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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 % $\pm$ 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.

Where the risk management process suggests that the non-automated sphygmomanometer can be exposed to high humidity for extended periods (such as a non-automated sphygmomanometer intended for outdoor use), extend the period appropriately.

After the treatment, re-assemble the non-automated sphygmomanometer, if necessary.

6 General requirements

6.1 General

Equipment or parts thereof using materials or having forms of construction different from those detailed in this part of ISO 81060, shall be accepted as equivalent if it can be demonstrated that an equivalent degree of safety and performance is obtained.

Planning and design of products applying this part of ISO 81060 should consider the environmental impact from the product during its life cycle. See also Annex B. Environmental aspects are addressed in Annex C.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

Check compliance by inspection of the risk management file.

6.2 Electrical safety

Non-automated sphygmomanometers that utilize electrical power shall meet the applicable requirements in IEC 60601-1, in addition to the requirements in this part of ISO 81060.

Check compliance by application of the tests of IEC 60601-1.

6.3 Mechanical safety

Rough surfaces, sharp corners and edges that can cause injury or damage shall be avoided or covered. Particular attention shall be paid to flange or frame edges and the removal of burrs.

Check compliance by inspection.

6.4 Mechanical strength

6.4.1 * Non-automated sphygmomanometers

Non-automated sphygmomanometers or their parts shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling. Stationary non-automated sphygmomanometers are exempt from the requirements of this subclause.

The non-automated sphygmomanometer shall function normally following a free fall from a distance, d, of 25 cm.

A non-automated sphygmomanometer that is marked “Shock Resistant” shall function normally following a free fall from a distance, d, of 1 m.

Check compliance by the following test.

Allow the non-automated sphygmomanometer to fall freely six times (once on each side) from a height = d on to a 50 mm $\pm$ 5 mm thick hardwood (hardwood density $>$ 600 kg/m^3) board lying flat on a concrete or a similar rigid base.

After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1.

6.4.2 * Non-automated sphygmomanometers for transport

Non-automated sphygmomanometers or their parts, intended for use during patient transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling.

After the following tests, the non-automated sphygmomanometer shall function normally.

a) Shock (according to IEC 60068-2-27):

- peak acceleration: 1 000 m/s^2 (102 g);
- duration: 6 ms;
- pulse shape: half sine;
- number of shocks: 3 shocks per direction per axis (18 in total).

b) Broad-band random vibration (according to IEC 60068-2-64):

- frequency range: 10 Hz to 2 000 Hz;
- resolution: 10 Hz;
- acceleration amplitude:
  - 10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$;
  - 100 Hz to 200 Hz: – 7 db/octave;
  - 200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$;
- duration: 30 min per each perpendicular axis (3 in total).

After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1.

6.4.3 * Non-automated sphygmomanometers containing a mercury manometer

A non-automated sphygmomanometer containing a mercury manometer shall not leak mercury following a free fall from a distance, d, of 1 m under conditions of normal use.

Check compliance by the following test.

Allow the non-automated sphygmomanometer to fall freely six times (once on each side) from a height = d on to a 50 mm ± 5 mm thick hardwood (hardwood density > 600 kg/m^3) board lying flat on a concrete or a similar rigid base. Care should be taken while testing to ensure that there is no escape of mercury into the environment should the non-automated sphygmomanometer under test fail.

After the test, visually inspect to check that there is no leakage of mercury from the manometer of the non-automated sphygmomanometer.

After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1.

7 Requirements

7.1 Pressure indicating means

7.1.1 * Limits of the error of the cuff pressure indication

Over the temperature range of 15 °C to 25 °C and the relative humidity range of 15 % to 85 % (non-condensing), for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to ± 3 mmHg (± 0,4 kPa).

Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing), for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to ± 3 mmHg (± 0,4 kPa) or 2 % whichever is greater.

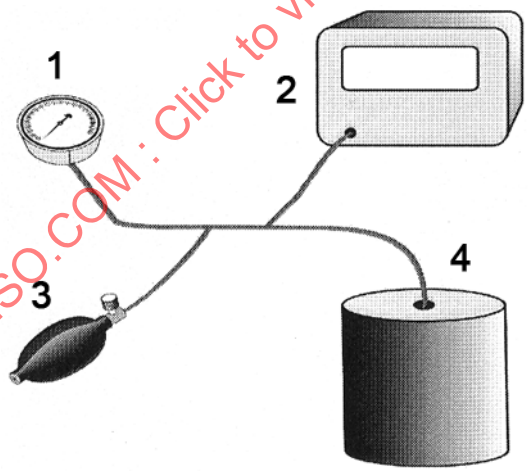
Check compliance by means of the following test.

a) Replace the cuff of the non-automated sphygmomanometer with a vessel (see Figure 1).

   Connect the calibrated reference manometer to the pneumatic system by means of a T-piece connector and hoses. After disabling the electromechanical pump (if fitted), connect the additional pressure generator to the pneumatic system by means of another T-piece connector.

b) Perform the test in pressure steps of not more than 50 mmHg between 0 mmHg and the maximum pressure on the scale.

c) Express the results as the difference between the indicated pressure of the non-automated sphygmomanometer being tested and the corresponding reading of the reference manometer.



Key

1 calibrated reference manometer with a maximum error of 0,8 mmHg (0,1 kPa)
2 non-automated sphygmomanometer to be tested
3 rigid metal vessel with a capacity of 500 ml ± 5 %
4 pressure generator

EXAMPLE Ball pump (hand pump) with a deflation valve.

Figure 1 — Test set-up for determining the limits of error of the cuff pressure indication

7.1.2 * Nominal range and measuring range

The nominal range for the cuff pressure measurement shall be disclosed in the accompanying document [see 12.2.1 l)]. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of cuff pressure measurement outside the nominal range of cuff pressure shall be clearly indicated as out of range.

For a non-automated sphygmomanometer, the nominal range for the cuff gauge pressure shall extend from 0 mmHg (0 kPa) to at least 260 mmHg (35 kPa).

