INTERNATIONAL STANDARD

ISO 81060-2

> Third edition 2018-11-29 **AMENDMENT 1** 2020-01

Non-invasive sphygmomanometers —

Part 2:

Clinical investigation of intermittent automated measurement type

AMENDMENT 1

iTeh STANDARD PREVIEW
Sphygmomanometres non invasifs—

S Partie 2: Investigation clinique pour type ponctuel à mesurage automatique

IAMENDEMENT 2md 1:2020

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This document was prepared jointly by Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, Subcommittee SC 3, Respiratory devices and related equipment used for patient care, and Technical Committee IEC/TC 62, Electrical equipment in medical practice, Subcommittee SC D, Electromedical equipment.

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Clause 3

Add the following after 3.4:

3.5

TOTAL LIMB CIRCUMFERENCE RANGE

range, from the smallest limb circumference to the largest limb circumference, intended by the MANUFACTURER for use with the AUTOMATED SPHYGMOMANOMETER

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5.1.4

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Replace the text with the following, and renumber the subsequent formulae:

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5.1.4 * Limb size distribution iteh ai/catalog/standards/sist/824ce915-0d23-4086-aeb8-

0cf50823f874/iso-81060-2-2018-amd-1-2020

- a) Limb circumferences shall be distributed as follows:
 - 1) at least 20 % of the subjects shall have a limb circumference which lies within each quarter of the TOTAL LIMB CIRCUMFERENCE RANGE;
 - 2) at least 10 % of the subjects shall have a limb circumference which lies within the highest octile of the TOTAL LIMB CIRCUMFERENCE RANGE; and
 - 3) at least 10 % of the subjects shall have a limb circumference within the lowest octile of the TOTAL LIMB CIRCUMFERENCE RANGE.
- b) Additionally, for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF shall be tested on at least N_{cuff} subjects as calculated according to Formula (1).

$$N_{\text{cuff}} = \frac{r_{\text{cuff}}}{2 \cdot r_{\text{total}}} \cdot N_{\text{total}} \tag{1}$$

where

 N_{total} is the total number of subjects in the study;

 $r_{\rm cuff}$ is the size of the limb circumference range for the individual cuff;

 r_{total} is the size of the TOTAL LIMB CIRCUMFERENCE RANGE.

ISO 81060-2:2018/Amd.1:2020(E)

- c) The CLINICAL INVESTIGATION REPORT shall provide the specified arm circumference range of each CUFF in centimetres (inches).
- d) The CLINICAL INVESTIGATION REPORT shall include plots showing all subject results by arm circumference, where the Y axis shows the difference between SPHYGMOMANOMETER-UNDER-TEST and REFERENCE BLOOD PRESSURE VALUES and the X axis shows the actual arm circumference of the subjects.
- e) These plots should also indicate the borders of each CUFF with vertical lines.
- f) Plots shall be provided for both:
 - 1) SYSTOLIC BLOOD PRESSURE; and
 - 2) DIASTOLIC BLOOD PRESSURE.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

5.2.3, list item h)

Replace the text with the following:

- h) *Cuffs for the reference Sphygmomanometer shall have:
 - 1) a bladder length of 75 % to 100 % of the upper arm circumference;
 - 2) a bladder width of 37 % to 50 % of the upper arm circumference; and (**Standards.iteh.ai**)
 - 3) a 2-piece construction comprising:
 - i) a distensible inner BLADDER; and https://standards.tteh.av/catalog/standards/sist/824ce915-0d23-4086-aeb8-

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ii) a non-distensible outer \$166082.3f874/iso-81060-2-2018-amd-1-2020

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

6.1.4

Replace the text with the following:

6.1.4 * Limb size distribution

- a) Limb circumferences shall be distributed as follows:
 - 1) at least 20 % of the subjects shall have a limb circumference which lies within each quarter of the TOTAL LIMB CIRCUMFERENCE range;
 - 2) at least 10 % of the subjects shall have a limb circumference which lies within the highest octile of the TOTAL LIMB CIRCUMFERENCE range; and
 - 3) at least 10 % of the subjects shall have a limb circumference within the lowest octile of the TOTAL LIMB CIRCUMFERENCE range.
- b) Additionally, for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF shall be tested on at least N_{cuff} subjects as calculated according to Formula (1).
- c) The CLINICAL INVESTIGATION REPORT shall provide the specified arm circumference range of each cuff in centimetres (inches).

- d) The CLINICAL INVESTIGATION REPORT shall include plots showing all subject results by arm circumference, where the Y axis shows the difference between SPHYGMOMANOMETER-UNDER-TEST and REFERENCE BLOOD PRESSURE values and the X axis shows the actual arm circumference of the subjects.
- e) These plots should also indicate the borders of each cuff with vertical lines.
- f) Plots shall be provided for both:
 - 1) SYSTOLIC BLOOD PRESSURE; and
 - 2) DIASTOLIC BLOOD PRESSURE.

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

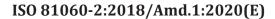
Annex C

Add the following entries:

bladder	ISO 81060-1:2007, 3.2
total limb circumference range	3.5

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