



EN English
Blood Pressure Cuff
Reusable

DEVICE DESCRIPTION:

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

INTENDED PURPOSE:

The blood pressure cuffs are non-sterile devices intended for use in measuring a patient's blood pressure. Blood pressure cuffs are used in conjunction with non-invasive blood pressure monitors.

INDICATIONS FOR USE:

The blood pressure cuffs are devices intended to be used with blood pressure measurement systems to screen for hypertension and monitoring of blood pressure.

ENVIRONMENT FOR USE:

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

PATIENT TARGET GROUP:

Pediatric, adult.

INTENDED USERS:

Trained medical professionals.

NECESSARY USER QUALIFICATIONS:

The end-user should receive training on the proper use of the device and be familiar with the indications for use, warnings, and cautions as stated in the IFU.

EXPECTED CLINICAL BENEFITS:

Reliable way to non-invasively monitor blood pressure. Reduced need for invasive monitoring lowering risk of arterial line-associated complications.

CONTRAINDICATIONS:

None known.

⚠️ WARNINGS:

- To prevent misconnections, follow the tubing from the blood pressure monitor and connect to the blood pressure cuff tubing.
- Do not connect cuff to intravascular fluid systems which may allow air to be pumped into a blood vessel, which could lead to serious patient injury.
- Blood pressure measurement is not recommended in those who have severe hemorrhagic tendencies or with sickle cell disease, as partial bleeding may be caused.
- Pressure applied to the tissue may result in purpura, neuralgia, skin avulsion, ischemia, thrombosis, and/or neuropathy.
- Do not place the cuff on limbs with intravenous infusion, arterial monitoring, or areas where circulation is compromised. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
- Only use on intact skin. Do not apply the cuff over a wound or inflammation as this may cause further injury to the area.
- When monitoring at frequent intervals or for extended periods of time, check limb frequently for signs of impeded blood flow, skin irritation or bruising. Switch to another limb if appropriate.
- The cuff should not be placed on the patient's arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.
- Do not obtain determinations more frequently than clinically indicated, weighing benefits of frequent measurement against risk.
- Do not overpressurize the cuff as this may cause erroneous reading or cause injury to the patient.

⚠️ CAUTIONS:

- If the blood pressure cuff is soiled and/or damaged, replace with a new one.
- Do not apply the cuff to the upper arm if the width of the cuff is greater than the length from the armpit to the elbow of the patient. This may cause erroneous or misleading blood pressure measurements.
- Consult physician if patient develops infection, skin irritation or material sensitization.
- Monitor the patient's skin for signs of irritation or discomfort during use.
- Follow instructions for proper care of device to prevent risk of contamination and injury.
- Do not sterilize the blood pressure cuffs as it may affect the safety and performance of the device.
- For more accurate blood pressure measurement, minimize limb movement and cuff motion during measurement.
- For continuous blood pressure monitoring using automated monitors without alarms, use only under direct supervision of a trained healthcare professional.
- When possible, to ensure accurate measurement, the patient should be comfortably seated with legs uncrossed, back and arm supported.
- Ensure that the rough side of the closure does not contact skin as it may cause irritation.
- Do not apply external pressure to the cuff while monitoring as it may impact the accuracy of the blood pressure values.

RESIDUAL RISKS:

Refer to warnings and cautions.

INSTRUCTIONS FOR USE:

- Read blood pressure monitor instructions prior to use.
- Verify compatibility between the monitor connector to cuff connector. Ensure the mating connectors are fully seated; disconnect and reconnect if needed.
- Select the correct blood pressure cuff size based on limb circumference.
 - Cuff width should be 2/3 of the length of the upper arm or thigh.
 - The inflatable part should encircle approximately 80% of the limb.
 - If limb circumference falls between 2 cuff sizes, choose the larger size.
- Inspect the cuff and connections prior to each use and after cleaning/disinfection. Check the cuff, tubing, and connection points for leaks, cracks, tears, fraying edges, discoloration, loose fittings, or other signs of wear or damage, particularly around the tube connection area. Do not use the device if any damage or deterioration is observed.
- Choose the appropriate limb with intact skin for blood pressure measurement. The upper arm (between the shoulder and elbow) is clinically preferred unless clinically contraindicated.
- Position the cuff correctly on the selected limb. Align the artery indicator marking over the brachial (arm) or femoral (thigh) artery.
- Confirm correct sizing on patient. 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. The cuff should be tight enough to prevent slipping but loose enough to allow one finger to slide between the cuff and the skin.
- Instruct patient to remain still and silent during the blood pressure reading (cuff inflation).
- Remove the cuff from the patient when monitoring has been suspended.
- For long term use, periodically inspect the cuff site for signs of skin irritation or pressure-related injury.