Check compliance by inspection.

7.2 Pneumatic system

7.2.1 * Air leakage

Air leakage shall not cause a pressure drop that exceeds 4 mmHg/min (0,5 kPa/min).

Check compliance by means of the following test. (If, because of technical reasons, this test cannot be performed, use an alternative test procedure specified by the manufacturer.)

a) Use the following apparatus:

   1) rigid metal cylinder;

   2) pressure generator;

EXAMPLE Ball pump (hand pump) with deflation valve.

   3) time-measuring device.

EXAMPLE Stopwatch.

b) Wrap the cuff around a cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference cylinder by (7 ± 2) %.

NOTE 1 Electro-mechanical pumps that are a part of the system can be used for this test. Valves that are permanently opened can be disconnected for this test.

NOTE 2 For this test no calibrated reference manometer is required because the cuff pressure display of the non-automated sphygmomanometer under test can be used when the error of the cuff pressure indication is taken into account. The advantage of this test is that the non-automated sphygmomanometer under test is in its original configuration. Additional connections can increase the leakage.

c) Because decreasing or increasing the pressure when changing to the next pressure step influences the thermodynamic equilibrium, wait at least 60 s before reading the values. Perform the measurement at least five pressure steps (e.g. 50 mmHg (7 kPa), 100 mmHg (14 kPa), 150 mmHg (20 kPa), 200 mmHg (27 kPa) and 250 mmHg (33 kPa)) over the whole measuring range. Test the air leakage over a period of 5 min, and determine the measured value from this. If the air leakage results in a pressure drop significantly different than 4 mmHg/min (0,5 kPa/min), the test period of 5 min can be reduced.

d) Express the air leakage as the pressure reduction per minute.

7.2.2 * Pressure reduction rate

Manually-operated and self-linearizing deflation valves shall be capable of adjustment to a deflation rate of 2 mmHg/s (0,3 kPa/s) to 3 mmHg/s (0,4 kPa/s). Deflation valves that control the deflation rate per pulse shall be capable of adjustment to a deflation rate of 2 mmHg/pulse (0,3 kPa/pulse) to 3 mmHg/pulse (0,4 kPa/pulse).

Check compliance of manually-operated deflation valves by functional testing. Check compliance of self-linearizing valves by means of the following test.

a) Use the following apparatus:

   1) T-piece;

   2) calibrated reference manometer with signal output port and an error less than 0,8 mmHg (0,1 kPa);

   3) human subjects;

   4) recording unit.

b) Select a subject whose limb size is approximately equal to the upper limit of limb circumferences for the cuff.

c) Connect the calibrated reference manometer to the cuff by means of a T-piece.

d) Connect the output port of the calibrated reference manometer to the recording unit.

e) Apply the cuff to the subject according to the accompanying document for the cuff.

f) Inflate the cuff to at least 200 mmHg (27 kPa).

g) Adjust the rate of deflation accordingly.

h) Remove the cuff.

i) Repeat steps e) to h) nine times.

j) Select a subject whose limb size is approximately equal to the lower limit of limb circumferences for the cuff.

k) Repeat steps e) to i).

l) Determine the rate of the pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure of 60 mmHg (8 kPa), 120 mmHg (16 kPa) and 180 mmHg (24 kPa). Calculate the pressure reduction rate as the mean value calculated separately for the pressures of 60 mmHg (8 kPa), 120 mmHg (16 kPa) and 180 mmHg (24 kPa) and for the various limb circumferences. If the pressure reduction rates are dependent on the pulse rate, record the pulse rate. In this case, express the result as pressure reduction per pulse.

7.2.3 * Rapid exhaust

During the rapid exhaust of the pneumatic system with the deflation valve fully open, the time for the pressure reduction from 260 mmHg (35 kPa) to 15 mmHg (2 kPa) shall not exceed 10 s.

Check compliance by means of the following test.

a) Use the following apparatus:

   1) rigid metal vessel, with a volume of 500 ml ± 5 %;

   2) calibrated reference manometer, with an error less than 0,8 mmHg (0,1 kPa);

   3) T-piece connector;

   4) time-measuring device.

EXAMPLE Stopwatch.

b) Perform the test with the metal vessel in place of the cuff.

c) Connect the calibrated reference manometer by means of a T-piece to the pneumatic system.

d) Inflate to the maximum pressure and open the valve for rapidly exhausting the pneumatic system.

e) Measure the time between 260 mmHg (35 kPa) to 15 mmHg (2 kPa) using the time-measuring device.

f) Ensure that the time is less than or equal to 10 s.

7.2.4 Cuff

The bladder length should be approximately 0,80 × the circumference of the limb at the midpoint of the intended range of the cuff. The width of the bladder should be at least 0,40 × the circumference of the limb at the midpoint of the intended range of the cuff.

NOTE These recommended dimensions are subject to ongoing consideration.

7.2.5 Cuff and bladder

The cuff and bladder and integral tubing shall maintain their integrity and be capable of withstanding an internal pressure equal to the maximum pressure intended for the cuff in normal use. For cuffs with removable bladder, the bladder shall be completely retained in the cuff during pressurization to the maximum pressure intended for the cuff in normal use.

Check compliance by means of the following test. (If, because of technical reasons, this test cannot be performed, use an alternative test procedure specified by the manufacturer.)

a) Use the following apparatus:

1) rigid metal cylinder;

2) pressure generator;

EXAMPLE Ball pump (hand pump) with deflation valve.

3) time-measuring device.

EXAMPLE Stopwatch.

b) Wrap the cuff around a cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference of the cylinder by (7 ± 2) %.

NOTE 1 Electro-mechanical pumps that are a part of the system can be used for this test. Valves that are permanently opened can be disconnected for this test.

NOTE 2 For this test, no calibrated reference manometer is required because the cuff pressure display of the non-automated sphygmomanometer under test can be used when the error of the cuff pressure indication is taken into account. The advantage of this test is that the non-automated sphygmomanometer under test is in its original configuration. Additional connections can increase the leakage.

c) Pump the cuff pressure to the maximum pressure as stated in the accompanying document for its use or the maximum indication on the non-automated sphygmomanometer, whichever is greater.

d) Hold the pressure for 5 min.

e) During these 5 min, ensure that the cuff does not open and the bladder does not creep out of the cuff.

