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Non-invasive sphygmomanometers —

Part 1: Requirements and test methods for non-automated measurement type

Sphygmomanomètres non invasifs —

Partie 1: Exigences et méthodes d'essai pour type à mesurage non automatique

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 81060-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

The preparation of a second part covering clinical evaluation for the automated measurement type is planned.

For automated measurement type non-invasive sphygmomanometers, see IEC 60601-2-30 [7].

Introduction

The minimum safety requirements specified in this part of ISO 81060 are considered to provide a practical degree of safety in the operation of non-automated sphygmomanometers.

The requirements are followed by specifications for the relevant tests.

A “rationale and guidance” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex A.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this part of ISO 81060 but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex A does not form part of the requirements of this part of ISO 81060.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Non-invasive sphygmomanometers —

Part 1:
Requirements and test methods for non-automated measurement type

1 * Scope

This part of ISO 81060 specifies requirements for non-automated sphygmomanometers, as defined in 3.11, and their accessories, which, by means of inflatable cuffs, are used for the non-invasive blood pressure measurement by operator observation.

This part of ISO 81060 specifies requirements for the safety and essential performance, including effectiveness and labelling, for non-automated sphygmomanometers and their accessories, including test methods to determine the accuracy of non-invasive blood pressure measurement.

The part of ISO 81060 covers non-invasive blood pressure measurement devices with a pressure-sensing element and display used in conjunction with means of detecting blood flow.

EXAMPLE 1 A stethoscope for detecting Korotkoff sounds, Doppler ultrasound or other manual methods.

Requirements for non-invasive blood pressure measurement equipment with electrically-powered pressure sensing elements and/or displays used in conjunction with other automatic methods determining blood pressure are specified in IEC 60601-2-30 [7].

Requirements for invasive blood pressure measurement equipment that directly measure blood pressure are specified in document IEC 60601-2-34 [8].

EXAMPLE 2 Measuring equipment, including associated transducers, that is used for the invasive measurement of circulatory system pressures.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7010:2003, *Graphical symbols — Safety colours and safety signs — Safety signs used in workplaces and public areas*

ISO 10993-1[1)], *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex E.

3.1
accompanying document
document accompanying a **non-automated sphygmomanometer** or accessory and containing information for those accountable for the installation, use and maintenance of the **non-automated sphygmomanometer** or accessory, the **operator** or the **responsible organization**, particularly regarding safety

[Modified from ISO 14971:2007, definition 2.1]

3.2
bladder
that part of the **cuff** that is inflatable

3.3
blood pressure
pressure in the systemic arterial system of the body

3.4
clearly legible
capable of being read by a person with normal vision

[IEC 60601-1:2005, definition 3.15]

3.5
cuff
part of the **non-automated sphygmomanometer** that is wrapped around the limb of the **patient**

NOTE A cuff might comprise a bladder and an inelastic part that encloses the bladder, or have an integral bladder (i.e., the cuff including the bladder are fixed together or are one piece).

3.6
expected service life
maximum period of useful life as defined by the **manufacturer**

[IEC 60601-1:2005, definition 3.28]

1) To be published. (Revision of ISO 10993-1:2003)

3.7
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the **manufacturer**

NOTE Intended use should not be confused with normal use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but also maintenance, service, transport, etc.

[IEC 60601-1:2005, definition 3.44]

3.8
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging or labelling of **non-automated sphygmomanometers**, or adapting **non-automated sphygmomanometers**, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [2] defines “labelling” as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers

or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this part of ISO 81060, that material is described as markings and the accompanying document.

NOTE 2 “Adapting” includes making substantial modifications to a non-automated sphygmomanometer already in use.

NOTE 3 In some jurisdictions, the responsible organization can be considered a manufacturer when involved in the activities described.

