Aneroid Sphygmomanometer

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the auscultatory method, within the limits prescribed by:


Introduction

Intended Use

Aneroid sphygmomanometers are used by professional healthcare providers and individuals trained in auscultatory blood pressure technique to determine systolic and diastolic blood pressure in humans and animals.

Contraindications

Aneroid sphygmomanometers are contraindicated for neonate use. Do not use with neonatal cuffs or neonate patients.

Warnings

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

WARNING: U.S. Federal law restricts this device to sale by or on the order of a physician.

WARNING: If luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel. Immediately consult a physician if this occurs.

WARNING: Do not allow a blood pressure cuff to remain on patient for more than 10 minutes when inflated above 10 mm Hg. This may cause patient distress, disturb blood circulation, and contribute to the injury of peripheral nerves.

WARNING: Safety and effectiveness with neonate cuffs (sizes from neo 1 to neo 5) is not established.

WARNING: Use only Welch Allyn manufactured blood pressure cuffs and accessories; substitution might result in measurement error.

WARNING: Only use the cuff when visible artery index marker falls within the range markings indicated on the cuff. Otherwise erroneous readings may result.

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.

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

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

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

Directions for Use

Connections

PSS-44
1. Attach the inflation bulb to the tube (if needed). Use alcohol to facilitate this.
2. Align and press the Durashock gauge with the FlexiPort adapter onto the cuff port.
3. Verify an airtight seal is achieved at all connection points.

PSS-45
1. Push the gauge stem into the adapter port until you feel it engage.
2. Connect the short cuff tube to the barb on the adapter.
3. Connect the barb on the inflation bulb valve to the long cuff tube.
4. Make certain an airtight seal is achieved at all connection points.

Operation

Blood pressure measurements can be affected by the position of the patient and their physiologic condition. Before beginning a measurement, ensure that the patient rests for at least five minutes, has support of their back and feet, and does not cross their legs. Passively support the patient’s lower arm and keep the upper arm at heart level. The procedure needs to take place in a quiet environment with no crying. Failure to follow these recommendations can result in inaccurate blood pressure measurements.

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

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 the 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.

2. Wrap the cuff around the arm with the artery index marker located over the brachial artery and with the lower edge of the cuff 2.5 cm above the bend in the elbow.

3. Inflate cuff rapidly to a level 30 mm Hg above estimated (or palpatory) systolic pressure.

4. Partially open the valve to allow deflation at a rate of 2 to 3 mm Hg per second. As the pressure falls, note systolic pressure and diastolic pressure detected with your stethoscope.

5. Rapidly release the remaining pressure and record measurements immediately. After a minimum of 30 seconds, repeat the above steps for a second reading.

Specifications

The aneroid sphygmomanometer is accurate to ±3 mm Hg. This product will maintain the safety and performance characteristics specified at temperatures ranging from 0°C to 46°C at a relative humidity level not to exceed 85%.

Standards

- European Standard EN 1060-1: 1995, Non-invasive sphygmomanometers - Part 1: General Requirements (except for section 9.3a for sizes 6, 7, 8, 9 disposable and reusable cuffs).
- European Standard EN 1060-3: 1997, Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems (FlexiPort cuff only).
Maintenance

Cleaning

Aneroid Gauge, Inflation Bulb, and Valve: Wipe the aneroid gauge, inflation bulb, and valve with slightly dampened cloth or alcohol pad.

Reusable One-Piece Cuff: Use one or more of the following methods and allow to air dry:

- Wipe with mild detergent and water solution (1:9 solution). Rinse.
- Wipe with Enzol® per manufacturer’s instructions. Rinse.
- Wipe with 0.5% bleach and water solution. Rinse.
- Wipe with 70% isopropyl alcohol.
- Launder with mild detergent in warm water (60°C/140°F maximum), normal wash cycle. Cuff is compatible with 5 wash cycles (Reusable only). Close port cuff with laundering plug (REF 5082-159).

Two-Piece Cuff and Bladder: Safely clean the cuffs with a damp cloth or wash in warm water (60°C/140°F maximum) with mild detergent. DO NOT PRESS WITH HOT IRON.

Before laundering the cuff:
1. Remove the bladder from the two-piece cuffs.
2. Place the hook and loop fasteners in the closed position.
4. Air dry completely and reassemble components.

Low-level disinfection procedure (FlexiPort Reusable cuffs only)
Prepare Enzol® enzymatic detergent according to manufacturer’s instructions. Apply port-cap (REF 5082-159) to cuff. Spray detergent solution liberally onto cuff and use a sterile brush to agitate the detergent solution over entire cuff surface for five minutes. Rinse continuously with distilled water for five minutes. To disinfect, first follow the cleaning steps above, then spray cuff with 1% bleach solution until saturated, agitate with a sterile brush over entire cuff surface for five minutes. Rinse continuously with distilled water for five minutes. Wipe off excess water with sterile cloth and allow cuff to air dry.

Calibration Check of Aneroid Sphygmomanometer

Quick Check of Calibration:
At zero pressure, make certain the pointer is within the oval surrounding the zero-pressure gradation on the dial. Although an unpressurized reading of zero does not guarantee accuracy at all scale points, failure of the pointer to indicate zero (± 3 mm Hg) is an obvious sign of error.

Full Check of Calibration:
The company recommends a full check of calibration at least every two years or according to local law and after maintenance and repair. Use the following procedure:
1. Connect the instrument under test to a high quality, known pressure source, and校验 it is calibrated for ±1.0 mm Hg, or Netech (REF 200-2000IN), which is calibrated for +/-1.0 mm Hg, works well for this application. Each meter is available. Contact your local PSS distributor.

校验 procedure:
2. Pressurize gauge to slightly above 300 mm Hg.
3. Bleed pressure down no faster than 10 mm Hg per second, stopping to check the pressure at 300, 250, 200, 150, 100, 50 (60 for US) and 0 mm Hg.

NOTE: Your ability to measure the accuracy of a gauge depends upon the sensitivity of the pressure standard you use for the calibration procedure.

If using a manometer (mercury column or aneroid gauge) rated at +/-3.0 mm Hg, an undetectable error of up to 6.0 mm Hg is possible. If using a device (e.g., digital pressure standard) rated at +/-0.1 mm Hg, an undetectable error of up to only 0.1 mm Hg is possible.

The company recommends using as sensitive as possible a pressure standard when performing calibration checks. A Setra Pressure Meter (REF 2270-01), which is calibrated for +/-0.1 mm Hg, or Netech (REF 200-2000IN), which is calibrated for +/-1.0 mm Hg, works well for this application. Each meter is available. Contact your local PSS distributor.

Warranty

Your Select™ Medical 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 the company or its authorized distributors. The company’s obligation is limited to the repair or replacement of components determined by the company 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 the company to have been caused by misuse, accident (including shipping damage), neglect, improper maintenance, modification, or repair by someone other than the company or one of its authorized service representatives.

*Gauge Warranty

Should the aneroid sphygmomanometer deviate from the +/-3 mm Hg accuracy specification during the warranty period, the company will recalibrate the sphygmomanometer at no charge. For questions, contact your Select™ Medical Products representative for assistance.

Gauge: Model PSS-45: Ten-year warranty
Model PSS-44: Three-year warranty

*Accessory Warranty: Inflation Bulb and Valve: One year
FlexiPort One-piece Blood Pressure Cuff: Three years
Two-piece Blood Pressure Cuff: Two years

These express warranties are 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 the company any other liability in connection with the sale of the product. The company 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.

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U.S. Patents 6,578,428; 6,036,718; and additional patents pending.