7.2.6 * Tubing connectors

Tubing connectors, if provided, shall incorporate a means of preventing accidental disconnection. Tubing connectors shall not be equipped with a connector that connects with a connector complying with ISO 594-1 or ISO 594-2.

Check compliance by inspection.

7.3 * Tamper proofing or unauthorized access

Means shall be provided to prevent tampering or unauthorized access:

— for all non-automated sphygmomanometers, any adjustment or function that affects accuracy;

— for mercury non-automated sphygmomanometers, the separation of reservoir and scale.

EXAMPLE Requiring a tool for opening or seal breakage.

It shall be clear to an operator if tampering or unauthorized access has occurred.

Check compliance by inspection.

7.4 Dynamic response in normal use

The delay in the settling of the cuff pressure indication shall not exceed 1,5 s for the change in indication from 200 mmHg to 50 mmHg or from 25 kPa to 5 kPa when the pressure in the system drops from 200 mmHg to 0 mmHg or from 25 kPa to 0 kPa.

Check compliance with the following test.

a) Use the following apparatus:

   1) time-measuring device;

EXAMPLE Stopwatch.

   2) pressure generator.

EXAMPLE Ball pump (hand pump), with deflation valve.

b) Connect the pressure generator directly (without a cuff) to the hose leading to the manometer of the non-automated sphygmomanometer.

c) When a gauge pressure of more than 200 mmHg or 25 kPa has been reached, occlude the tube and remove the pressure generator.

d) After removing the occlusion from the tube, measure the time between the change in indication from 200 mmHg to 50 mmHg or 25 kPa to 5 kPa.

e) Check that the time does not exceed 1,5 s.

8 Additional requirements for non-automated sphygmomanometer with mercury manometer

8.1 * Internal diameter of the tube containing mercury

The nominal internal diameter of the tube containing mercury shall be at least 3,9 mm. The tolerance on the diameter shall not exceed ± 0,2 mm. See also 12.2.1 q).

Check compliance by means of the following test.

a) Use limit plug gauges or similar devices, with a tolerance of less than 0,05 mm.

b) Check the nominal internal diameter of the tube at each end using the limit plug gauge.

8.2 * Portable non-automated sphygmomanometer

A portable non-automated sphygmomanometer shall be provided with an adjusting or locking mechanism to secure it in the position for use as indicated in the accompanying document.

Check compliance by inspection.

8.3 * Prevention of mercury spillage during transport

To prevent the spillage of mercury during transport, a means shall be provided of keeping the mercury in its reservoir.

Check compliance by inspection.

8.4 * Prevention of mercury spillage in normal use

A mercury gravity **non-automated sphygmomanometer** shall incorporate a means (stopping device) at the top of the tube that both permits the inward and outward flow of air and prevents the passage of liquid mercury. The reservoir itself shall be fitted with a means (stopping device) to prevent mercury from flowing out of the reservoir neck and into the attached tubing and permits the inward and outward flow of air.

Check compliance by means of the following test.

a) Use the following apparatus:

   1) collecting vessel of adequate size to contain the non-automated sphygmomanometer under test;

   2) calibrated reference manometer, with an error of less than 0,8 mmHg (0,1 kPa);

   3) T-piece connector;

   4) pressure generator.

EXAMPLE Ball pump (hand pump) with a deflation valve.

b) Place the non-automated sphygmomanometer to be tested in the collecting vessel.

c) Connect the pressure generator and a T-piece connector attached to a calibrated reference manometer directly to the hose leading to the mercury reservoir.

d) Use the pressure generator to raise the pressure in the non-automated sphygmomanometer to 100 mmHg (13,3 kPa) greater than the maximum scale reading on the test manometer.

e) Maintain this pressure for 5 s and then release the pressure in the system.

f) Check that no mercury has been spilt.

8.5 Quality of the mercury

The mercury shall have a purity of not less than 99,99 %.

Check compliance by testing or by inspection of the declaration of the supplier of the mercury.

9 Non-automated sphygmomanometers with aneroid manometer

9.1 * Scale mark at zero

If a tolerance zone is shown at zero, it shall not exceed ± 3 mmHg (± 0,4 kPa) and shall be clearly indicated. Graduations within the tolerance zone may be used.

Check compliance by inspection.

9.2 * Zero

The movement of the elastic sensing element, including the pointer, shall not be obstructed within 6 mmHg (0,8 kPa) below zero.

Neither the dial nor the pointer shall be adjustable by the operator.

Check compliance by inspection.

9.3 Hysteresis error

The hysteresis error throughout the pressure range shall not exceed 4 mmHg (0,5 kPa).

Check compliance by means of the following test.

a) Use the following apparatus:

   1) rigid metal vessel, with a capacity of 500 ml ± 5 %;

   2) calibrated reference manometer, with an error less than 0,8 mmHg (0,1 kPa);

   3) pressure generator;

EXAMPLE Ball pump (hand pump) with a deflation valve.

   4) T-piece connectors.

b) Replace the cuff with the rigid metal vessel.

c) Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system.

d) After disabling the electro-mechanical pump (if fitted) connect the additional pressure generator to the pneumatic system by means of another T-piece connector.

e) Test the non-automated sphygmomanometer with increasing pressure steps of not more than 50 mmHg or 7 kPa to the scale maximum; hold the pressure for 5 min and then decrease it by the same steps.

f) Do not tap on the manometer housing to reduce the friction to move the pointer.

g) Disconnect the calibrated reference manometer during the 5 min at maximum pressure.

h) Express the results as the difference between the indicated values on the non-automated sphygmomanometer at the same test pressure steps when decreasing the pressure and when increasing the pressure.

9.4 * Construction and materials

The construction of the **non-automated sphygmomanometer** and the material for the elastic sensing elements shall ensure adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature.

