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AMENDMENT 2
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Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

AMENDMENT 2

Sphygmomanomètres non invasifs —

Partie 2: Investigation clinique pour type ponctuel à mesurage automatique

AMENDEMENT 2

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Non-invasive sphygmomanometers —

Part 2:
Clinical investigation of intermittent automated measurement type

AMENDMENT 2

Scope

Add the following as the last paragraph in the scope:

> This document is not applicable to CLINICAL INVESTIGATIONS of a set of CUFFS that are not of same materials and construction. Each type of CUFF set is required to be evaluated separately according to this document.

4.2

Add two additional list items after list item c) and before the compliance check:

d) All subjects shall be unique.

e) A subject shall only be used once in a clinical investigation.

5.1.4

Replace the subclause with the following:

5.1.4 * Limb size distribution

a) For a CLINICAL INVESTIGATION with only one CUFF, the requirements in 5.1.4 d) to i) apply based on the limb circumference range (r_{cuff}) of that CUFF.

b) For a CLINICAL INVESTIGATION with more than one CUFF to limit the overlap of all CUFFS intended for use with a SPHYGMOMANOMETER, Formula (17) shall apply.

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

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

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.

d) 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 12 subjects, N_{cuff} shall be a minimum of 12 subjects.

$$N_{cuff} = \frac{r_{cuff}}{2 \cdot r_{total}} \cdot N_{total} \quad (18)$$

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.

e) 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 12 subjects, N_{cuff} shall be a minimum of 12 subjects.

$$N_{cuff} = \frac{r_{cuff}}{2 \cdot r_{total}} \cdot N_{total} \cdot \frac{r_{cuff}}{12} \quad (19)$$

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.

f) 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.

g) The CLINICAL INVESTIGATION REPORT shall provide the specified arm circumference range of each CUFF in cm.

h) 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 using different colours or symbols.

3) Plots shall be provided for both:

i) SYSTOLIC BLOOD PRESSURE; and

ii) DIASTOLIC BLOOD PRESSURE.

i) 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.

6.1.1

Replace the list item b) with the following:

b) For each PATIENT, at least 5 but no more than 10 valid BLOOD PRESSURE MEASUREMENTS shall be taken.

6.1.4

Replace the subclause with the following:

6.1.4 * Limb size distribution

a) For a CLINICAL INVESTIGATION with only one CUFF, the requirements in 6.1.4 d) to i) apply based on the limb circumference range (r_{cuff}) of that CUFF.

b) For a CLINICAL INVESTIGATION with more than one CUFF to limit the overlap of all CUFFS intended for use with a SPHYGMOMANOMETER, Formula (17) shall apply.

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

d) 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.

e) 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

f) 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 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.

g) The CLINICAL INVESTIGATION REPORT shall provide the specified arm circumference range of each CUFF in cm.

h) 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 using different colours or symbols.

3) Plots shall be provided for the following:

i) SYSTOLIC BLOOD PRESSURE;

ii) DIASTOLIC BLOOD PRESSURE; and

iii) MAP, if the AUTOMATED SPHYGMOMANOMETER is so equipped.

i) 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 the following:

i) SYSTOLIC BLOOD PRESSURE;

ii) DIASTOLIC BLOOD PRESSURE; and