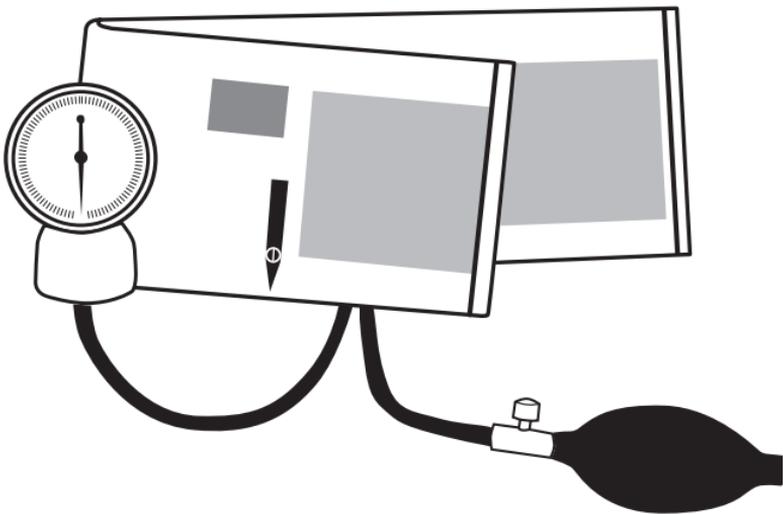

Aneroid Sphygmomanometer

Use, Care, & Maintenance



Device Description and Intended Use

An aneroid sphygmomanometer is used by professional healthcare providers and individuals trained in the auscultatory blood pressure technique to determine systolic and diastolic blood pressure in humans.

Contraindications:

Aneroid sphygmomanometers are contraindicated for neonate use. Do not use with neonatal cuffs or neonate patients. Review the size chart (right) for proper limb range usage.

Size Chart

Cuff	Size	Limb Range Inches	CM
Infant	7I	3.5 to 5.5	9 to 14
Child	9C	5.1 to 7.6	13 to 19.5
Small Adult	10SA	7.4 to 10.6	19 to 27
Adult	11A	9 to 15.7	23 to 40
Large Adult	12X	13.3 to 19.6	34 to 50
Thigh	13T	15.7 to 25.9	40 to 66

Symbol Definitions

The following symbols are associated with your aneroid sphygmomanometer.

Symbol	Definition
	Important Warning/Caution
	Not made with natural rubber latex
	Circumference Size
	Conforms to EU Standards

Symbol	Definition
	Authorized European Representative's Information
	Manufacturer's Information
	Temperature Limit
	Humidity Limitation

General 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:** Do not allow a blood pressure cuff to remain on patient for more than 10 minutes when inflated above 10 mmHg. This may cause patient distress, disturb blood circulation, and contribute to the injury of peripheral nerves.
-  **WARNING:** If luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intra-vascular fluid systems, allowing air to be pumped into a blood vessel. Immediately consult a physician if this occurs.
-  **WARNING:** Safety and effectiveness with neonate cuff sizes 1 through 5 is not established.
-  **WARNING:** If this equipment is modified, appropriate inspection and testing must be conducted to ensure its continued safe use.
-  **WARNING:** Do not apply cuff to delicate or damaged skin. Check cuff site frequently for irritation.
-  **WARNING:** Only use the cuff when the range markings indicated on the cuff show that the proper cuff size is selected, otherwise erroneous readings may result.
-  **WARNING:** Allow space between patient and cuff. Two fingers should fit in this space if the cuff is correctly positioned.
-  **WARNING:** Do not apply cuff to limbs used for IV infusion.
-  **WARNING:** Patient should remain still during measurement to avoid erroneous readings.
-  **WARNING:** When using with an infant or child cuff, extra care must be taken to prevent over-inflation. With smaller cuffs (infant or child) the cuff can inflate to over 300mmHg with just two full compressions of the bulb. To prevent discomfort or injury to the patient and damage to the instrument, bulb should only be partially squeezed, so that each “stroke” inflates the cuff in 40mmHg to 60mmHg increments until inflated to the desired level.

⚠ WARNING: This product may contain a chemical known to the state of California to cause cancer, birth defects, or other reproductive harm.