The difference in the pressure indication of the **non-automated sphygmomanometer** before and after 10 000 full-scale cycles (where a full-scale cycle is a pressure change from 20 mmHg or less to full scale, and then back to 20 mmHg or less) shall be not more than 3 mmHg (0,4 kPa) throughout the pressure range.

Check compliance by means of the following test.

a) Use the following apparatus:

   1) alternating pressure generator, which generates a sinusoidal pressure variation below 20 mmHg (3 kPa) and above 220 mmHg (30 kPa) at a maximum rate of 1 Hz.

b) Start the procedure specified in 7.1.1.

c) Connect the non-automated sphygmomanometer directly to the alternating pressure generator and perform 10 000 alternating pressure cycles.

d) One hour after the stress test, perform the procedure as specified in 7.1.1 at the same pressure levels as before the stress test.

e) Express the results as differences between the indicated values on the reference manometer and non-automated sphygmomanometer at the same test pressure steps before and after the stress test.

10 Cleaning, sterilization and disinfection

10.1 Reusable non-automated sphygmomanometer and parts

All components specified for re-use in the accompanying documents, and which come into contact with the patient shall be capable of being either cleaned and disinfected or cleaned and sterilized.

Check compliance by a review of the accompanying documents for methods of cleaning and disinfection or cleaning and sterilization (see 12.2.2) and by inspection of the relevant validation reports.

10.2 Non-automated sphygmomanometer and parts requiring processing before use

All components specified in the accompanying documents to be cleaned and disinfected or cleaned and sterilized before use and which come into contact with the patient shall be capable of being cleaned and disinfected or cleaned and sterilized.

Check compliance by a review of the accompanying documents for methods of cleaning and disinfection or cleaning and sterilization (see 12.2.2) and by inspection of the relevant validation reports.

10.3 Non-automated sphygmomanometer and parts delivered sterile

Non-automated sphygmomanometers or accessories labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Check compliance by inspection of the relevant validation reports.

11 Biocompatibility

Non-automated sphygmomanometers and parts thereof intended to come into contact with biological tissues, cells, body fluids, or breathing gases shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Check compliance by inspection of the relevant validation reports.

12 Information supplied by the manufacturer

12.1 Accompanying document

The non-automated sphygmomanometer and accessories shall have accompanying document(s) containing at least the instructions for use and a technical description. The accompanying document shall be regarded as a part of the non-automated sphygmomanometer.

NOTE The purpose of the accompanying document is to promote the safe use of the non-automated sphygmomanometer during its expected service life.

The accompanying document shall identify the non-automated sphygmomanometer by including, as applicable, the following:

— name or trade-name of the manufacturer, and an address to which the responsible organization can refer;

— model or type reference.

The accompanying document shall specify any special skills, training and knowledge required of the intended operator or the responsible organization and any restrictions on locations or environments in which the non-automated sphygmomanometer can be used.

The accompanying document(s) shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Check compliance by inspection.

12.2 Instructions for use

12.2.1 General

The instructions for use shall include:

a) the intended use of the non-automated sphygmomanometer, in particular:

— intended medical indication;

EXAMPLE 1 Conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

— any known restrictions on use or contra-indication(s) to the use of the non-automated sphygmomanometer;

— intended patient population;

EXAMPLE 2 Age, weight, health, condition.

— intended part of the body or type of tissue applied to or interacted with;

— intended conditions of use;

EXAMPLE 3 Environment including hygienic requirements, frequency of use, location, mobility.

b) a brief description of the non-automated sphygmomanometer, including its significant physical and performance characteristics;

c) all information necessary to operate the non-automated sphygmomanometer in accordance with its specification;

EXAMPLE Explanations of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and accessories, and replacement of material that is consumed during operation.

d) how the non-automated sphygmomanometer functions;

e) an explanation of the selection of a suitable cuff size and application to the patient;

f) an explanation of operating steps of the non-automated sphygmomanometer including:

— adjustment of the pressure reduction rate;

— patient position in normal use (see Bibliography [18]), including:

— comfortably seated,

— legs uncrossed,

— back and arm supported,

— middle of cuff on the upper arm at the level of the right atrium,

— a recommendation that the patient relax as much as possible and not talk or move during the measurement procedure,

— a recommendation that 5 min should elapse before the first reading is taken;

— operator position in normal use;

— a recommendation for the use of K5 in auscultation of adults;

NOTE 1 K5 is the point at which the Korotkoff sounds can no longer be heard.

— * a recommendation for the use of K4 in auscultation of children aged 3 to 12.

NOTE 2 K4 is the change in the tones heard through a stethoscope from a clear tapping sound to a muffled sound.

— * a recommendation for the use of K5 in auscultation of pregnant female patients, unless sounds are audible with the cuff deflated, in which case K4 should be used (see Bibliography [18]);

g) the information required in 4.4;

h) a description of all markings on the non-automated sphygmomanometer;

EXAMPLE Figures, symbols, warning statements, abbreviations and indicator lights.

i) for cuffs, the information required in 4.6;

j) * the nature and frequency of the maintenance needed to ensure that the non-automated sphygmomanometer operates accurately and safely at all times;

k) if installation of the non-automated sphygmomanometer or its parts is required, a reference to where the installation instructions are to be found (e.g. the technical description);

l) the nominal range of cuff pressure measurement (see 7.1.2);

m) a statement, if applicable, that the performance of the non-automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude;

n) for non-automated sphygmomanometers intended for use in environmental conditions beyond those specified in this part of ISO 81060, the limits of the error of the cuff pressure indication over those environmental conditions;

o) if the non-automated sphygmomanometer is intended to be dismantled by the operator, the correct method of reassembly;

p) recommended storage conditions.

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

q) internal nominal diameter and tolerance of the tube containing mercury;

r) detailed instructions for the safe handling of mercury (see Annex B);

s) for portable non-automated sphygmomanometers, a caution regarding the necessity to maintain the verticality of the mercury column to perform a valid measurement;

t) information concerning the disposal of the non-automated sphygmomanometer or components thereof.

