SLOVENSKI STANDARD
SIST EN ISO 81060-2:2020/oprA2:2023

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Neinvazivni sfigmomanometri - 2. del: Klinične raziskave avtomatiziranih vrst merjenja s prekinitvami - Dopolnilo A2 (ISO 81060 2:2018/DAM 2:2023)

Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type - Amendment 2 (ISO 81060 2:2018/DAM 2:2023)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart - Änderung 2 (ISO 81060 2:2018/DAM 2:2023)

Sphygmomanomètres non invasifs - Partie 2: Investigation clinique pour type ponctuel à mesurage automatique - Amendment 2 (ISO 81060 2:2018/DAM 2:2023)

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ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

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Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

AMENDMENT 2

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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* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

AMENDMENT 2

1.0

Add the following as the last paragraph in the scope:

This document is not applicable to CLINICAL INVESTIGATIONS of a series of CUFFS that are not of same materials and construction.

5.1.4

Replace the subclause with the following:

5.1.4 * Limb size distribution

a) To limit the overlap of all CUFFS intended for use with a SPHYGMOMANOMETER, Formula (17) shall apply.

b) If the distribution of CUFFS is not in accordance with Formula (17), multiple CLINICAL INVESTIGATIONS with subsets of these CUFFS shall be performed separately.

$$\frac{\sum r_{\text{cuff}}}{r_{\text{total}}} \leq 1{,}35 \qquad (17)$$

where

r_{cuff} is the limb circumference range for the individual CUFF in cm; and

r_{total} is the TOTAL LIMB CIRCUMFERENCE RANGE in cm.

c) For CUFFS having a size of the limb circumference range (r_{cuff}) of 12 cm or less:

1) at least 40 % of the subjects allocated to this CUFF shall have a limb circumference which lies within the upper half of the specified range of use of the CUFF;

2) at least 40 % of the subjects allocated to this CUFF shall have a limb circumference within the lower half of the specified range of use of the CUFF;

3) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of 12 cm or less shall be tested on at least N_{cuff} subjects as calculated according to Formula (18); and

$$N_{\text{cuff}} = \frac{r_{\text{cuff}}}{2 \cdot r_{\text{total}}} \cdot N_{\text{total}} \tag{18}$$

where

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

r_{cuff} is the limb circumference range for the individual CUFF in cm;

r_{total} is the TOTAL LIMB CIRCUMFERENCE RANGE in cm.

4) if *N*cuff, according to Formula (18) is less than 12 subjects, *N*cuff shall be a minimum of 12 subjects.

d) For CUFFS having a size of the limb circumference range (r_{cuff}) of more than 12 cm and less than or equal to 16 cm:

1) at least 20 % of the subjects allocated to this CUFF shall have a limb circumference which lies within each quartile of the limb circumference range;

2) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of more than 12 cm and less than or equal to 16 cm shall be tested on at least N_{cuff} subjects as calculated according to Formula (19); and

$$N_{\text{cuff}} = \frac{r_{\text{cuff}}}{2 \cdot r_{\text{total}}} \cdot N_{\text{total}} \cdot \frac{r_{\text{cuff}}}{12} \tag{19}$$

where

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

r_{cuff} is the limb circumference range for the individual CUFF in cm; and

r_{total} is the TOTAL LIMB CIRCUMFERENCE RANGE in cm.

3) if *N*cuff, according to Formula (19) is less than 12 subjects, *N*cuff shall be a minimum of 12 subjects.

e) For CUFFS having a size of the limb circumference range (r_{cuff}) of greater than 16 cm:

1) at least 20 % of the subjects allocated to this CUFF shall have a limb circumference which lies within each quartile of the limb circumference range;

2) at least 10 % of the subjects allocated to this CUFF shall have a limb circumference which lies within the highest octile of the limb circumference range;

3) at least 10 % of the subjects allocated to this CUFF shall have a limb circumference within the lowest octile of the limb circumference range;

4) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of 16 cm and more shall be tested on at least N_{cuff} subjects as calculated according to Formula (19); and

5) if *N*cuff, according to Formula (19) is less than 12 subjects, *N*cuff shall be a minimum of 12 subjects.

f) The CLINICAL INVESTIGATION REPORT shall provide the specified arm circumference range of each CUFF in centimetres (inches).

g) 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.

