



International  
Standard

**ISO 81060-2**

**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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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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, 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

#### 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.

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#### 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 ( $r_{\text{cuff}}$ ) 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.

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

where

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

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

- d) For CUFFS having a size of the limb circumference range ( $r_{\text{cuff}}$ ) 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  $N_{\text{cuff}}$  subjects as calculated according to Formula (18); and
  - 4) if  $N_{\text{cuff}}$ , according to Formula (18) is less than 12 subjects,  $N_{\text{cuff}}$  shall be a minimum of 12 subjects.

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

where

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

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

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

- e) For CUFFS having a size of the limb circumference range ( $r_{\text{cuff}}$ ) 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  $N_{\text{cuff}}$  subjects as calculated according to Formula (19); and
- 3) if  $N_{\text{cuff}}$ , according to Formula (19) is less than 12 subjects,  $N_{\text{cuff}}$  shall be a minimum of 12 subjects.

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

where

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

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

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

- f) For CUFFS having a size of the limb circumference range ( $r_{\text{cuff}}$ ) 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  $N_{\text{cuff}}$  subjects as calculated according to Formula (19); and