

SORIMEX

Reusable NIBP cuff



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Instructions for using and storing reusable NIBP cuffs

1. General description

NIBP cuffs are designed for an approximate, non-invasive measurement of blood pressure by creating pressure on the appropriate part of the patient's body (arm / thigh). The design of reusable NIBP cuffs takes into account different product types:

- MSWZ - NIBP cuff single tube with inflation bag
- MSWB - NIBP cuff single tube without inflation bag
- MDWZ - NIBP cuff double tube with inflation bag
- MDWB - NIBP cuff double tube without inflation bag

The cuffs covered by this manual include the following product categories:

- A - for adults
- SA - for adults, small
- LA - for adults, large
- LAL - for adults, large, long
- T - for thigh
- P - for children
- I - for infants
- N - for newborns

The cuff is equipped with flexible connections (air tubes) through which air is supplied via adapters to create the right pressure.

This manual does not apply to cuffs intended for single use.

NIBP cuffs are classified as Class I and are supplied non-sterile.

2. Cuff characteristics

The cuffs are manufactured in different versions: with an inner inflation bag and without an inner inflation bag and with a single and double tube connections. The cuffs and inner bags are latex free.

The outer coating of the cuff is water- and stain-resistant and can be easily cleaned and disinfected.

3. Terms of use

The NIBP cuff and its tubing must be disinfected and cleaned before each use. The cuff can not be placed on the same arm as the SpO2 sensor.

4. Application

Adjust the cuff to the arm / thigh circumference.

Put the cuff on, making sure the  symbol is above the brachial or femoral artery.

Make sure that the cuff adheres to the patient's body with no excessive pressure and without free spaces in between. If it is difficult to obtain, use a different sized cuff. Fasten the velcro-type self-adhesive strips.

If the cuff has been damaged during use, the air tubing has clogged, visible, unremovable dirt appeared or if the malfunction detection system to which the cuff is connected indicates a malfunction, replace the cuff with a new one. After putting on the NIBP cuff, make sure that the air tube is positioned in a way that reduces the potential for patient entanglement or product damage.

Proper and safe use of the cuff and its tubing requires regular inspections, which should be carried out at least once or several times a month, depending on the frequency of use and disinfection of the air tubing. Inspect the tubing visually. Inspect the mechanical integrity of the connection. Do not use a cuff that seems to have any mechanical defects.

5. Recommended cleaning, disinfection, sterilization, service and storage

Before cleaning, remove the inner inflation bag from the cuff, if such bag has been used in the cuff.

The outside coating should be cleaned with warm water and soap. Clean the cuff and tubing gently with a soft cloth with soapy water or 70% isopropyl alcohol solution.

The product should dry out before use. Do not use corrosive or chemical products, except for 70% isopropyl alcohol solution. Using excessive force when cleaning can damage the cuff coating. Continuous bending of air tubes during use and cleaning can also result in their breaking. This type of damage is not covered by the warranty.

Avoid contact with strong solvents: aromatic, chlorinated, ketone, ether or ester.

Disinfection

Before disinfection, remove the inner inflation bag from the cuff, if such bag has been used in the cuff. 70% isopropyl alcohol or 70% ethanol are the safe and recommended solutions for disinfecting the cuff.

Other disinfectants intended for disinfecting medical devices may also be used, but only if they do not adversely affect the cuff (please read the instructions for using these solutions before using them).

Sterilization

The preferred sterilization method is sterilization with ethylene oxide (follow the procedure provided by the gas sterilizer supplier). After sterilization and before use, the cuff should be thoroughly ventilated. Sterilization by other methods could permanently damage the cuff.

6. Packaging and storage

NIBP cuffs are packed individually. The cuffs should be stored in their original packaging in accordance with the indicated storage conditions so that the time of use of the product can be as long as possible.

Storage conditions:

- temperature: 0°C to +50°C,
- relative humidity: 10% to 85%, avoid condensation

When not in use, cuffs should be loosely rolled, without any sharp bends.

7. Warnings

The NIBP cuffs are not sterile upon delivery to the client. The cuffs may only be connected to devices designed for non-invasive blood pressure measurement. The apparatus to which the cuff is connected should meet the requirements of the applicable regulations. When installing the cuff, follow the instructions for using the device.

Putting the NIBP cuff on the same limb as the SpO₂ sensor is not recommended. NIBP cuffs may only come into contact with intact skin of the patient. After monitoring the patient's blood pressure, the product should be immediately removed from the limb.

Only qualified personnel with appropriate knowledge should connect the cuff to the device.

NIBP cuffs are designed for use with specific types of monitors. The user is responsible for checking the compatibility of the cuff and tubing with the device before use.

The incompatibility of these elements may lead to a reduction in accuracy and effectiveness of measurements, and in extreme cases it may result in product damage.

Generally, no allergic reactions were observed in cases of cuff-skin contact. However, such a reaction can not be entirely excluded in people who are particularly susceptible to allergy.

Because the skin's ability to tolerate the cuff varies from person to person, a frequent change of the monitoring area may be necessary in some cases.

Do not use a cuff suspected of having mechanical defects or cuffs which packaging has been damaged. Do not use a cuff which has been soaked in water.

Do not change or modify the cuff in any way. Such actions may affect the correct functioning and accuracy of the obtained measurements.

Disposal of used cuff should be in accordance with local laws and regulations.

8. Warranty

The warranty period lasts one year starting on the date of sale.

The warranty does not cover defects resulting from improper use and storage.

Symbole / Symbols / Symbole / Символы



Catalogue number



Lot number



Expiry date



Warning



Manufacturer



The date of production - included in the lot number, numbers from 2 to 7 in the LOT number



The product does not contain natural rubber latex



Read the instructions for use



Keep away from sunlight



Keep dry