NOTE The instructions for use are intended for the operator and the responsible organization and should contain only the information most likely to be useful to the operator or responsible organization. Additional details can be contained in the technical description. See also 12.3.

The instructions for use shall be in a language that is acceptable to the intended operator.

12.2.2 Cleaning, disinfection and sterilization

For non-automated sphygmomanometer parts or accessories that can become contaminated through contact with the patient or with body fluids or expired gases during normal use, the instructions for use shall contain:

a) the details about cleaning and disinfection or cleaning and sterilization methods that may be used;

b) a list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such non-automated sphygmomanometer parts or accessories can tolerate.

See also 10.1 and 10.2.

This requirement does not apply to any material, component, accessory or non-automated sphygmomanometer that is marked as intended for single use, unless the manufacturer specifies that the material, component, accessory or non-automated sphygmomanometer is to be cleaned and disinfected or cleaned and sterilized before use (see 10.2).

12.2.3 Maintenance

The instructions for use shall inform the operator or responsible organization that the reference manometer used for calibration should be traceable against international or national measurement standards.

The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the non-automated sphygmomanometer.

Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the recommended frequency to be applied, but not necessarily including details about the actual performance of such maintenance.

For non-automated sphygmomanometers containing rechargeable batteries that are intended to be maintained by anyone other than service personnel, the instructions for use shall contain instructions to ensure adequate maintenance.

12.2.4 Accessories, supplementary equipment, used material

The instructions for use shall include a list of accessories, detachable parts and materials that the manufacturer has indicated are intended for use with the non-automated sphygmomanometer.

12.2.5 Environmental protection

The instructions for use shall:

a) identify any risks associated with the disposal of waste products, residues, etc., and of the non-automated sphygmomanometer and accessories at the end of their expected service life;

b) provide advice on minimizing these risks;

c) provide a caution to comply with regional law when non-automated sphygmomanometer or accessory is discarded;

d) provide a warning to comply with regional law when a mercury sphygmomanometer is discarded.

12.2.6 Reference to the technical description

The instructions for use shall contain the information specified in 12.3 or a reference to where the material specified in 12.3 is to be found (e.g. in a service manual).

Compliance with the requirements of 12.2 is checked by inspection of the instructions for use in the language of an intended operator.

12.3 Technical description

The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the non-automated sphygmomanometer, and preparing it for use.

This shall include:

a) the permissible environmental conditions of use including conditions for transport and storage;

b) all characteristics of the non-automated sphygmomanometer, including range(s) and accuracy of the displayed values or an indication where they can be found;

c) any correction factors to be applied for changes in ambient conditions;

d) a warning statement that addresses the hazards that can result from unauthorized modification of the non-automated sphygmomanometer, e.g. a statement to the effect:

— "WARNING: No modification of this equipment is allowed."

— "WARNING: Do not modify this equipment without authorization of the manufacturer."

— "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure its continued safe use."

If the technical description is separable from the instructions for use, it shall contain:

e) the information required in 4.4;

f) for cuffs, the information required in 4.6;

g) a brief description of the non-automated sphygmomanometer, how the non-automated sphygmomanometer functions and its significant physical and performance characteristics;

h) instructions for correct replacement of interchangeable or detachable parts that the manufacturer specifies as replaceable by service personnel;

i) for a non-automated sphygmomanometer containing a mercury manometer:

— the nominal internal diameter and tolerance of the tube containing mercury (see 8.1),

— the material of the tube containing mercury;

j) where replacement of a component could result in an unacceptable risk, appropriate warnings that identify the nature of the hazard and, if the manufacturer specifies the component as replaceable by service personnel, all information necessary to safely replace the component;

k) a statement that the manufacturer will make available on request, circuit diagrams, component part lists, descriptions, calibration instructions or other information that will assist service personnel to repair those parts of the non-automated sphygmomanometer that are designated by the manufacturer as repairable by service personnel;

l) instructions for the operator or responsible organization in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.

NOTE 1 The technical description is intended for the responsible organization and service personnel.

The manufacturer may designate the minimum qualifications for service personnel. If present, these requirements shall be documented in the technical description.

NOTE 2 Some authorities with jurisdiction impose additional requirements for qualification of service personnel.

Compliance with the requirements of 12.3 is checked by inspection of the technical description.

Annex A
(informative)

Rationale and guidance

General

This annex provides a rationale for some requirements of this part of ISO 81060 and is intended for those who are familiar with the subject of this part of ISO 81060 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this part of ISO 81060. The numbering is, therefore, not consecutive.

Clause 1 Scope

Because the significance of blood pressure measurement with non-automated sphygmomanometers has been recognised and the number of professional operators is growing rapidly, care should be taken to ensure that the available non-automated sphygmomanometers are as safe and accurate as possible. Blood pressure is routinely measured by either automated sphygmomanometers or non-automated sphygmomanometers.

Many sphygmomanometers are purchased by individuals on the advice of their physicians or in response to mass advertising. In addition, individuals can use automated equipment in pharmacies and other retail stores. Blood pressure measurement in the home and in similar unsupervised settings gives the consumer the responsibility of interpreting results and deciding whether further action (i.e. seeing a physician) is necessary. The effectiveness of this unsupervised screening and interpretation in the detection of hypertension depends on the accuracy and reproducibility of the particular sphygmomanometer and rests on the assumption that the consumer has adequate information to operate the sphygmomanometer correctly and that the sphygmomanometer is safe for unsupervised use. Non-automated sphygmomanometers are not generally acceptable for these unsupervised uses because a non-automated sphygmomanometer requires extensive training for proper operation.

Subclause 3.9 Model or type reference

The model or type reference is intended to establish the relationship of the non-automated sphygmomanometer to commercial and technical publications, to accompanying documents, and that between separable parts of the non-automated sphygmomanometer. It is also important for identifying a non-automated sphygmomanometer or accessories in case of a safety alert or other required corrective action.

