

Blood Pressure Cuff Reusable

ΕN

DEVICE DESCRIPTION: The device is nonsterile and reusable. A blood pressure cuff has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder.

INTENDED PURPOSE: NIBP cuffs are used in conjunction with non-invasive blood pressure monitors.

INDICATIONS: Screen for hypertension and monitoring of blood pressure.

FOR USE IN: Hospitals, sub-acute, medical clinics, pre-hospital, home, surgical centers, skilled nursing facilities.

PATIENT TARGET GROUP: Newborn, infant, pediatric, adult.

EXPECTED CLINICAL BENEFITS: Reliable way to non-invasively monitor blood pressure.

CONTRAINDICATIONS: Refer to AHA guidelines

WARNINGS: Refer to AHA guidelines for list of warnings.

- To prevent misconnections, follow the tubing from the blood pressure monitor and connect to the blood pressure cuff tubing.
- Never allow any liquid to enter the tubes of the cuffs. If liquid has entered the cuff tubes, it should be discarded.
- If the cuff has been contaminated with blood or other bodily fluids, it should be discarded.

CAUTIONS:

- Consult physician if patient develops infection, skin irritation or material sensitization.
- Follow cleaning instructions to avoid risk of infection and contamination.

 Failure to adequately rinse the cuff with water may result in residual cleaning solution irritating the patient's skin.

INSTRUCTIONS: Contact your country's Competent Authority to report any serious incident. Dispose of device in accordance with local, state, or national regulations. Follow instructions for proper care of device to prevent risk of contamination and injury. Follow AHA guidelines for blood pressure measurement. Instruct patient to remain still and not talk during BP reading. For long-term use check cuff site for skin irritation. Check for leaks at connections and for proper placement prior to use. Do not overpressurize.

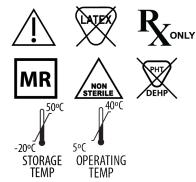
INSTRUCTIONS FOR USE:

- 1. Read blood pressure monitor instructions prior to use.
- Verify compatibility of monitor connector to cuff connector. Disconnect and reconnect mating connector to monitor if necessary.
- Select the correct blood pressure cuff size based on limb circumference. If limb circumference falls between 2 cuff sizes, choose the larger size.
- Select the limb of the patient to be used for the blood pressure measurement. Normally the upper arm between the patient's elbow and shoulder is generally preferred.
- Apply the cuff to the selected limb area with the artery marking arrow over the brachial or femoral artery.
- Ensure Index line falls within the index range. If it does not, choose a larger or smaller cuff that fits correctly.
- Secure/fasten cuff snugly. A properly secured cuff will have a snug fit, but still allow a finger to fit between the cuff and patient.

CLEANING:

- Prepare a cleaning detergent such as Enzol, Cidezyme or Burnishine and a disinfecting solution such as Cidez, Isopropyl Alcohol, Sporicidin or 10% bleach solution in separate containers. Follow manufacturer instructions for proper solution preparation.
- 2. Apply liberal amounts of the cleaning detergent on the cuff and allow it to sit for a minimum of 1 minute.

 Note: If cuff is to be submerged or soaked in liquid, cuff tubes should be capped. Liquid must not be introduced into the cuff tubes.
- 3. Use a soft brush or cleaning cloth to remove stains.
- 4. Rinse thoroughly with water.
- Apply disinfecting solution on the cuff until fully saturated. Let sit for a minimum of 5 minutes.
- 6. Rinse thoroughly with water.
- 7. Allow cuff to air dry before use.



Manufactured for:

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