Baxter

Welch Allyn FlexiPort

Reusable Blood Pressure Cuff

Instructions for use

℞ ONLY

For information about any Baxter product, contact Baxter Technical Support: baxter.com/contact-us.

901043 BLOOD PRESSURE CUFF, REUSABLE

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This manual is applicable to all REF REUSE-XX-XXX.

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Introduction

Intended use

Welch Allyn FlexiPort Reusable 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.

FlexiPort blood pressure cuffs are intended to be used by a clinically trained, medical professional.

Indications for use

FlexiPort blood pressure cuffs are intended to be used for patient health screening assessment to determine patient's systolic/diastolic blood pressure when used in conjunction with non-automated and automated sphygmomanometers.

Contraindications

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

Symbol descriptions

For information on the origin of these symbols, see the Welch Allyn symbols glossary: welchallyn.com/symbolsglossary

#	Product identifier	REF	Reorder number
LOT	Lot Code Number		Manufacturer
MD	Medical Device		Humidity limitation
	Range		Temperature limit
ARTERY INDEX MARKER	Artery index marker		Stacking limit by number
GTIN	Global Trade Item Number	EU REP	European Union Authorized representative

	Limb circumference (min/max)		Not made with natural rubber latex
	Consult instructions for use symbol for an electronic instruction for use (eIFU) • A copy of the IFU is available on this website. • A printed copy of the IFU can be requested and will be provided free of charge within 7 calendar days.		

Safety

Warnings

The warning statements in this manual identify conditions or practices that could lead to illness, injury, or death. Warning symbols will appear with a grey background in a black and white document.

WARNING Possible measurement error. Use only approved blood pressure cuff, sphygmomanometers 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 Baxter blood pressure tubing. Using these connectors on blood pressure cuff tubing creates the risk of mistakenly connecting this tubing to a patient's 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 1–2 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.

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

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

Cautions

The caution statements in this manual identify conditions or practices that could result in damage to the equipment or other property, or loss of data.

CAUTION Do not press cuff with a hot iron.

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

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

Residual risk

This product complies with relevant mechanical safety, performance, and biocompatibility standards. However, the product cannot completely eliminate potential patient or user harm from the following:

- Harm from mechanical hazards,
- Harm from device, function, or parameter unavailability,
- Harm from misuse error, such as inadequate cleaning, and/or
- Harm from device exposure to biological triggers that may result in a severe systemic allergic reaction.

Notice to users and/or patients in the EU

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Operation

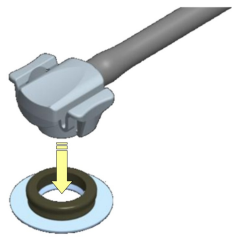
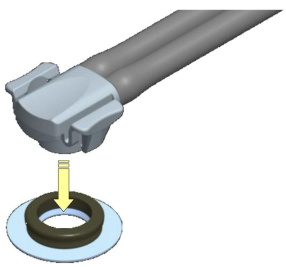
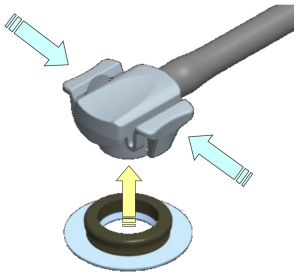
Use the **FlexiPort** blood pressure cuff the same as a traditional blood pressure cuff. The blood pressure cuff works with manual and automated sphygmomanometers.

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

Operational Pressure Range: 0–300 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.

Cuff connections

Port fitting with 1 tube	Port fitting with 2 tubes	Squeeze to release tube
		

Accessories

FlexiPort blood pressure cuff washing cap	REF: 5082-159

Cleaning and low-level disinfection

Warnings and cautions

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 For the **FlexiPort** cuffs, install washing cap before cleaning or damage to the cuff bladder may occur.

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.
- 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** 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 a damp cloth.
- Wipe with a 0.0375-0.65% sodium hypochlorite solution. Rinse with a damp cloth.
- Wipe with 70% isopropyl alcohol. Rinse with a damp cloth.

