OMRON

Instruction Manual

HEM-907

Small/Medium/Large size adult arm cuff

S :HEM-CS19-PD
M :HEM-CR19-PD
L :HEM-CL19-PD

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MADE IN JAPAN

Read all of the instructions in the manual before you operate the unit and keep the manual near the unit at all the times for future reference. Refer to the manual of your Blood Pressure Monitor.

Disclaimer

Our company assumes no responsibility for the following:

1. Failures, damage, or injuries due to maintenance or repair work performed by other than our company or a company that we specify.
2. Failures or damage to one of our products caused by a product of another manufacturer not delivered by us.
3. Failures, damage, or injuries due to maintenance or repair work using a repair part other than a part that we specify.
4. Failures, damage, or injuries caused by failure to observe the safety instructions and operational procedures given in this manual.
5. Use of the product in conditions that do not conform to the product usage conditions indicated in this manual, including installation.
6. Failures, damage, or injuries due to modification or inappropriate repair of the product.
7. Failures, damage, or injuries due to natural calamities such as fire, earthquake, flooding, or lightning.

Principles

1. The contents of this manual are subject to change without prior notice.
2. Considerable care has been taken in the preparation of this manual. In the unlikely event that an error or other problem is discovered in the manual, please contact us.
3. Unauthorized reproduction of all or part of this manual is prohibited. Use other than individual (corporate) use without the permission of our company is prohibited by copyright.

Intended Use

Intended purpose

This cuff is intended to be used for a digital monitor that measures blood pressure and pulse rate of adult patients.

Intended patients

Adult patient population

Intended users

Legally certified medical experts, such as doctor, nurse.

Limitation

Patient's arm circumference must be:

- HEM-CS19-PD: 17-22 cm
- HEM-CR19-PD: 22-32 cm
- HEM-CL19-PD: 32-42 cm

Type of use

This cuff is intended to be multiple patient multiple use.

The clinical features below can be obtained if this cuff is used with specified OMRON blood pressure monitor.

- Clinical benefit
- Indication
- Contraindications
- Side effects

Clinical benefit

Patient's blood pressure can be measured non-invasively.

Indication

The device is used for healthy individuals and patients with hypertension related diseases in medical professional environments such as clinics, hospitals and physicians' office.

Contraindications

- DO NOT use this cuff on:
  - An injured upper arm
  - An upper arm under medical treatment
  - An upper arm on which intravenous drip or a blood transfusion is being performed
  - An upper arm on which an SpO2 sensor, IBP catheter, or other instrument is attached
  - An upper arm with a shunt for hemodialysis
- DO NOT apply the arm cuff on your arm while on an intravenous drip or blood transfusion.
- DO NOT use the device on infants, toddlers, children or persons who cannot express themselves.
- Do not attach the cuff to a patient under the use of a pump oxygenator.
- Do not inflate the cuff without attaching it to an arm.

Side effects

- Taking measurements more often than necessary may cause bruising due to blood flow interference.
- Inflating to a higher pressure than necessary may result in bruising of the arm where the cuff is applied.
- Stop using the device if the patient experiences skin irritation or discomfort.

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

- Do not connect the air tube or cuff to the tubing of other devices connected to the body.
- Do not use at extremely high temperature, high humidity, or high altitude. Use only within the required ambient conditions.
- Properly connect the connectors
- Do not spray, pour, or spill liquids into or onto the cuff.
- If a cuff is used on some patients with an infection, treat the cuff as medical waste. Otherwise, an infection may result.

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

- Do not use thinner, benzene, or other solvents to wipe the cuff.
- Do not sterilize by autoclave or gas sterilization (EOG, formaldehyde gas, high-concentration ozone, etc.).
- Use the appropriate cuff size to ensure correct measurements.
- Do not use the cuff if it is damaged or has holes.

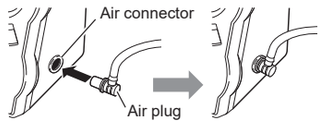
How to Apply the Arm Cuff

1. Select a cuff appropriate for the patient.

Arm circumference	Size of the arm cuff
17 - 22 cm	Small size adult arm cuff
22 - 32 cm	Medium size adult arm cuff
32 - 42 cm	Large size adult arm cuff

- Use a suitable cuff size. Otherwise, incorrect measurement may result.