Subclause 4.1 Units of measurement

Parallel or dual scales of mmHg and kPa are not acceptable as this represents a potential source of reading error. The numbering of the two scales is relatively close if the factor of 10 is disregarded (see Figure A.1). In critical, stressful situations a correct reading cannot be guaranteed, e.g. a reading for the systolic blood pressure of 150 mmHg (20 kPa) will be recorded as 200 mmHg. Single scales require less concentration than dual scales to ensure correct readings.

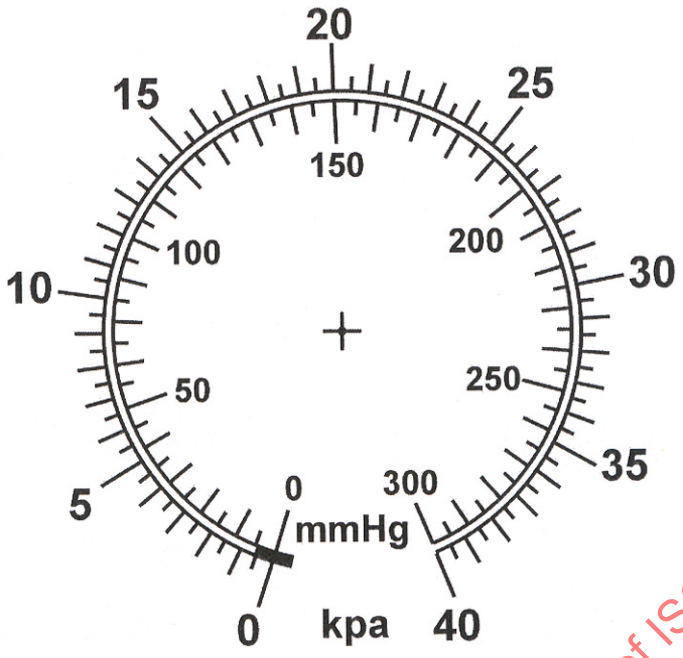


Figure A.1 — Example of a dual scale units of measure

Subclause 4.2 Legibility of markings

Markings on non-automated sphygmomanometers, cuffs or their components are expected to be clearly legible by an operator over the range of normal illumination levels where the non-automated sphygmomanometer is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design (see Bibliography [18]:

— 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;

— 500 lx to 1 000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;

— 1 000 lx to 2 000 lx is recommended for visual tasks of low contrast or very small size: e.g. reading handwriting in hard-pencil on poor-quality paper.

If markings are not legible to the operator under the expected conditions of use, there would be an unacceptable risk.

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are express as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. log MAR = log(6/6) = 0 for normal vision.

Subclause 4.3 Durability of markings

The rubbing test is performed with distilled water, methylated spirits and isopropyl alcohol. Methylated spirits or ethanol 96 % is defined in the European Pharmacopoeia as a reagent in the following terms: C_2H_6O (MW46.07). Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C_3H_8O (MW60.1).

Subclause 4.4 Marking of non-automated sphygmomanometer

c)

Although the non-automated sphygmomanometers should have a serial number, the cuffs can have a batch number instead because they are manufactured in lots.

e)

The numbering of the scale cannot exceed the measurement range because the operator needs to have confidence in the reading. If the numbering exceeds the measurement range, it can lead to confusion. When all displayed values or possible readings on the scale are within the specified limits of error, there should be no doubt about the accuracy of any reading.

f)

Two safety signs are required because of the hazards associated with mercury. It is a "mandatory action" for operators to read the instructions for use so that they are aware of chemical hazards associated with mercury. In addition, the general warning informs the operator that a hazard is present.

Subclause 4.5 Usability of reading

Operators need to be able to reliably, repeatably and accurately read the scale of a non-automated sphygmomanometer. Since the operator is interpreting the changing indication of the manometer to determine the patient's blood pressure, it is vital that the non-automated sphygmomanometer provide adequate control of the rate of pressure reduction in combination with the reading the scale. Errors caused by parallax or illegible scales can cause measurement error. Manufacturers should consider performing this test as a usability test and not just relying on a single observer.

Subclause 5.1 Type tests

In order to ensure that all non-automated sphygmomanometers conform to this part of ISO 81060, the manufacturer or installer should take measures during manufacture, installation and assembly to ensure that each item satisfies all requirements, even if they are not completely tested individually during manufacture, installation or assembly.

Such measures could take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety or performance;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests need not be identical with type tests, but can be adapted to manufacturing conditions.

Production tests would, of course, be restricted to conditions (possibly derived from type tests) that would simulate the worst-case situation.

Subclause 5.2 Representative sample

The type test sample or samples need to be representative of the units intended for the responsible organization.

Subclause 5.5 Humidity preconditioning treatment

To prevent condensation when the non-automated sphygmomanometer is placed in the humidity cabinet, the temperature of such a cabinet should be equal to or slightly lower than the temperature of the non-automated sphygmomanometer when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of + 20 °C to + 32 °C and then “stabilized” at the initial value. Although the effect of the cabinet temperature on the absorption of humidity is recognised, it was felt that the reproducibility of test results would not be substantially impaired and the cost-reducing effect would be considerable.

Subclause 6.4.1 Non-automated sphygmomanometers

Non-automated sphygmomanometers in normal use will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, a non-automated sphygmomanometer needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in normal use.

These tests were chosen by first reviewing the results of the work published in other patient monitoring standards where those committees (see Bibliography [1] [3]) qualitatively assessed the relative severity of the scenarios within various environments, home, healthcare facilities and transport (wings and wheels), by various sizes and types of equipment (i.e. hand-held, portable and mobile).

