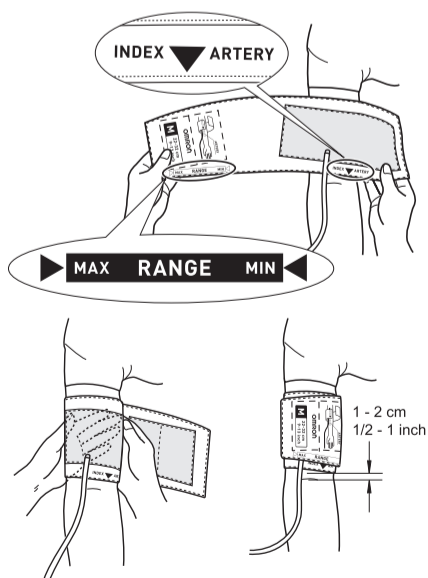
1.

SIZE	Tube length : 1,000 mm / 39 inches	Arm Circumference	
		(cm)	(inch)
SS	HXA-GCFSS-PBAP	12 - 18	5 - 7
S	HXA-GCFS-PBAP	17 - 22	7 - 9
M	HXA-GCFM-PBAP	22 - 32	9 - 13
L	HXA-GCFL-PBAP	32 - 42	13 - 17
XL	HXA-GCFXL-PBAP	42 - 50	17 - 20

2.



3.



Instructions for Use

Intended Use

Medical Purpose

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

Intended User

This product is to be used by doctors, nurses, technicians, or other medical professionals.

Type of Use

This device is intended to be multiple patient multiple use.

Patient Population

This device is intended for use on adults and children.

Environment

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

Precautions for Use

- Read and understand "Notes on Safety" in these instructions, and the manual for the blood pressure monitor.
- The cuff has not been sterilized.
- Reusable.
- This product is a consumable supply item. It will be replaced free of charge only if found to be damaged or defective within the sales package.
- 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.

Notes on Safety

Warning

- 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.
- 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.
- Ensure that the cuff tube does not become wrapped around the patient's arm or other body parts.
- Only connect this cuff to the specified products. There is a risk of inaccurate readings should these cuffs be used with other manufacturer's products.

Caution

- If a doctor has indicated that the patient has hemorrhagic diathesis or hypercoagulability, check the condition of the arm after measurement.
- Make sure the connections are tight. An air leak will result in incorrect 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.
- Do not sterilize by autoclave, ultraviolet irradiation, radiation, gas sterilization (EOG, formaldehyde gas, high concentration ozone, etc.). In addition do not clean or sterilize using a method other than that indicated in "Wiping and Storage" directions, and do not wash. The cuff may become deformed and correct measurement will not be possible.
- Do not store in a location where corrosive gas is generated. The cuff may become deformed and correct measurement will not be possible.
- Do not allow any liquids inside the cuff. If a liquid gets in the cuff, dry the inside well. If used with even a slight amount of liquid in the cuff, the liquid may enter the monitor to which the cuff is connected and cause the monitor to malfunction.
- Do not inflate the cuff when it is not wrapped on the upper arm. This may damage the cuff.
- Do not leave in direct sunlight or ultraviolet light. This may damage the cuff and cause it to deteriorate.
- The cuff is a consumable product. If it becomes damaged, replace it. Correct measurement may not be possible with a damaged cuff.
- Do not use the cuff if it is damaged or has holes. It may burst during measurement.
- Do not directly touch the end of the cuff plug. Oil or other substances from your hands may cause the cuff plug to come out during measurements.

Description of icons (Fig. A)

- ① Attachment diagram
- ② Range indicator of arm circumferences to help selection of the correct cuff size.
- ③ Range pointer and brachial artery alignment position
- ④ Caution
- ⑤ CE Marking
- ⑥ Manufacturer
- ⑦ Need for the user to follow the instruction manual thoroughly for your safety (Background: blue)
- ⑧ EU-representative
- ⑨ Need for the user to consult the instruction manual
- ⑩ Temperature limitation
- ⑪ Humidity limitation
- ⑫ Atmospheric pressure limitation
- ⑬ LOT number
- ⑭ Medical device
- ⑮ Reference catalogue number

Product production date is integrated in the 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 and the last 2 digits mean day of production.

How to Use the Cuff

1. Select the cuff size that is appropriate for the circumference.
 - There are two cuff tube lengths available.
 - 1,000 mm / 39 inches (HXA-GCF**--PBAP)
2. Connect the cuff plug (b) to the connector (a) of the blood pressure monitor.
 - If the cuff plug comes out during measurements and measurements cannot be taken, wipe off clearly the adhered substances of the end of the cuff plug and connector of the blood pressure monitor with a cloth dipped in diluted alcohol, and then start measuring again after the cuff plug and connector have completely dried.
- 3-1. Make sure the cuff tube is not bent.
 - The cuff tube should be on the peripheral side.
- 3-2. 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.
- 3-3. Make sure that the INDEX ARTERY "▼" is within the MAX RANGE MIN range.
 - If outside the 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 - 2 cm (1/2 - 1 inch) 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.
4. During measurement, keep the brachial artery on which the cuff is wrapped at the same height as the right atrium of the heart.

Wiping and Storage

- Wipe 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).
- For disposal, have a company that specializes in medical waste disposal dispose of the cuff.

Specifications

Usage environment	Temperature: 5 - 40°C (41 - 104°F)
	Humidity: 15 - 85% RH (no condensation)
Storage environment	Temperature: -20 - 60°C (-4 - 140°F)
	Humidity: 10 - 95% RH (no condensation)
Durable period (Service life)	1 year or 50000 times of use, whichever comes first.
Cuff pressure range	Pressure: 0 to 299 mmHg