Cleaning and low-level disinfection (**FlexiPort** cuffs, tubing, and port fittings)

Preparation for cleaning

Install washing cap REF 5082-159 onto cuff port.

Cleaning only (cuffs, tubing, and port fittings)

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.
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.
   a. Soft brush to remove visible soil.
   b. Water rinse.
   c. Damp dry and inspect.
2. Disinfect: Thoroughly re-saturate (spray or immerse) all surfaces of the cuff and accessories with a 0.65% sodium hypochlorite solution. Do not allow liquid to ingress into bladder.
3. Soft brush all surfaces. Allow a 3-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. With washing cap in place, thoroughly water rinse. Do not allow liquid ingress into bladder.
2. Damp dry with a clean cloth.
3. Remove washing cap and allow to air dry.

Inspection after cleaning or cleaning and disinfection

Inspect cuff for deterioration and adequate closure integrity, and then inflate to assess for leaks. Do not use if you identify any abnormalities in the cuff.

Environmental specifications

Storage temperature	-20 °C–55 °C (-4 °F–131 °F)
Storage relative humidity	15%–95% (noncondensing)
Operating temperature	10 °C–40 °C (50 °F–104 °F)
Operating relative humidity	15%–90% (noncondensing)

Safe disposal

Users must adhere to all federal, state, regional, and/or local laws and regulations as it pertains to the safe disposal of medical devices and accessories. If in doubt, the user of the device shall first contact Baxter Technical Support for guidance on safe disposal protocols.

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

Lot code (marked directly on cuff)

Lot decoder

FlexiPort Lot code: YYYY-MM-DD-TT

Where Y = Year, M = Month, D = Day, T = Tool

Standards and compliance

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.

FlexiPort blood pressure cuffs are designed to function within the limits prescribed by ANSI/AAMI/ISO 81060-1:2007 (EN/ISO 81060-1:2012) non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type.

FlexiPort blood pressure cuffs are designed to function with automated sphygmomanometers tested to:

- ANSI/AAMI/ISO 81060-2:2018/AMD 1:2020, non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type.

Compliance statements

Unconfigured cuff

- REUSE-XX

ISO 80369 Exempt

FlexiPort connector is not considered a small bore connector by virtue of its inner-fluid pathway greater than 8.5mm diameter (ISO 80369-1 Section 3.13)

HP (bayonet or rectus connector)

- REUSE-XX-1HP

Compliant to ISO 80369-5

MQ (quarter turn locking or sub-miniature connector) and TP (Welch Allyn DuraShock and 767 wall/ mobile aneroid connectors)

- REUSE-XX-1MQ
- REUSE-XX-2MQ
- REUSE-XX-2MF
- REUSE-XX-1TP
- REUSE-XX-2TP
- REUSE-XX-1TPE
- REUSE-XX-2TPE
- REUSE-XX-2BV
- REUSE-XX-2BVC

Compliant to ISO 80369-1

WARNING As this blood pressure cuff is configured with an alternative small-bore connector design different from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur between this blood pressure cuff and a medical device using a different alternative small-bore connector, which can result in a hazardous situation causing harm to the patient. Special measures need be taken by the user to mitigate these reasonable foreseeable risks.

SC (screw connector)

- REUSE-XX-1SC
- REUSE-XX-2SC
- REUSE-XX-2SCC

Supplied tube set should be used as a permanent adapter for blood pressure hose. Order non-configured **FlexiPort** REUSE blood pressure cuffs (REUSE-XX) for future use with converted blood pressure hose (80369-5 Annex H, Obsolete limb cuff inflation connectors).

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, Inc., Inc. 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.

These express warranties are in lieu of any and all other warranties, expressed 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 and other liability in connection with the sale of the Welch Allyn **FlexiPort** Reusable 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 hence.

*Welch Allyn **FlexiPort** Reusable Blood Pressure Cuff: 3-year warranty.