List of Titles

American National Standard

ANSI/AAMI SP10:1992/A1:1996

Electronic or automated sphygmomanometers, Amendment 1

AAMI Association for the Advancement of Medical Instrumentation

List of Titles

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SP10A ANSI/AAMI SP10A—1996

Amendment to
ANSI/AAMI SP10–1992:

American National Standard

for

Electronic or Automated Sphygmomanometers

Developed by
Association for the Advancement of Medical Instrumentation

Approved 21 November 1996 by
American National Standards Institute

Special Considerations for Devices Intended for Pediatric Use

The following sections contain additional requirements, test methods, and rationale for automated sphygmomanometers that are labeled for use for neonates. An addition to Annex D is also included that describes special data gathering to be used for validating these devices. Except where noted, these devices must meet all the requirements set forth in section 4 of the standard.

1 Scope

1.2 Inclusions.

Add the following paragraph after the existing paragraph in this section of the current standard:

Note—The standard, including the proposed amendment, covers neonatal or newborn and adult categories. Pediatric or child category is not specifically addressed and cannot be until more data become available. The committee suggests that in most instances, the recommendations for adult category should be applied to pediatric or child category as well.

1.3 Exclusions. *Delete the following text, which appears at the end of the first paragraph in this section of the standard, and the subsequent note:*

...Also excluded from this standard are automated, indirect, neonatal blood pressure monitors.

NOTES—Although the specific performance requirements of this standard are not appropriate for neonatal monitors, the general provisions and direction of this standard might be useful in the assessment of such devices.

3 Definitions

Add the following text after section 3.6 sphygmomanometer *in the existing standard:*

3.7 neonatal or newborn. 28 days or less of age if born at term (37 weeks gestation or more); otherwise, up to 44 gestational weeks.

3.8 pediatric or child. (other than newborn). Aged from 29 days to 18 years.

3.9 adult. Greater than 18 years of age.

3.10 normal condition. Condition in which all means provided for protection against safety hazards are intact.

3.11 single-fault condition. Condition in which a single means for protection against a safety hazard in equipment is defective or a single abnormal condition is present.

4 Requirements

4.1.3 Information manual

Add the following text after l) Product warranty information *in this section of the standard:*

m) Whether or not the device is intended for neonatal use. If intended for neonatal use;

- The maximum pressure that can be applied by the monitor and cuff when used with neonates.
- The range of blood pressures which the device can accommodate when used with neonates.
- The maximum pressure which will be utilized in the neonatal mode to measure the patient's blood pressure under normal operating circumstances.
- The initial inflation pressure to which the device will pump when measuring the blood pressure of a neonate.

4.3.1.1 Maximum cuff pressure

Add the following paragraph after the existing paragraph in this section of the current standard:

For devices intended for neonatal use when in neonatal mode. Under normal operating conditions without fault insertion, the maximum cuff pressure shall be limited to 150 mmHg. Under any single fault condition, the maximum cuff pressure shall not exceed 330 mmHg for more than 10 seconds, or remain above 10 mmHg for longer than 5 minutes.

5 Tests

5.3.1.1 Maximum cuff pressure

Add the following paragraph after the existing paragraph in this section of the current standard:

For devices intended for neonatal use when in neonatal mode. The tests described in 5.3.1.1 are applicable under conditions of a single fault in which the 150 mmHg limiting system is defeated. Additionally, the same test conducted under no fault conditions shall not result in the maximum cuff pressure exceeding 150 mmHg.

Annex A

A.4.1 Labeling requirements

Add the following paragraphs after the second paragraph in this section of the current standard:

Neonatal subjects pose special problems in measuring and validating blood pressures. Many sphygmomanometers may be capable of measuring blood pressures in both adults and children, but not in neonates. Thus, this standard requires specific labeling for those devices intended for use in neonates.

Recommendations made by the Second Task Force on Blood Pressure Control in Children* include the need to consider newborn, child, and adult standards. For sphygmomanometers, while neonates are clearly a special issue, there are no similarly clear reasons for treating children separately from adults. Thus, all the requirements

in this standard apply to adults and children.

* Report of the Second Task Force on Blood Pressure Control in Children—1987. Pediatrics 79:1-25, 1987.

A.4.3.1.1 Maximum pressure

Add the following after the second paragraph in this section of the current standard:

Neonatal populations. The higher the pressure, the more agitated and angry the subject is likely to become. For infants and neonates, this is especially true. On the other hand, no data are available to suggest a specific maximal pressure based on safety. For ordinary use, there appears to be no reason to apply more than 150 mmHg to neonates, and this is the value recommended in this standard. This will reduce the likelihood of obtaining inaccurate blood pressures from motion artifacts as a result of discomfort. However, to avoid special problems associated with pressure limiting techniques, 330 mmHg is still the allowable maximum pressure in the event that the 150 mmHg limiting system fails.

A.4.4.2 Overall system efficacy

Add the following paragraph after the last paragraph in this section of the current standard:

Neonatal populations. Auscultation is not appropriate for the newborn. Thus, the standard for devices intended for neonatal use must be intra-arterial measurements. The accuracy issue for these measurements is associated with infant weight, and it is for this reason that three weight classes are recommended in Annex D.2. In recognition of the difficulty of performing these studies, the minimal number of subjects is recommended to be 15. The committee judged that this number would permit a reasonable estimate of the accuracy of the instrument while not creating too formidable a task for performing the required studies.

Annex D

D.2 Data gathering

The following text should appear after the last paragraph in this section of the current standard:

For devices intended for neonatal use when in neonatal mode. The recommendations described in this section apply also to sphygmomanometers intended for pediatric use, except for those labeled as “neonatal“ devices. The subject database shall be documented and shall contain no fewer than 15 neonatal subjects. A minimum of 5 and a maximum of 10 sets of paired measurements shall be made, with measurements spaced at least three minutes apart. All data shall be used. The minimum number of entries paired values, taking all subjects into consideration, shall be 100.

1) less than 1,000 grams
2) 1,001 to 2,500 grams
3) greater than 2,500 grams

In the clinical setting, BP is seldom, if ever, measured in the healthy term newborn. Neonatal intensive care nurseries primarily treat preterm newborns. Technical problems with the accuracy of BP in small preterm newborns (< 1,000 grams) have led to the suggestion of statistically “oversampling“ smaller infants out of proportion of their birth incidence.

The validation for neonates must use intra-arterial measurements as the standard since auscultation is not appropriate.