SLOVENSKI STANDARD
SIST EN ISO 81060-2:2020/oprA1:2020

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Neinvazivni sfigmomanometri - 2. del: Klinične raziskave avtomatiziranih vrst merjenja s prekinitvami - Dopolnilo A1 (ISO 81060-2:2018/Amd 1:2020)

Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type - Amendment 1 (ISO 81060-2:2018/Amd 1:2020)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart - Änderung 1 (ISO 81060-2:2018/Amd 1:2020)

Sphygmomanomètres non invasifs - Partie 2: Investigation clinique pour type ponctuel à mesurage automatique - Amendement 1 (ISO 81060-2:2018/Amd 1:2020)

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AMENDMENT 1
2020-01

Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

AMENDMENT 1

Sphygmomanomètres non invasifs —

Partie 2: Investigation clinique pour type ponctuel à mesurage automatique

AMENDEMENT 1

Reference number
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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

5.1.4

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

5.1.4 * 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).

$$N_{cuff} = \frac{r_{cuff}}{2 \cdot r_{total}} \cdot N_{total} \quad (1)$$

where

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

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

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

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

   3) a 2-piece construction comprising:

      i) a distensible inner BLADDER; and

      ii) a non-distensible outer sleeve.

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).

