American National Standard

Nonautomated sphygmomanometers

Association for the Advancement of Medical Instrumentation

4.5.2.2 Valve/cuff exhaust rate

The valve shall be adjustable so as to control the pressure drop in a volume of no more than 80 cc at a rate of 20 mm Hg in 10 sec at initial differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.5.2.3 Release rate

With the valve fully opened, a volume of at least 200 cc shall be reduced from a pressure of 250 mm Hg to a pressure of 20 mm Hg in a maximum of 4 sec.

4.5.3 Self-bleeding pressure control valve

4.5.3.1 Valve/Cuff exhaust rate

When the valve is in the self-bleeding position and when it is used with the cuff for which it is intended, it shall be possible to reduce the cuff pressure at the maximum rate of 6 mm Hg/sec to a minimum rate of 2 mm Hg/sec throughout the 250- to 50-mm Hg range.

4.5.3.2 Release rate

With the valve fully opened, a volume of at least 200 cc shall be reduced from a pressure of 250 mm Hg to a pressure of 20 mm Hg in a maximum of 4 sec.

4.5.4 Hose connectors

The maximum pressure drop, caused by leakage, through joined metal or plastic hose connectors shall be 10 mm Hg in 10 sec for a volume of no more than 80 cc at differential pressures of 250 mm Hg, 150 mm Hg, and 50 mm Hg.

4.6 Requirements for the inflatable bladder and cuff

4.6.1 Inflatable bladder

4.6.1.1 Dimensions

The cuff bladder length shall be at least 0.80 times the circumference of the limb at the midpoint of cuff application. The width of the cuff bladder shall be minimally 0.37 (optimally 0.40) times the circumference of the limb at the midpoint of cuff application.

4.6.1.2 Pressure capacity

The bladder and integral tubing shall be capable of withstanding a differential pressure of 330 mm Hg.

4.6.2 Cuff

The following requirements apply to bandage, hook, contact closure, and other types of cuffs.

4.6.2.1 Dimensions

For bandage cuffs, the full cuff length shall extend beyond the end of the inflatable bladder by at least the equivalent of the length of the bladder for which the cuff is intended; the total length of the cuff shall be sufficient to ensure that the cuff does not slip or become loose when the bladder is inflated to 300 mm Hg. For hook, contact closure, and other types of cuffs, the cuff shall, as a minimum, be of sufficient length to completely encircle the largest circumference limb for which it is intended, maintaining its full width throughout this length.

4.6.2.2 Pressure capacity

The cuff shall be capable of completely retaining the bladder for which it is intended when the bladder is inflated to a mlnlmum pressure of 330 mm Hg.

4.6.2.3 Cuff closures/construction

The cuff closures and stitching shall be adequate to ensure that the cuff integrity is maintained and the other requirements of this standard are met, after 1,000 open-close cycles of the closure and after 10,000 pressure cycles to 300 mm Hg.

NOTE-Disposable cuffs are exempt from this requirement.

4.6.3 Cuff with integral bladder

4.6.3.1 Dlmenslons

The cuff bladder length shall be at least 0.80 times the circumference of the limb at the midpoint of cuff application. The width of the cuff bladder shall be minimally 0.37 (optimally 0.40) times the circumference of the limb at the midpoint of cuff application. The cuff shall, as a minimum, be of suffiient length to encircle the largest circumference limb for which it is intended, maintaining its full width throughout this length.

4.6.3.2 Pressure Capacity

The bladder and integral tubing shall be capable of withstanding an internal pressure of 330 mm Hg.

4.6.3.3 Cuff closures/construction

The cuff closures and stitching shall be sufficient to maintain the integrity of the cuff and bladder and to ensure compliance with the other requirements of this standard after 1,000 open-close cyles of the closure and after 10,000 pressure cydes to 300 mm Hg

NOTE-Disposable cuffs are exempt from this requirement.

4.7 Requirements for system leakage

The sphygmomanometer system shall not lose pressure at a rate greater than 1 mm Hg per second.

5 Tests

This section contains referee test methods by which compliance of the device with the requirements of section 4 can be verified; the paragraph numbers below correspond, except for the first digit, with the paragraph numbers of section 4. These test methods are not intended for use by end users of the device, nor are they intended for use in quality control or lot-to-lot testing by manufacturers. The methods are intended for type testing, referee testing, or design qualification.

5 . 1 Labeling

Compliance with the labeling requirements of 4.1 can be determined by visual inspection.