Welch Allyn® FlexiPort® Blood Pressure Cuffs

Soft, Vinyl, and Reusable versions

Instructions for use

749414 DIR 80025281 Ver. A, Revised 2019-09

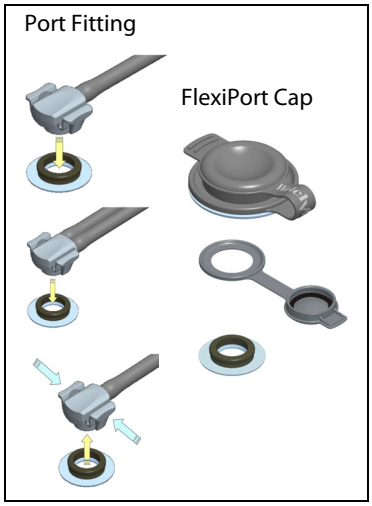
CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner. This device should be used by trained personnel.

Standards

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

- AAMI/ANSI/EN/ISO 81060-1:2007 specification for non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type.

Cuff connections and symbols



GTIN Global Trade Item Number
Reorder number
LOT Lot number
REF Product identifier
Consult directions for use
Limb circumference (min/max)
Not made with natural latex
RANGE Range
Artery symbol
Index edge

CE EC REP Regulatory Affairs Representative, Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, County Meath, Republic of Ireland

Welch Allyn, Inc.
4341 State Street Road, Skaneateles Falls, NY 13153 USA
Tel: 800-535-6663 (USA only) or 315-685-4560
Fax: 315-685-3361 hillrom.com

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

PATENTS / PATENT hillrom.com/patents
May be covered by one or more patents. See above Internet address.
The Hill-Rom companies are the proprietors of European, US, and other patents and pending patent applications.

For information about any Hillrom product, contact Hillrom Technical Support: hillrom.com/en-us/about-us/locations/.

Introduction

Intended use

Flexiport pediatric through adult blood pressure cuffs are noninvasive blood pressure cuffs intended for use in conjunction with non-automated and automated sphygmomanometers to determine blood pressure in pediatric through adult patients.

Contraindications

Flexiport pediatric through adult blood pressure cuffs are contraindicated for neonate use.

Warnings

A warning statement in this manual identifies a condition or practice which, if not corrected or discontinued immediately could lead to injury, illness, or death.

WARNING Possible measurement error. Use only approved blood pressure cuffs and accessories; substitution might result in measurement error.

WARNING Inaccurate measurement risk. Only use the cuff when the artery index marker falls within the printed range indicated on the cuff, otherwise erroneous readings may result.

WARNING Patient injury risk. Never install luer lock connectors on Hillrom blood pressure tubing. Using these connectors on blood pressure cuff tubing creates the risk of mistakenly connecting this tubing to a patients intravenous line and introducing air into the patients circulatory system.

WARNING Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.

WARNING Allow space for 1 to 2 fingers between patient and cuff.

WARNING Do not apply cuff to limbs used for IV infusion.

WARNING Minimize cuff movement and limb motion during readings.

WARNING Ensure an airtight seal at all connection points prior to use.

Cautions

A caution statement in this manual identifies information within the manual to avoid equipment failure.

CAUTION Do not press cuff with a hot iron.

CAUTION Do not inflate cuff unless the hook and loop is closed.

CAUTION Do not allow foreign debris to ingress into tubes or port on cuff.

CAUTION Do not use steam or heat to sterilize the cuff, or tubing.

CAUTION Do not exceed 250 mmHg with thigh size disposable cuffs at or above 30 °C/86 °F.

CAUTION Intravenous Systems (IV) - Do not connect cuffs with luer lock connectors to intravenous fluid systems or fluid may enter the cuff.

Operation

Use the Flexiport blood pressure cuff the same as a traditional blood pressure cuff. The blood pressure cuff works with manual and automated sphygmomanometers.

Select cuff size appropriate for the patient's arm circumference. The applicable range, in centimeters, is printed on each cuff.

Operational Pressure Range: 0 to 300 mmHg

NOTE The "Artery Index Marker" on the cuff should fall within the "Range" indicated on the cuff. If the artery index marker falls short of range, use a larger cuff to ensure accurate results. If the artery index marker is past the range, use a smaller cuff to ensure accurate results.

Cleaning and Low-level disinfection

WARNING Cleaning and disinfection procedures must be conducted by persons trained in medical device cleaning and disinfection.

WARNING Consult the cleaning and germicidal cleaner agents' manufacturer's instructions for their proper use and germicidal efficacy.

CAUTION FlexiPort Cap must be installed into cuff tubing prior to cleaning or damage to cuff bladder may occur. Do not allow liquid to ingress into bladder tubing.