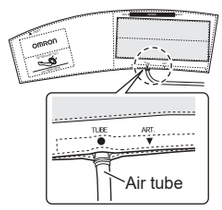
2. Insert the air plug securely into the air connector of your monitor.



- Please check your present product as to which plug you must use. Using the wrong plug may cause air leakage and incorrect readings.

3. Check the air tube.

- Make sure that the air tube protrudes from the [TUBE] mark on the cuff as the illustration shown on the right.

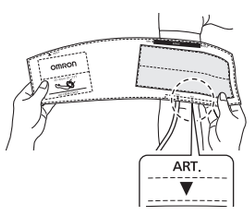


4. Have the patient rest the arm with the palm facing up.

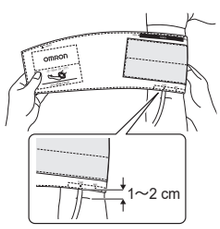
- The arm cuff must be attached on the right upper arm.
- If the arm cuff is wrapped over a thick cloth or the patient's sleeve is rolled up and pressure is applied on the arm, an accurate measurement result will not be obtained.



5. Place the cuff on the upper arm. Align the [ART.] mark on the arm cuff with the artery on the inner side of the upper arm.

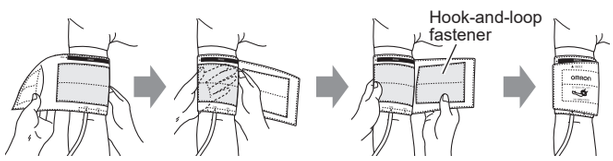


6. The bottom edge of the arm cuff must be 1 to 2 cm above the inside elbow.

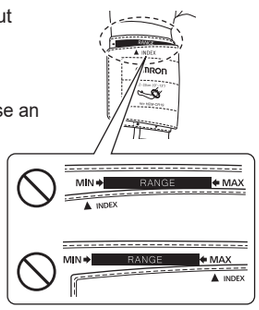


7. Wrap the cuff securely with both hands, so it can not move around patient's arm.

- Make sure that the air tube is positioned on the inside of patient's arm.
- The cuff does not have to be wrapped aligning the edges. Still correct measurement will be obtained.



- If the [▲INDEX] mark is positioned out of range of the [RANGE] mark as the illustration to the right, that means the patient's arm circumference and the size of the cuff don't match. Choose an appropriate cuff and reapply it.
- If the cuff is not wrapped securely around the patient's arm, the arm may become numb or a measurement cannot be taken accurately.



8. Keep the arm with the cuff attached at the level of the heart.

- For correct measurements, keep the cuff level flush with the patient's heart.



Maintenance Procedures

Wiping

Wipe the cuff using a soft cloth moistened with the diluted alcohol or diluted neutral (mild) detergent.

Specifications

Product description	Small size adult arm cuff	Medium size adult arm cuff	Large size adult arm cuff
Model	HEM-CS19-PD REF HEM-CS19	HEM-CR19-PD REF HEM-CR19	HEM-CL19-PD REF HEM-CL19
Arm circumference	17 - 22 cm	22 - 32 cm	32 - 42 cm
Cuff dimensions (approximately value)	111 x 357 mm	146 x 517 mm	174 x 649 mm
Air tube length	1.5 m		
Cuff pressure range	Pressure: 0 to 299 mmHg		
Accuracy	Pressure: ±3 mmHg		
Classification	Class I		
Operating conditions	+10 to +40 °C, 15 to 90 % RH (non-condensing), 700 to 1060 hPa		
Storage/Transport conditions	-20 to +60 °C, 10 to 95 % RH (non-condensing), 700 to 1060 hPa		
Package contents	Cuff, 2 air plugs, instruction manual		
Durable period (Service life)	1 years or 20,000 times of use, whichever comes first.		

Symbols description

CE	CE Marking
LOT	LOT number
MD	Medical device
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
▲ INDEX	Range pointer and brachial artery alignment position
ART. ▼	Artery mark
MIN RANGE MAX	Range indicator of arm circumferences to help selection of the correct cuff size
REF	Reference catalogue number
	Date of manufacture
X YYY	Recycle mark X: Material number Y: Material abbreviation Refer to 97/129/EC for more information.
	Need for the user to follow this instruction manual thoroughly for your safety. (Background: blue)
	Arm circumference
UDI	Unique device identifier
UK CA	UKCA marking
	Recycling instruction for packaging elements

CE UK CA



- 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.