# 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 1 MD1 2020

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### Non-invasive sphygmomanometers —

#### Part 2:

## Clinical investigation of intermittent automated measurement type

#### AMENDMENT 1

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:  $\frac{150\ 81060-2:2018/AMD1:2020}{1000-2:2018/AMD1:2020}$ 

**5.1.4** \* Limb size distribution iteh.ai/catalog/standards/sist/c5097c2b-2c58-485d-9cd3-

650296914e59/iso-81060-2-2018-amd1-2020

- 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  $N_{\text{cuff}}$  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

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

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

 $r_{\rm total}$  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; ISQ 81060-2:2018/AMD1:2020 https://standards.itch.avcatalog/standards/sist/c5097c2b-2c58-485d-9cd3-
    - ii) a non-distensible outer \$feeve. 914e59/iso-81060-2-2018-amd1-2020

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  $N_{\text{cuff}}$  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.

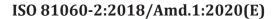
#### Annex C

Add the following entries:

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

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