Aneroid Sphygmomanometer

This IFU pertains to ADC® models: 809D, 809SPU,and the 774 series.

Intended Use:

This package contains one (1) aneroid manometer for use with an aneroid sphygmomanometer. 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.

Contraindications:

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

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: Consult the original equipment manufacturer's instructions for use when installing this manometer. When modifying any blood pressure measurement device, care must be taken to verify the accuracy of the device by comparing it to a calibrated reference manometer. Reference manometers must be calibrated in accordance with national or international measurement standards.

WARNING: Safety and effectiveness with neonate cuff sizes 1 through 5 is not established.

WARNING: Extreme shock and vibration may reduce the accuracy of this manometer over time. Care should be taken to avoid conditions that would subject the manometer to shock and vibration.

WARNING: Do not attempt to disassemble or modify this manometer.

CAUTION: Do not allow a blood pressure cuff to remain on arm 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 WHEN USED INSTITUTIONALLY: 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.

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: This manometer has a range of 0 mmHg through 300 mmHg. It can be used with inflation systems and blood pressure equipment that can accommodate this range. Consult the manufacturer's instructions on appropriate age and size restrictions on the intended patient population of the complete device.

CAUTION: When selecting a cuff for use on a patient, refer to the manufacturer's instructions on proper cuff size selection and placement.

CAUTION: Refer to the manufacturer's instructions on the proper operation of the inflation system that will be used with this manometer.

CAUTION: When using this manometer with an inflation system for the determination of patient blood pressure, refer to the manufacturer's instructions supplied with the inflation system/blood pressure device to ensure proper patient positioning and preparation prior to measurement.

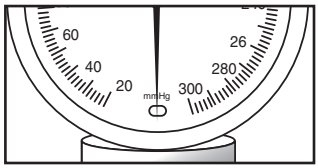
CAUTION: Extreme altitudes may affect blood pressure readings. Your device has been designed for normal environmental conditions.

Connecting the manometer:

The port at the bottom of the manometer will friction fit onto the tubing of most commercially available two tube cuff and bladder systems.

Please note that this gauge is designed for use with TWO tube systems where one tube connects to the manometer and the other connects to the inflation source (bulb and valve)

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. 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 standards. No manometers that have their indicator needle resting outside of this mark are acceptable for use.

The manufacturer recommends a calibration check every 2 years.

Standards:
ANSI/AAMI/ISO 81060-1:2007

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
This manometer is warranted to remain accurate for a period of 1 year from date of purchase.

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

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.

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.

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