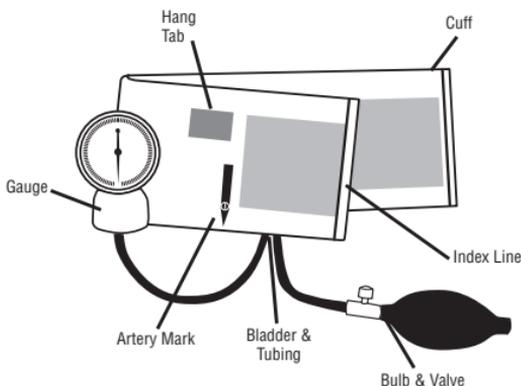
⚠ CAUTION: To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within a temperature range of 50°F (10°C) to 104°F (40°C), with a relative humidity range of 15%-85% (non-condensing).

⚠ CAUTION: Extreme altitudes may affect blood pressure readings. Your device has been designed for normal environmental conditions.

Operation of Pocket Aneroids

This booklet contains operating and maintenance information for pocket aneroid sphygmomanometers. Please read and retain.

Your pocket aneroid sphygmomanometer consists of an aneroid manometer (gauge), complete inflation system, (latex-free inflation bladder, squeeze bulb, and the valve), a zippered carrying case, and operating instructions.



Most models come preassembled and ready for use. If assembly is required, attach gauge and bulb and valve assemblies to the tubes as shown in illustration. To facilitate, use alcohol or soapy water.

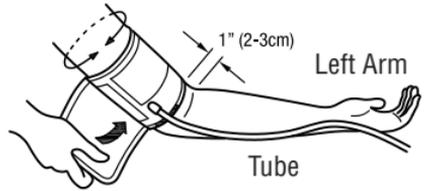
Measurement Procedure

1. Patient Position

The patient should sit or lie comfortably. The arm should be fully supported on a flat surface at heart level. (If the arm's position varies, or is not level with the heart, measurement values obtained will not be consistent with the patient's true blood pressure.) When seated, the patient should have their back and arm supported, and their legs should not be crossed. The patient should relax prior to measurement comfortably for five (5) minutes and should refrain from talking or moving during measurement. Observer should view manometer in a direct line to avoid "Parallax error".

2. Apply the cuff

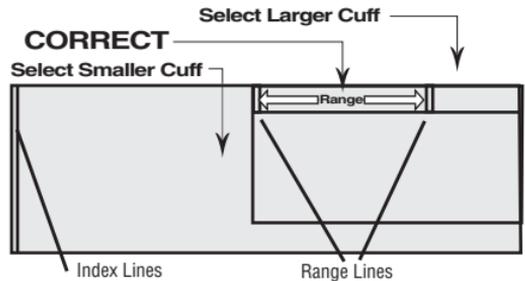
Nylon cuffs are specially designed to promote the precisely accurate determination of blood pressure. Index and range markings ensure use of the correct cuff size. The artery mark indicates proper cuff positioning.



(Figure 1)

Place the cuff over the bare upper arm with the artery mark positioned directly over the brachial artery. The bottom edge of the cuff should be positioned approximately (1") one inch (2-3cm) above the antecubital fold. Wrap the end of the cuff not containing the bladder around the arm snugly and smoothly and engage adhesive strips (Figure 1).

NOTE: If the unit is equipped with a calibrated nylon cuff, featuring Index and Range markings, a correct fit may be verified by checking that the Index Line falls between the two Range Lines. (Figure 2).



(Figure 2)

3. Inflate the cuff

Close the valve by turning thumbscrew clockwise.

Palpate the radial artery while inflating the cuff. Be sure to inflate cuff quickly by squeezing bulb rapidly.

Inflate cuff 20-30 mmHg above the point at which the radial pulse disappears.

NOTE: Cuff pressure range is 0 mmHg to 300 mmHg.

4. Position the Stethoscope

Position the chestpiece in the antecubital space below the cuff, distal to the brachium. Do not place chestpiece underneath the cuff, as this impedes accurate measurement. Use the bell side of a combination stethoscope for clearest detection of the low pitched Korotkoff (pulse) sounds.

5. Deflate the cuff

Open the valve to deflate the cuff gradually at a rate of 2-3 mmHg per second.

6. Measurement

Record the onset of Korotkoff sounds as the systolic pressure, and the disappearance of these sounds as diastolic pressure. (Some healthcare professionals recommend recording diastolic 1 and diastolic 2. Diastolic one occurs at phase 4).