1) These plots should also indicate the arm circumference limits of each CUFF with vertical lines.

2) Data points from each CUFF should be indicated differently.

3) Plots shall be provided for both:

   i) SYSTOLIC BLOOD PRESSURE; and

   ii) DIASTOLIC BLOOD PRESSURE.

h) The CLINICAL INVESTIGATION REPORT shall include Bland-Altman plots showing all subject results, where the Y axis shows the difference between SPHYGMOMANOMETER-UNDER-TEST and REFERENCE BLOOD PRESSURE values and the X axis shows the average of the SPHYGMOMANOMETER-UNDER-TEST and REFERENCE BLOOD PRESSURE values.

1) Plots shall be provided for both:

   i) SYSTOLIC BLOOD PRESSURE; and

   ii) DIASTOLIC BLOOD PRESSURE.

Check conformance by inspection of the CLINICAL INVESTIGATION REPORT.

6.1.4

Replace the subclause with the following:

6.1.4 * Limb size distribution

a) To limit the overlap of all CUFFS intended for use with a SPHYGMOMANOMETER, Formula (17) shall apply.

b) If the distribution of CUFFS is not in accordance with Formula (17), multiple CLINICAL INVESTIGATIONS with subsets of these CUFFS shall be performed separately.

c) For CUFFS having a size of the limb circumference range (r_{cuff}) of 12 cm or less:

1) at least 40 % of the subjects allocated to this CUFF shall have a limb circumference which lies within the upper half of the specified range of use of the CUFF;

2) at least 40 % of the subjects allocated to this CUFF shall have a limb circumference within the lower half of the specified range of use of the CUFF;

3) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of 12 cm or less shall be tested on at least N_{cuff} subjects as calculated according to Formula (18); and

4) if *N*cuff, according to Formula (18) is less than 4 subjects, *N*cuff shall be a minimum of 4 subjects.

d) For CUFFS having a size of the limb circumference range (r_{cuff}) of more than 12 cm and less than or equal to 16 cm:

1) at least 20 % of the subjects allocated to this CUFF shall have a limb circumference which lies within each quartile of the limb circumference range;

2) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of more than 12 cm and less than or equal to 16 cm shall be tested on at least N_{cuff} subjects as calculated according to Formula (19); and

3) if *N*cuff, according to Formula (19) is less than 4 subjects, *N*cuff shall be a minimum of 4 subjects

e) For CUFFS having a size of the limb circumference range (r_{cuff}) of greater than 16 cm:

1) at least 20 % of the subjects allocated to this CUFF shall have a limb circumference which lies within each quartile of the limb circumference range;

2) at least 10 % of the subjects allocated to this CUFF shall have a limb circumference which lies within the highest octile of the limb circumference range;

3) at least 10 % of the subjects allocated to this CUFF shall have a limb circumference within the lowest octile of the limb circumference range; and

4) for a SPHYGMOMANOMETER intended for use with multiple CUFF sizes, each CUFF having a size of the limb circumference range of greater than 16 cm shall be tested on at least N_{cuff} subjects as calculated according to Formula (19); and

5) if *N*cuff, according to Formula (19) is less than 4 subjects, *N*cuff shall be a minimum of 4 subjects.

f) The CLINICAL INVESTIGATION REPORT shall provide the specified arm circumference range of each CUFF in centimetres (inches).

g) 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.

1) These plots should also indicate the arm circumference limits of each CUFF with vertical lines.

2) Data points from each CUFF should be indicated differently.

3) Plots shall be provided for both:

i) SYSTOLIC BLOOD PRESSURE; and

ii) DIASTOLIC BLOOD PRESSURE.

h) The CLINICAL INVESTIGATION REPORT shall include Bland-Altman plots showing all subject results, where the Y axis shows the difference between SPHYGMOMANOMETER-UNDER-TEST and REFERENCE BLOOD PRESSURE values and the X axis shows the average of the SPHYGMOMANOMETER-UNDER-TEST and REFERENCE BLOOD PRESSURE values.

1) Plots shall be provided for both:

i) SYSTOLIC BLOOD PRESSURE; and

ii) DIASTOLIC BLOOD PRESSURE.

Check conformance by inspection of the CLINICAL INVESTIGATION REPORT.