

Environmental Specifications

CAUTION: Store and use the cuff within stated temperature and humidity ranges. Otherwise, the cuff might not meet performance specifications.

Storage temperature: -20°C to 70°C (-4°F to 158°F)

Storage relative humidity: 15% to 95% (noncondensing)

Operating temperature: 10°C to 40°C (50°F to 104°F)

Operating relative humidity: 15% to 90% (noncondensing)

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Mat. 720572 Ver. A

Single Patient Use Blood Pressure Cuff

Instruction For Use

R_x ONLY



Cat. **30509-11,**
30509-12,
30509-13,
30509-14,
30509-MLT

CAUTION: U.S. federal law restricts the blood pressure cuffs to sale by or on the order of a physician or licensed healthcare practitioner. This device should be used by trained personnel.

Standards

This device is designed to function within the limits prescribed by:

- American National Standard ANSI/AAMI SP10:2002/(R)2008 and ANSI/AAMI SP10:2002/A1:2003, Manual, electronic, or automated sphygmomanometers.
- EN 1060-1:2009, Specification for non-invasive sphygmomanometers – Part 1: General requirements.
- EN 1060-2:2009, Specification for non-invasive sphygmomanometers – Part 2: Supplementary requirements for mechanical sphygmomanometers (except for section 7.1.3.1).
- AAMI/ISO 81060-1:2007, Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type (except for section 7.2.1).

Introduction

Intended Use

The Blood Pressure Cuffs are intended to be used on the upper arm in conjunction with noninvasive blood pressure measurement systems. The cuff is nonsterile and is available in pediatric through adult sizes. The device is not intended for neonatal applications. The blood pressure cuff is not designed, sold or intended for use, except as indicated.

Contraindications

The Blood Pressure Cuffs are contraindicated for neonate use. Do not use on neonate patients.



Warnings

The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death.

WARNINGS: Intravenous (IV) systems—Do not connect cuffs with luer lock connectors to IV fluid systems. Otherwise, air might enter the patient. Do not reuse a cuff on more than one patient. Reusing a cuff on more than one patient might cause cross-contamination. Do not clean, disinfect, or sterilize the cuff. These methods have not been tested for effectiveness or impact to cuff performance. Use the cuff only when the port falls within the range indicator window on the cuff. Otherwise, erroneous readings might result. Do not apply the cuff to areas on the patient where skin is delicate or damaged. Check the cuff site frequently for irritation. Do not apply the cuff to an arm used for IV infusion. Inflating the cuff on this arm might interrupt IV flow. Minimize cuff movement and arm motion during readings. Excessive movement might affect readings. Ensure an airtight seal at all connection points before use. Excessive leaking might affect readings. When applying the cuff to the patient, allow space for 1 to 2 fingers between the patient's upper arm and the cuff to ensure proper fit.

Cautions

The caution statements in this manual identify conditions or practices that could damage the equipment or other property.

CAUTIONS: Close the hook-and-loop fastener before inflating the cuff. Failure to properly close the fastener might lead to cuff damage. Keep debris out of the port on the cuff. Debris in the cuff port can damage the cuff. Intravenous (IV) systems – Do not connect cuffs with luer lock connectors to intravenous fluid systems. Otherwise, fluid might enter the cuff and damage it.

Operation

Use the Cardinal Health Blood Pressure Cuff the same as a traditional blood pressure cuff. These cuffs work with one-tube or two-tube manual and automated sphygmomanometers.

Notes:

- The cuff works with one-tube and two-tube manual and automated sphygmomanometers.
- The cuff works only with FlexiPort fittings.
- Use the cuff one or more times on one patient and then discard it.
- Do not reuse the cuff on another patient.
- Do not attempt to clean, sterilize, or disinfect the cuff.

To take a blood pressure measurement:

1. To apply the cuff, align the artery marker (1) on the cuff with the brachial artery and wrap the cuff around the upper arm, so that the part of the cuff with the range indicator window (3) is on top of the port (2).
2. Ensure that the port (2) shows through the range indicator window (3) and connect the FlexiPort fitting (4) to the port through the range indicator window. (If the port does not fall within the range indicator window, select a different cuff size.)
3. Take the blood pressure measurement.
4. To remove the cuff, disconnect the FlexiPort fitting from the port.
5. Unwrap the cuff from the upper arm.

