# *Instructions for Blood Pressure cuff*

## *Introduction*

**Product name:** Blood Pressure Cuff

**Service life:** 3 years

**Product model and configuration:**

**KM series (reusable cuff):**

| Model | Applicable to | Application site | Limb circumference |
|---|---|---|---|
| KM-221 | Infant | Arm | 6cm - 11cm |
| KM-222 | Infant | | 8cm - 13cm |
| KM-232 | Child | | 10cm - 19cm |
| KM-233 | Child | | 18cm - 26cm |
| KM-241 | Adult | | 21cm - 35cm |
| KM-242 | Adult | | 27cm - 42cm |
| KM-243 | Adult | | 40cm - 48cm |
| KM-244 | Adult | Thigh | 46cm - 66cm |
| KM-333 | Child | Arm | 18cm - 26cm |
| KM-341 | Adult | | 21cm - 35cm |
| KM-342 | Adult | | 27cm - 42cm |
| KM-343 | Adult | | 40cm - 48cm |

**KN series (reusable cuff):**

| Model | Applicable to | Application site | Limb circumference |
|---|---|---|---|
| KN-221 | Infant | Arm | 6cm - 11cm |
| KN-231 | Child | | 10cm - 19cm |
| KN-233 | Child | | 18cm - 26cm |
| KN-241 | Adult | | 25cm - 35cm |
| KN-243 | Adult | | 33cm - 47cm |
| KN-244 | Adult | Thigh | 46cm - 66cm |

**Intended use:** The blood pressure cuff is indicated for use in manual measurement and automatic non-invasive blood pressure monitoring. It's applicable to be used with a compatible monitor.

## *Instructions for use*

⚠ Appropriate cuff should be selected according to the age and arm/thigh circumference of the subject. Its width should be 2/3 of the length of the upper arm/thigh. The inflatable part should be long enough to permit wrapping approximately 80% of the limb. When cuff sizes overlap for a specified circumference, choose the larger size.

⚠ Check the cuff before use, replace the cuff when aging, tearing or weak closure is apparent. Do not use a damaged cuff.

⚠ Select the appropriate blood pressure measurement site. Inspect patient's limb prior to application.

⚠ When applying the cuff, unfold and wrap around the upper arm/thigh evenly to the appropriate tightness. The cuff should be tightened to a degree where insertion of one finger is allowed

⚠ Locate the cuff in such a way that the artery mark "⬇" is at a location where the clearest pulsation of brachial artery is observed.

⚠ Remember to empty any residual air in the cuff before the measurement is commenced.

## *Operating Environment*

Ambient temperature range: -10℃- 40℃; Relative humidity: 10% - 85%;

Atmospheric pressure: 50kPa - 106.0kPa

The cuff should be stored and used within the specified temperature and humidity range, or it may cause damage to the cuff or inaccurate measurement results.

## *Cleaning and Disinfection*

1. Prepare the enzymatic detergent or equivalent and distilled water, and 10% bleach solution in separate spray bottles.
2. Spray detergent liberally on cuff, tubing and hose. If dirt is dried on, allow the detergent to soak in to the cuff for one minute.
3. Wipe smooth surface with a soft cloth. Use a soft-bristle brush on visibly stained areas and irregular surfaces.
4. Note: Take particular care when cleaning the bulb and control valve knob on a complete inflation system. Do not allow fluid to enter back valve or saturate control valve knob. Remove visible contaminants from the periphery and the underside of the control valve knob.
5. Rinse with copious amounts of distilled water.
6. To disinfect, spray 10% bleach solution on cuff until saturated and allow to soak for five minutes. Wipe away excess solution and rinse again with distilled water. Allow cuff to air dry.

## *Warnings and Precautions*

⚠ Blood pressure measurement is prohibited to those who have severe hemorrhagic tendencies or with sickle cell disease, as partial bleeding may be caused.

⚠ Continuous measurement may result in purpura, neuralgia and lack of blood.

⚠ Do not place the cuff on limbs with transfusion tubes, intubations or skin lesions on the area, as damage may be caused to the limbs.

⚠ Avoid compressing or restricting the connection tubing.

⚠ Minimize limb movement and cuff motion during measurement.

⚠ Check the site and limb frequently, especially when monitoring at frequent intervals and/or over extended periods of time.

⚠ Remove the cuff from the patient when the measurement has been taken.

⚠ Use cuff only under direct supervision by trained healthcare professional when attached to automated monitors without alarms.

⚠ Before use, empty the cuff until there is no residual air inside. Do not allow the cuff to twist or bend.

⚠ Do not twist the cuff hose or put heavy things on it.

⚠ Please hold the connector of the hose while connecting and disconnecting it to the device.

⚠ If arrhythmia or auricular fibrillation occurs, take the measurement again.

⚠ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

| | | | |
|---|---|---|---|
| CE | CE mark | SN | Serial number |
| EC REP | Authorised representative in the European Community | LOT | Batch code |
| | Manufacturer | CN YYYY-MM-DD | Country of manufacture (CN stands for Made in China) and Date of manufacture |
| MD | Medical device | | Caution |
| | Refer to the accompanying documents (Background: blue; Symbol: white) | | Follow WEEE regulations for disposal |
| 40℃ -10℃ | Temperature range | 85% 10% | Relative humidity |
| 106kPa 50kPa | Atmospheric pressure | UDI | Unique device identifier |

**Manufacturer: Shenzhen Creative Industry Co., Ltd.**
Address: 1001, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, 518055 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

**EC-Representative: Shanghai International Holding Corp. GmbH (Europe)**
Address: Eiffestraβe 80, 20537 Hamburg, Germany

256-100046-00 V1.2 2025-11