[Modified from IEC 60601-1:2005, definition 3.55]

3.9
*** model or type reference**
combination of figures, letters or both used to identify a particular model of **non-automated sphygmomanometer** or accessory

[Modified from IEC 60601-1:2005, definition 3.66]

3.10
nominal
value quoted for reference purposes that is subject to agreed tolerances

[IEC 60601-1:2005, definition 3.69]

3.11
non-automated sphygmomanometer
instrument used for the non-invasive measurement of the **blood pressure** by utilizing an inflatable **cuff** with a pressure-sensing element, a valve for deflation, and a display used in conjunction with a stethoscope or other manual methods for estimating **blood pressure**

NOTE Components of these instruments include manometer, cuff, valve for deflation (often in combination with the valve for rapidly exhausting the pneumatic system), hand pump or electro-mechanical pump for inflation of the bladder, and connection hoses. A non-automated sphygmomanometer can also contain electro-mechanical components for pressure control.

3.12
non-invasive blood pressure measurement
indirect measurement of the **blood pressure** without arterial puncture

3.13
normal use
operation, including routine inspection and adjustments by any **operator**, and stand-by, according to the instructions for use

NOTE Normal use should not be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purpose, but maintenance, service, transport, etc., as well.

[IEC 60601-1:2005, definition 3.71]

3.14
operator
person handling equipment

[IEC 60601-1:2005, definition 3.73]

3.15
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

[IEC 60601-1:2005, definition 3.76]

3.16
pneumatic system
part of the **non-automated sphygmomanometer** that includes all pressurized and pressure-controlling components

EXAMPLES Cuff, tubing, connectors, valves, transducer and pump.

3.17
portable
term referring to transportable equipment intended to be moved from one location to another while being carried by one or more persons

[IEC 60601-1:2005, definition 3.85]

3.18
responsible organization
entity accountable for the use and maintenance of a **non-automated sphygmomanometer**

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the patient, operator and responsible organization can be one and the same person.

NOTE 2 Education and training is included in “use.”

[Modified from IEC 60601-1:2005, definition 3.101]

3.19
stationary
term referring to equipment that is not intended to be moved from one place to another

[IEC 60601-1:2005, definition 3.118]

3.20
type test
test on a representative sample of the **non-automated sphygmomanometer** with the objective of determining if the **non-automated sphygmomanometer**, as designed and manufactured, can meet the requirements of this document

[Modified from IEC 60601-1:2005, definition 3.135]

4 Identification and marking

4.1 * Units of measurement

The cuff pressure shall be indicated in either millimetres of mercury (mmHg) or kilopascals (kPa).

Check compliance by inspection.

4.2 * Legibility of markings

The markings required by 4.4, 4.6, and 4.7 shall be clearly legible under the following conditions:

a) for warning statements, instructive statements, safety signs and drawings on the outside of the non-automated sphygmomanometer, from the intended position of the person performing the related function;

b) for markings on the inside of the non-automated sphygmomanometer or non-automated sphygmomanometer parts, from the intended position of the person performing the related function.

Check compliance for a clearly legible marking by the following test.

1) Position the non-automated sphygmomanometer or its part so that the viewpoint is the intended position of the operator; or the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

2) Ensure that the ambient luminance is the least favourable level in the range of 100 lx to 1 500 lx.

3) Ensure that the observer has a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), corrected if necessary.

4) The observer correctly reads the marking from the viewpoint.

4.3 * Durability of markings

The markings required by 4.4 and 4.6 shall be removable only with a tool or by appreciable force and shall be sufficiently durable to remain clearly legible during the expected service life of the non-automated sphygmomanometer. In considering the durability of the markings, the effect of normal use shall be taken into account.

Check compliance by inspection and the following tests.

After all the other tests of this document have been performed:

a) markings are rubbed by hand, without undue pressure, first for 15 s with a cloth soaked with distilled water, then for 15 s with a cloth soaked with methylated spirits and then for 15 s with a cloth soaked with isopropyl alcohol.

b) legibility of markings are tested to the requirements of 4.2;

c) adhesive labels shall not have worked loose or become curled at the edges.