CAUTION Use only the cleaning or germicidal cleaner agent types listed or damage to cuff may occur.

CAUTION Repeated reprocessing may cause degradation of device; follow inspection procedures to assure integrity of device.

CAUTION Do not aggressively scrub cuff as damage to cuff markings and/or cuff closure integrity may occur.

Materials

- Neutral pH enzymatic-based cleaning detergent.
- Bleach-based germicidal cleaner suitable for use on healthcare equipment and capable of low-level disinfection. For example: A cleaner including 1:10 dilution of bleach (6500 ppm sodium hypochlorite) and detergent. Reference EPA-registered disinfectants: http://www.epa.gov/oppad001/chemregindex.htm
- Clean or sterile cloths, soft brush, soaking tray, and potable rinse water (softened preferred).

Cleaning (FlexiPort reusable cuffs, tubing, and port fittings)

The following types of wipes are compatible for use on the FlexiPort Reusable Cuffs. The user must inspect after cleaning to verify that removal of soil and contaminants is complete.

Use one or more of the following methods and allow to air dry:

- Wipe with enzymatic cleaner per manufacturer's instructions. Rinse with damp cloth.
- Wipe with 0.5% bleach and water solution. Rinse with damp cloth.
- Wipe with 70% isopropyl alcohol. Rinse with damp cloth.

Cleaning and low-level disinfection for one-piece blood pressure cuffs

Preparation for cleaning

Install FlexiPort Cap onto cuff port. Do not allow liquid to ingress into bladder tubing. See below for appropriate cap per cuff.

- FlexiPort Cap REF: 5082-159 for FlexiPort Style Reusable, Soft, and Vinyl disposable blood pressure cuffs

Cleaning only (cuffs and connector accessories)

1. Prepare neutral pH enzymatic cleaning detergent solution per manufacturer instructions.
2. Immerse or soak cuff and accessories in solution. Do not allow liquid to ingress into bladder tubing.
3. Soft brush all surfaces of the cuff and accessories to remove visible soil. Repeat as necessary.

Clean and disinfect (cuffs)

1. Clean: Thoroughly saturate (spray or immerse) all surfaces of the cuff and accessories with germicidal cleaner. Do not allow liquid to ingress into bladder tubing.
   - Soft brush to remove visible soil.
   - Water rinse.
   - Damp dry and inspect.
2. Disinfect: Thoroughly re-saturate (spray or immerse) all surfaces of the cuff and accessories with germicidal cleaner.
3. Soft brush all surfaces. Allow a 5 minute wet contact time or longer, if directed by the germicidal cleaner manufacturer. Do not exceed 10 minutes of wet contact time.

After cleaning or cleaning and disinfection

1. Thoroughly water rinse. Do not allow liquid to ingress into bladder tubing.
2. Damp dry with a clean cloth.
3. Remove FlexiPort Cap (if applicable) and allow to air dry.
4. Inspect cuff for deterioration, adequate closure integrity, and inflate to assess for leaks. Do not use if any abnormalities are found. Do not allow liquid to ingress into bladder tubing.

Environmental specifications

NOTE Comply with regional law when non-automated sphygmomanometer or accessories are discarded.

Storage temperature	-20°C to 55°C (-4°F to 131°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)

Legal Statement

Welch Allyn, Inc. ("Welch Allyn") assumes no responsibility for any injury to anyone that may result from (i) failure to properly use the product in accordance with the instructions, cautions, warnings, or statement of intended use published in this manual, or (ii) any illegal or improper use of the product.

Warranty

Your Welch Allyn® product, when new, is warranted to be free from original defects in material and workmanship and to perform in accordance with manufacturer's specifications under normal use and service. The warranty period begins from the date of purchase from Welch Allyn or its authorized distributors. Welch Allyn's obligation is limited to the repair or replacement of components determined by Welch Allyn to be defective within the warranty period. These warranties extend to the original purchaser and cannot be assigned or transferred to any third party. This warranty shall not apply to any damage or product failure determined by Welch Allyn to have been caused by misuse, accident (including shipping damage), neglect, improper maintenance, modification, or repair by someone other than Welch Allyn or one of its authorized service representatives.

FlexiPort Blood Pressure Cuff Warranty

Flexiport Reusable Cuff: Three-year warranty

This express warranty is in lieu of any and all other warranties, express or implied, including the warranties of merchantability and fitness for a particular purpose, and no other person has been authorized to assume for Welch Allyn any other liability in connection with the sale of the FlexiPort Blood Pressure Cuff. Welch Allyn shall not be liable for any loss or damages, whether direct, incidental, or consequential, resulting from the breach of any express warranty, except as set forth herein.

Hillrom™