After that qualitative assessment, those committees assessed the relevant particular standards for environmental testing in the IEC 60068 series[6] and their respective rationales, as well as the IEC 60721 series[9] of guidance documents. In selecting the requirements, those committees reviewed other sources for material related to these tests (e.g. FDA Reviewers Guidance for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with the standard IEC 60721-3-7[11]. There is also a guidance document, IEC/TR 60721-4-7[12], that helps to correlate environmental condition classes of IEC 60721-3-7 to environmental tests according the IEC 60068 series. The aforementioned standards specify three classes of mechanical conditions, 7M1, 7M2 and 7M3. Those committees found the classes 7M1 and 7M3 to best represent the conditions seen during patient transport within healthcare facilities and patient transport outside healthcare facilities, respectively. Those committees agreed different tests and test levels should be applied to instruments intended for use in a healthcare facility than instruments intended for use during patient transport outside the healthcare facility.

Verifying that the instrument is functioning within the manufacturer's specifications while the vibration (random and sinusoidal) tests are being conducted is not believed necessary. This line of thought was considered and it was decided that the test done in this manner would be overly burdensome and would only add a minimum additional level of safety that would not justify the costs. Verifying proper functioning after completion of the tests was believed adequate.

Subclause 6.4.2 Non-automated sphygmomanometers for transport

Non-automated sphygmomanometers in normal use, used for patient transport outside a healthcare facility, will be subjected to mechanical stresses (e.g. vibration, shock, bump and drop) and could randomly be subjected to additional stresses. Therefore, instruments intended to be used for patient transport outside a healthcare facility need to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high level shocks. Rough handling and transfer of instruments is expected in these environments.

An additional shock test for this class of instrument is added even though there are no established generalized test programmes that exactly reproduce the range of vibration and shock conditions that instruments might meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this clause have been chosen on the basis that instruments tested to these levels are likely to withstand the normal dynamic disturbances that they will meet when used in the range of vehicles and aircraft (including helicopters) likely to be used for transporting patients.

The use of instruments in road ambulance, fixed wing and rotary wing aircraft, naval vessels, etc., can require additional tests and verification of safety when used in these environments.

Subclause 6.4.3 Non-automated sphygmomanometers containing a mercury manometer

To protect against the harmful effects that can be caused by the spillage of mercury, an additional drop test is required for a non-automated sphygmomanometer that contains mercury. The sphygmomanometer is expected to be dropped in a condition of normal use, i.e. open. The chosen acceptance criterion does not relate to the functioning of the instrument, but the prevention of environmental contamination.

Subclause 7.1.1 Limits of the error of the cuff pressure indication

Many national and international organizations recommended an accuracy of ± 3 mmHg (0,4 kPa). This level of accuracy has been achieved in the past, and as technology advances, there seems to be no reason to broaden the permissible tolerance. An accuracy of ± 3 mmHg (0,4 kPa) should certainly be produced at room temperature; however, a wider tolerance is permitted under conditions of reasonably extended temperature ranges, such as might occur in ambulances or outdoors.

Subclause 7.1.2 Nominal range and measuring range

Many non-automated sphygmomanometers utilizing mercury gravity manometers currently being sold and used have a cuff pressure range of 0 mmHg to 260 mmHg (0 kPa to 35 kPa). This range has been found to be satisfactory for the measurement of human blood pressure and has been accepted by the medical profession. If the non-automated sphygmomanometer is not capable of measuring cuff pressures up to at least 260 mmHg (35 kPa), the systolic pressure of a hypertensive individual might not be adequately determined. For purposes of comparison, this range is stipulated for non-automated sphygmomanometers utilizing either aneroid or mercury gravity manometers.

Non-automated sphygmomanometers can be exposed to extremes of temperature, humidity and atmospheric pressure during shipment, storage and use. Because such exposure is often unavoidable, the non-automated sphygmomanometer should be designed and manufactured to remain accurate under adverse environmental conditions. No measurement device, however, particularly an electronic one, is completely invulnerable to all conceivable environmental extremes. Provision has therefore been made in this part of ISO 81060 to help ensure that the non-automated sphygmomanometer maintains its accuracy over defined ranges of temperature, humidity and atmospheric pressure. Furthermore, the non-automated sphygmomanometer is expected to withstand defined vibration and shock conditions, as well as a reasonable number of uses without degradation of performance.

Subclauses 7.2.1 Air leakage and **7.2.2 Pressure reduction rate**

The standard method of estimating blood pressure using the Korotkoff sounds specifies that the deflation rate should be between 2 mmHg/s and 3 mmHg/s (0,3 kPa/s and 0,4 kPa/s). This is the accepted practice for use in both normal and hypertensive patients.

Non-automated sphygmomanometers are commonly used for other purposes, including estimating pressure in patients in shock and as a venous tourniquet for inserting intravenous cannulae. Much lower leak rates are required for these applications.

Non-automated sphygmomanometers also have to be calibrated and leak tested. Excessive leak rates can make this difficult.

With patients in shock it is often necessary to “hover” around the systolic pressure to hear whether the much quieter sounds that occur in shock are present or not. This is not possible with a leak rate of 1 mmHg/s (0,13 kPa/s). It should be possible with a leak rate of 6 mmHg/min or 0,8 kPa/min (value used in the AAMI standard), 4 mmHg/min or 0,5 kPa/min (value used in the European standard) and 2 mmHg/min or 0,3 kPa/min (value used in Japanese standards). The value of 4 mmHg/min (0,5 kPa/min) was chosen as a practical compromise for this part of ISO 81060 as 2 mmHg/min (0,3 kPa/min) is difficult to measure.

For use as a venous tourniquet, a pressure of 40 mmHg to 80 mmHg (5 kPa to 11 kPa) is appropriate. This could be maintained for 40 s, 6 min, 10 min and 20 min at each of the above rates. All but 1 mmHg/s (0,13 kPa/s) allow sufficient time for venous access.

Calibration is difficult with a leak, but should be possible at 6 mmHg/min (0,8 kPa/min).

To perform a leak test, the adiabatic effect on pressure caused by inflation have to be allowed to reach equilibrium. The test specifies that 60 s should elapse before the test is performed, and that it should last for a further 5 min after which time the pressure in the device will have fallen by 300 mmHg (40 kPa), 36 mmHg (5 kPa), 24 mmHg (3 kPa) and 12 mmHg (1,6 kPa) at the various leak rates, and none of them will be at the pressures specified for the test. Only a leak rate of 2 mmHg/min (0,3 kPa/s) will have the pressure reasonably close to the specified pressure at the end of the test, although the rate of 4 mmHg/min (0,5 kPa/s) could be acceptable.

