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**Non-invasive mechanical
sphygmomanometers**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry, through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law.

Consequently **JIS T 4203:1990** is replaced with this Standard.

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Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, or utility model right. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public and the utility model right.

Non-invasive mechanical sphygmomanometers

Introduction

This Japanese Industrial Standard has been prepared based on OIML R 16-1 published in 2002, with some modifications of the technical contents including the change of measuring range. Annex JA in this Standard specifies the technical criteria and test methods related to the structure and performance which are among the requirements for a specified measuring instrument by the Measurement Act. Those requirements apply to an aneroid type among of non-invasive mechanical sphygmomanometers based on the Measurement Act [hereafter referred to as “the aneroid type sphygmomanometer by the Measurement Act”]. Conformity with this Standard alone does not mean having passed the license examination defined in the Measurement Act.

The portions with continuous sidelines or dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JE. Annex JA to Annex JD are not specified in the corresponding International Standard.

1 Scope

This Standard specifies general, performance and mechanical and electrical safety requirement for non-invasive mechanical sphygmomanometers and their accessories which by means of an inflatable cuff, are used for the non-invasive measurement of blood pressure.

This Standard applies only to the device which makes a measurement at extremities of the human body.

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

OIML R 16-1:2002 *Non-invasive mechanical sphygmomanometers* (MOD)

In addition, symbols, which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards indicated below (including amendments) shall be applied, except the provision in 9.4.1.

JIS T 0601-1 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*

JIS Z 8103 *Glossary of terms used in measurement*

3 Terms and definitions

For the purposes of this Standard, the terms and definitions in JIS T 0601-1 and JIS Z 8103 apply, and the rest shall be as follows.

3.1 blood pressure

pressure in the arterial system of the body

3.2 non-invasive blood pressure measurement

indirect measurement of the arterial blood pressure without arterial puncture

3.3 pneumatic system

system that includes all pressurized and pressure-controlling parts such as cuff, tubing, connectors, valves, transducer and pump

3.4 cuff

component of the sphygmomanometer, comprising a bladder and a sleeve, which is wrapped around the limb of the patient

3.5 bladder

inflatable component of the cuff

3.6 sleeve

essentially inelastic part of the cuff that encloses the bladder

3.7 non-invasive mechanical sphygmomanometer

sphygmomanometer which uses a mercury or an aneroid manometer (except for another mechanical measuring device) for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff (which is adjustable for air pressure in the cuff and manometer) and exhaust valve, which is typically provided with a hand or electromechanical pump to fill the cuff with air

3.8 deflation valve

valve for controlled exhaust of the pneumatic system during measurement, which is manually adjustable

3.9 rapid exhaust valve

valve for rapidly exhausting the pneumatic system

3.10 measured value

value of physical amount indicated by a manometer

3.11 scale mark

figure, dot, line or other symbols used for the indication of the measured value or the related value

3.12 analogue indication device

set of scale marks continuously indicating measured values

3.13 instrumental error

the balance obtained by subtracting the true indication from the actual indication of a measuring instrument

3.14 hysteresis error

the difference of readings observed under the same pressure (except for the maximum pressure and minimum pressure of a measuring range) when increasing¹⁾ the pressure and when decreasing the pressure

Note ¹⁾ The indication means going far from the zero point.

3.15 maximum pressure

the upper limit of the measurement range, namely the maximum pressure that can be measured

3.16 minimum pressure

the lower limit of the measurement range, namely the minimum pressure that can be measured

4 Units

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

5 Classification

The type of non-invasive mechanical sphygmomanometers shall be as follows.

- a) mercury column type sphygmomanometer
- b) aneroid sphygmomanometer

NOTE : The type is referred to as an aneroid type sphygmomanometer.

6 Maximum permissible errors and rated operation conditions

6.1 Maximum permissible errors

The maximum permissible errors under the rated operation condition of non-invasive mechanical sphygmomanometers shall be as follows, when tested in accordance with 10.1.

- a) ± 0.4 kPa (± 3 mmHg) or less, for a mercury column type sphygmomanometer in use
- b) ± 0.5 kPa (± 4 mmHg) or less, for an aneroid sphygmomanometer in use

6.2 Rated operation conditions

The rated operation conditions of non-invasive mechanical sphygmomanometers shall be as follows.

- a) Ambient temperature range of 15 °C to 25 °C
- b) Relative humidity range of 20 % to 85 %

7 Measuring range and scale interval

7.1 Measuring range

The range of the blood pressure which can be measured with a non-invasive mechanical sphygmomanometer (the measuring range of the air pressure in the cuff) shall include 3 kPa to 35 kPa (20 mmHg to 260 mmHg). However, the measuring range for only the mercury column type sphygmomanometer is allowed to include 3 kPa to 33 kPa (20 mmHg to 250 mmHg).

7.2 Scale interval

The scale interval shall be either of the following, provided that it may be as specified in JA.6.2 for aneroid sphygmomanometers.

- a) 0.2 kPa for a scale graduated in kPa
- b) 2 mmHg for a scale graduated in mmHg

7.3 Scale

The scale of an analogue indication device shall comply with the following matters. The example of the scale in accordance with the following matters is shown in figure 1.