REPROCESSING INSTRUCTIONS:

Note: Only wipes containing the specified active ingredients and validated contact times may be used.

Cleaning Steps

- Remove one disinfectant wipe containing quaternary ammonium compounds and isopropyl alcohol.

- Clean all blood pressure cuff surfaces, including tubing, seams, edges, folds, and any textured areas, using overlapping strokes to ensure complete coverage.
- Ensure all surfaces are completely moistened and maintain continuous wet contact for a minimum of 15 seconds.
 - Use additional wipes as needed to maintain wetness and full surface coverage for the full contact time.
 - A new lint-free wipe should be used if the wipe becomes visibly soiled or no longer maintains adequate wetness.
- Allow the blood pressure cuff to air dry completely.
- Proceed to disinfection once dry.

Disinfection Steps

Note: After cleaning, disinfection may be performed using one of the following approved disinfectant wipes containing the listed active ingredients. Follow the specified wet contact time and air-dry instructions.

	Quaternary Ammonium Compounds + Isopropyl Alcohol Wipe	Sodium Hypochlorite Wipe	Hydrogen Peroxide Wipe
Total Cleaning & Disinfection Cycles	2,000	500	2,000

INSTRUCTIONS FOR DISINFECTANT WIPES
Quaternary Ammonium Compounds + Isopropyl Alcohol Wipe

Active Ingredients:

- n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides (0.25%)
 - n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides (0.25%)
 - Isopropyl Alcohol (55.0%)
- Remove one disinfectant wipe containing the active ingredients listed above.
 - Thoroughly wet all surfaces of the blood pressure cuff, including tubing, seams, edges, folds, and any textured areas, using overlapping strokes to ensure complete coverage.
 - Ensure all surfaces remain visibly wet with the disinfectant for 3 minutes.
 - Use additional wipes as needed to maintain wetness and full surface coverage for the full contact time.
 - Allow the blood pressure cuff to air dry completely.

Sodium Hypochlorite Wipe

Active Ingredient:

- Sodium Hypochlorite (0.91%)
- Remove one disinfectant wipe containing sodium hypochlorite.
 - Thoroughly wet all surfaces of the blood pressure cuff, including tubing, seams, edges, folds, and any textured areas, using overlapping strokes to ensure complete coverage.
 - Ensure all surfaces remain visibly wet with the disinfectant for 4 minutes.
 - Use additional wipes as needed to maintain wetness and full surface coverage for the full contact time.
 - Allow the blood pressure cuff to air dry completely.

Hydrogen Peroxide Wipe

Active Ingredient:













- Hydrogen Peroxide (1.4%)
- Remove one disinfectant wipe containing hydrogen peroxide.
 - Thoroughly wet all surfaces of the blood pressure cuff, including tubing, seams, edges, folds, and any textured areas, using overlapping strokes to ensure complete coverage.
 - Ensure all surfaces remain visibly wet with the disinfectant for 2 minutes.
 - Use additional wipes as needed to maintain wetness and full surface coverage for the full contact time.
 - Allow the blood pressure cuff to air dry completely.

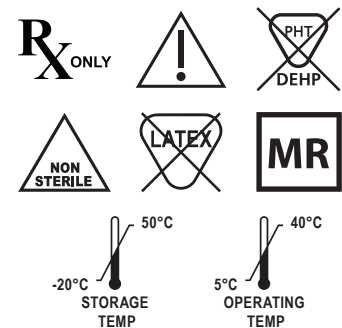
SAFE DISPOSAL:

Decontaminate and dispose of all potentially biohazardous material. Dispose of device in accordance with local, state or national regulations.

INCIDENT REPORTING:

Notice to the user that any serious incident that has occurred in relation to the device should be reported to the manufacturer at support@roiscs.com, and the competent authority of the Member State in which the user and/or patient is established. If the patient's physical symptoms worsen or experience a sudden change in their condition (e.g., increased shortness of breath, fever, dizziness) call the physician.

SYMBOL GLOSSARY	
	Manufacturer
	Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Cautions
	Warnings
	Not made with natural rubber latex
	Not made with DEHP
	Storage Temperature
	Operating Temperature
	Magnetic Resonance (MR) Safe
	Non-sterile
	Catalog number
	Consult instructions for use



Manufactured for:
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