NOTE: It is recommended that K4 be used in children aged 3 to 12, and K5 should be used for pregnant female patients unless sounds are audible with the cuff deflated, in which case K4 should be used. K5 should be used for all other adult patients.

After measurement is completed, open valve fully to release any remaining air in the cuff. Remove cuff.

Care and Maintenance

STORAGE:

Pocket Gauge: After measurement, fully exhaust cuff then wrap cuff around gauge and bulb and store in zippered carrying case.

NOTE: This product will maintain the safety and performance characteristics specified at temperatures ranging from 50°F to 104°F (10°C to 40°C) at a relative humidity level of 15% to 85%.

This device can be safely stored at temperatures ranging from -4°F (-20°C) to 131°F (55°C) with a relative humidity of 90%.

Manometer: Your pocket aneroid gauge requires minimal care and maintenance.

The manometer may be cleaned with a soft cloth but should not be dismantled under any circumstances.

Gauge accuracy can be checked visually; simply be certain the needle rests within the printed oval when the unit is fully deflated (Figure 3).



NOTE: Store gauge with valve in full exhaust position.

(Figure 3)

Should the indicator needle of the manometer rest outside of this calibration mark, then the manometer must be re-calibrated to within ± 3 mmHg when compared to a reference device that has been certified to national or international measurement standards. A manometer whose indicator needle is resting outside of this mark, is NOT acceptable for use.

In the event that the gauge is ever in need of calibration, simply return for service. Damaged or broken parts will be replaced as needed at a minimal charge. Refer to the warranty for specific details of warranty coverage.

The manufacturer recommends a calibration check every 2 years.

Cuff Cleaning and Disinfecting

NOTE: 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 .5% bleach and water solution. Rinse.
 - Wipe with 70% isopropyl alcohol.
 - Launder with mild detergent in warm water, normal wash cycle. Remove bladder first. Cuff is compatible with 5 wash cycles.
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Low Level Disinfection

Prepare Enzol enzymatic detergent according to the manufacturer's instructions. 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 10% 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.

⚠ CAUTION: Do not iron cuff.

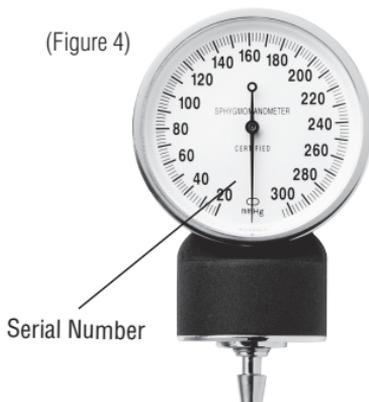
⚠ CAUTION: Do not heat or steam sterilize cuff.

Manometer Quality Control

A Serial number and Lot number are automatically assigned to every aneroid during manufacturing, ensuring every item is "controlled".

The Serial Number can be located on the faceplate of each aneroid (Figure 4).

The Lot number is located on the box end label (Figure 5).



(Figure 5)

Standards

ANSI/AAMI/ISO 81060-1:2007 • EN/ISO 81060-1: 2012

Disposal

When your sphygmomanometer has reached its end of life, please be sure to dispose of it in accordance with all regional and national environmental regulations. Devices that have become contaminated should be disposed of in accordance with all local ordinances and regulations.

Warranty

The manufacturer warrants its products against defects in materials and workmanship under normal use and service as follows:

- Warranty service extends to the original retail purchaser only and commences with the date of delivery.

Warranty duration is as follows:

<u>Manometer</u>	<u>Inflation System</u>
5 YEARS	1 YEAR
10 YEARS	1 YEAR
20 YEARS	3 YEARS
LIFE	3 YEARS

What is Covered: Calibration, repair, or replacement of parts and labor.

What is Not Covered: Transportation charges. Damages caused by abuse, misuse, accident, or negligence. Incidental, special, or consequential damages. Some states do not allow the exclusion or limitation of incidental, special, or consequential damages, so this limitation may not apply to you.

Implied Warranty: Any implied warranty shall be limited in duration to the terms of this warranty and in no case beyond the original selling price (except where prohibited by law). This warranty gives you specific legal rights and you may have other rights which vary from state to state.

To Obtain Warranty Service: Send item(s) postage paid to: Warranty Service Center, 55 Commerce Dr., Hauppauge, NY 11788. Please include your name and address, phone no., proof of purchase, and a brief note explaining the problem.

For Australian Consumers

Our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonable foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.