4.4 * Marking of non-automated sphygmomanometer

The non-automated sphygmomanometer, the cuff and/or their components shall be marked clearly and legibly with the following:

a) the name or trademark and address of the manufacturer;

b) model or type reference;

c) * where appropriate, an identification reference to the serial or batch number, or Symbol 5.16 or 5.14 from ISO 15223-1:2007;

d) the non-automated sphygmomanometer and its parts shall be marked with regard to proper disposal, as appropriate;

e) * the numbering on the scale or digital display shall not exceed the measurement range as determined in 7.1.2.

The following is additionally required for a non-automated sphygmomanometer containing a mercury manometer:

f) * safety sign for mandatory action “Refer to instruction manual/booklet” in accordance with M002 of ISO 7010:2003 and safety sign for warning “General warning” in accordance with W-001 of ISO 7010:2003;

g) an indication that the tube contains mercury.

Check compliance by inspection.

4.5 * Usability of reading

Means shall be provided to address legibility and parallax error of reading the scale of a non-automated sphygmomanometer in normal use by ensuring that there is an indication to the operator when the parallax error results in a reading error that exceeds ± 2 mmHg (0,3 kPa).

Check compliance by the tests of 4.2.

The observer reads the scale with an error of less than ± 2 mmHg (0,3 kPa) from the viewpoint.

4.6 Marking of the cuff

The cuff shall additionally be marked with the following information:

a) indication of the correct positioning for the cuff over the artery;

b) indication the limb circumference for which it is appropriate (see 7.2.4).

Check compliance by inspection.

4.7 Marking of the non-automated sphygmomanometer packaging

The packaging of a non-automated sphygmomanometer, the cuff or their components shall be marked with the following:

a) details to enable the responsible organization to identify the contents of the packaging;

b) for a sterile non-automated sphygmomanometer, cuff or component, the appropriate Symbol 5.20. 5.21, 5.22, 5.23 or 5.24 from ISO 15223-1:2007;

c) for a non-automated sphygmomanometer, cuff or component with an expiry date, Symbol 5.12 from ISO 15223-1:2007;

d) for a single use non-automated sphygmomanometer, cuff or component, the words “single use only” or “do not re-use” or Symbol 5.2 from ISO 15223-1:2007;

e) any special storage and/or handling instructions;

f) the intended use of the cuff.

Check compliance by inspection.

5 General requirements for testing non-automated sphygmomanometers

5.1 * Type tests

The tests described in this standard are type tests.

5.2 * Representative sample

Type tests are performed on a representative sample of the item being tested.

NOTE Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

5.3 Environmental conditions

General conditions of normal use shall include the following.

a) Unless otherwise specified in this part of ISO 81060, the non-automated sphygmomanometer complies with this part of ISO 8106 under the least favourable working conditions within the environmental temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing).

b) The non-automated sphygmomanometer is shielded from other influences (for example, draught), which might affect the validity of the tests.

5.4 Repairs and modifications

In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the non-automated sphygmomanometer for the test can agree, either upon the presentation of a new sample on which all tests influencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.

5.5 * Humidity preconditioning treatment

Prior to the tests described in Clause 7, the non-automated sphygmomanometer or its parts shall be subjected to a humidity preconditioning treatment.

Set up the complete non-automated sphygmomanometer or its parts. Detach covers used during transport and storage.

Perform the humidity preconditioning treatment in a humidity cabinet containing air with a relative humidity of 85 % ± 5 %. Maintain the temperature of the air in the cabinet, at all places where a non-automated sphygmomanometer can be located, within 2 °C of any convenient temperature, T, in the range of + 20 °C to + 32 °C. Before being placed in the humidity cabinet, bring the non-automated sphygmomanometer to a temperature between T and T + 4 °C, and maintain this temperature for at least 4 h before the humidity treatment.

Keep the non-automated sphygmomanometer and its parts in the humidity cabinet for 48 h.