

Blood Pressure Cuff Disposable

ΕN

DEVICE DESCRIPTION: The device is nonsterile, disposable and for single patient use. 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: Newborns, infant, pediatric, adult.

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

CONTRAINDICATIONS: Refer to AHA auidelines

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.

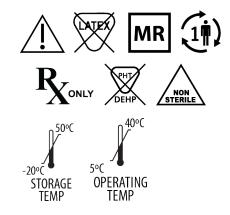
CAUTIONS: Consult physician if patient develops infection, skin irritation or material sensitization. If the blood pressure cuff is soiled and/or damaged, replace with a new one.

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. This product is disposable and is not

intended for prolonged use. 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.



Manufactured for:
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