- a) The scale shall be designed and arranged so that the measuring values can be read clearly and are easily recognized.
- b) The distance between adjacent scale marks shall be 0.7 mm or longer.
- c) The thickness of the scale marks shall not exceed 20 % of the smallest scale spacing. The scale marks shall have the same thickness, except for the scale mark indicating 0 kPa (0 mmHg).
- d) Each fifth scale mark shall be indicated by greater length.
- e) Each tenth scale mark shall be numbered a figure (representing the value of the pressure indicated by the scale mark).

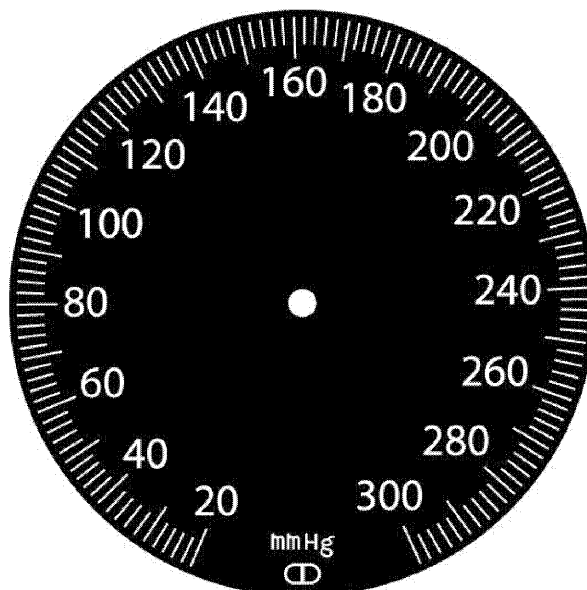


Figure 1 Example of an aneroid manometer scale

8 Performance

8.1 General

8.1.1 Air leakage

Air leakage from the pneumatic system of non-invasive mechanical sphygmomanometers shall not exceed a pressure drop of 0.5 kPa/min (4 mmHg/min), when testing shall be carried out in accordance with 10.4.

8.1.2 Deflation valve

The deflation valves shall be capable of adjustment to a deflation rate. The deflation rate of deflation valves shall be adjustable from 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s), when testing shall be carried out in accordance with 10.5.

8.1.3 Rapid exhaust valve

The time of the rapid exhaust of the valve shall not exceed 10 s, when testing shall be carried out in accordance with 10.6.

8.2 Mercury column type sphygmomanometers

8.2.1 Mercury losses

The mercury column type sphygmomanometers shall have no losses of mercury, when testing shall be carried out in accordance with 10.7.

8.2.2 mercury stopping device

A device ²⁾ shall be placed in the tube to prevent mercury from being spilled during use and transport. This device shall be such that the time taken for the mercury column to fall shall not exceed 1.5 s, when testing shall be carried out in accordance with 10.8.

Note ²⁾ For example: stopping device, locking device, etc.

8.3 Aneroid sphygmomanometer

8.3.1 Temperature characteristics

For aneroid sphygmomanometers, when testing shall be carried out in accordance with 10.2, the instrumental error shall not exceed 0.4 kPa (3 mmHg).

8.3.2 Storage environment

For aneroid sphygmomanometers, when testing shall be carried out in accordance with 10.3, the instrumental error shall not exceed ± 0.5 kPa (± 4 mmHg).

8.3.3 Hysteresis error

For aneroid sphygmomanometers, when testing shall be carried out in accordance with 10.9, the hysteresis error throughout the pressure range shall not exceed 0.5 kPa (4 mmHg).

8.3.4 Durability

For durability of aneroid sphygmomanometers, when testing shall be carried out in accordance with 10.10, the hysteresis error throughout the pressure range shall not exceed 0.4 kPa (3 mmHg).

9 Structure

9.1 General

9.1.1 Size of bladders

The optimum bladder size is one with dimensions such that its width is 40 % of the limb circumference at the midpoint of the cuff application, and its length is at least 80 % preferably 100 %, of the limb circumference at the midpoint of cuff application.

9.2 Mercury column type sphygmomanometers

9.2.1 Internal diameter of the tube containing mercury

The nominal internal diameter of the mercury tube shall be at least 3.0 mm. The tolerance on diameter shall not exceed ± 0.2 mm.

9.2.2 Portable devices

A portable device shall be provided with an adjusting or locking mechanism to secure it in the specified position of use.

9.2.3 Quality of the mercury

The quality of the mercury shall be as follows.

- a) The mercury shall have a purity of not less than 99.99 % according to the declaration of the supplier of the mercury.
- b) The mercury shall exhibit a clean meniscus and shall not contain air bubbles.

9.2.4 Dials

Graduations shall be permanently marked on the tube containing mercury or the dial. If numbered at each fifth scale mark, the numbering shall be alternately on the right-hand and left-hand side of and adjacent to, the tube.

9.3 Aneroid sphygmomanometer

9.3.1 The starting point of a pointer

The starting point of a pointer shall be as follows.

- a) The starting point of a pointer shall be marked on a dial.
- b) The starting point means the point which is indicated by a pointer when pressure is not applied to a sphygmomanometer.
- c) The starting point of a pointer is allowed to have a range of ± 0.4 kPa (± 3 mmHg).

9.3.2 Stopper

For aneroid sphygmomanometer, the movement of the elastic sensing element including the pointer shall not be obstructed within 0.8 kPa (6 mmHg) below zero.