The rate of pressure release recommended by the American Heart Association is 2 mmHg/s to 3 mmHg/s (0,3 kPa/s to 0,4 kPa/s). To ensure that the valve can control this rate, the maximum valve leakage should not exceed one-half (1,0 mmHg/s or 0,13 kPa/s) of the minimum acceptable rate, as determined in the total pneumatic system under operating conditions. The volume of the smallest bladder in normal use (excluding the neonatal cuff) is approximately 80 ml. The leakage should be measured at three pressures throughout the range to verify proper functioning of the check valve within the adjustable valve, particularly at the lower pressures.

A standard adult cuff has an in-use bladder volume of approximately 200 ml. After the diastolic pressure is determined, the compression should be released as rapidly as possible. Occasional emergencies also necessitate rapid reduction of the bladder pressure to facilitate immediate removal of the cuff. Since the diastolic pressure is usually less than 90 mmHg (12 kPa), a valve meeting the requirements of this subclause should function satisfactorily at lower pressures.

The volume of air in the bladder directly affects the measurement of the air leakage. It has to be standardized. In tests intended to replicate the recommended application of a cuff to a human upper arm, it was found that a rigid cylinder provided a satisfactory phantom. This showed that the inner circumference of the cuff had to be approximately 7 % more than the circumference of the cylinder for optimal results (unpublished tests performed by Physikalisch-Technische Bundesanstalt).

Subclause 7.2.3 Rapid exhaust

In an emergency situation, it can be necessary to deflate the cuff rapidly. Rapid exhaust also assists more rapid repetitive measurements.

Subclause 7.2.6 Tubing connectors

This requirement addresses the known hazards associated with cross-connections. There is a demonstrated unacceptable risk associated with the use of Luer connectors with patients, including neonatal patients, in the cuffs and tubing. Three-way adaptors are readily available in the clinical environment, so that a reverse Luer connector affords very little protection from this risk.

The manufacturer is free to choose any other appropriate connector.

Subclause 7.3 Tamper proofing or unauthorized access

Tamper proofing is a safety feature. It is intended to prevent the non-automated sphygmomanometer from being adjusted by unauthorized and untrained persons or from an accidentally performed adjustment. In the risk assessment performed during the development of this part of ISO 81060, the security of settings was identified as a potential risk, which the committee determined should be minimized by tamper proofing.

The need for and complexity of security of settings depends on the complexity of the non-automated sphygmomanometer and the importance of the settings to patient safety. The effectiveness of any security system depends critically on its implementation by the responsible organization. Only the responsible organization can adequately control the security system so that operators cannot compromise it. In some

legacy equipment, access to configuration of settings has not been restricted. In such instances, operators have, intentionally or unintentionally, changed settings. Patient safety can be compromised if the non-automated sphygmomanometer calibration is improperly changed.

Subclause 8.1 Internal diameter of the tube containing mercury

Too narrow tubing can result in measurement errors due to, for example, poor visibility, mercury separation, and excessive meniscus. The minimum tube dimension specified is sufficient to avoid this type of measurement error.

An excessive meniscus occurring in a very narrow tube is the result of capillary attraction, which causes the mercury level in contact with the tube wall to be below the level in the centre of the tube. The angle of contact at the edge of the liquid surface is about 132° between mercury and glass but varies with the cleanliness of the glass surface and the purity of the mercury. It is therefore good practice to use the level of the mercury column in the centre of the tube for obtaining more accurate pressure values.

Mercury separation is the most serious risk, because if the filtering element at the top of the calibrated tube becomes blocked by separated mercury, the manometer is then an "air compression" manometer as pressure is applied. The air above the mercury column becomes compressed and resists the rise of the mercury in response to applied pressure. The minimum tube dimension of 3,9 mm represents a compromise between the minimum of 4,0 mm required by the International Organization of Legal Metrology (OIML, 1973) and the 3,8 mm-diameter tubes of some commercially available non-automated sphygmomanometers.

Subclause 8.2 Portable non-automated sphygmomanometer

Since the accuracy of a mercury manometer is affected by the inclination relative to gravity, means need to be provided to ensure the correct positioning of the reservoir and the tube containing mercury relative to the position of operation. Otherwise, inaccurate readings can occur.

Subclause 8.3 Prevention of mercury spillage during transport

Leakage of dangerous materials (e.g. mercury) is a potential hazard. During transport, it is necessary to keep the mercury in the reservoir to minimize the risk of spillage.

Subclause 8.4 Prevention of mercury spillage in normal use

Mercury spillage is unacceptable because mercury loss sufficient to lower the level in the calibrated tube to below “0” will introduce a serious error in readings, even though the error will be uniform over the range of the non-automated sphygmomanometer. Prevention of mercury spillage is also necessary because the loss of a large quantity will make the non-automated sphygmomanometer unusable at the higher end of its scale if insufficient mercury to cover the entire range remains in the non-automated sphygmomanometer. Mercury spillage is also a hazard to the operator. For these reasons, it is essential that manometers of a non-automated sphygmomanometer be fitted with devices to prevent the escape of mercury through the top of the tube (by means of a porous device), through the bottom of the tube during shipment (by means of a temporary seal) and through the reservoir.

Subclause 9.1 Scale mark at zero

For the aneroid gauge, a tolerance zone at zero is a good indication that the gauge movement has not been damaged. When the pointer leaves the tolerance zone at zero, the operator should suspect that the cuff pressure measurement might be inaccurate.

Subclause 9.2 Zero

The indication at zero is important for non-automated sphygmomanometers that contain an aneroid manometer because the pointer can indicate that the manometer has become inaccurate. A positive or negative pressure indication outside the given tolerance zone is strong evidence that the manometer has become inaccurate. Thus an adjustable dial can conceal the malfunction of a non-automated sphygmomanometer.