(ii) *Maximum indicating device (constriction)*—The thermometers shall have a maximum indicating device (constriction) constructed in the capillary, between the mercury bulb and the scale in order to prevent the mercury in the stem from returning to the bulb on cooling. It shall be located in the bore between the top of the bulb and the bottom of the scale.

(a) The maximum indicating device shall pass the hardness test prescribed in Appendix A when an acceleration of 600 m/sec2 is applied at the closed end of the bulb for a period of at least 2 minutes.

(iii) *Locator*—A locator may be drawn on the stem before the start of the scale to facilitate positioning the thermometer so that the mercury column is in full view. The locator may comprise a thick (1 mm of more) dot or line or a rectangle of 1 x 3 mm.

(iv) *Bulb*—The bulb shall be cylindrical with a smooth rounded end and shall be in alignment with the stem.

(a) The diameter of bulb and the joint of bulb with stem shall nowhere exceed that of the stem. The joint shall be smooth and regular.

(b) The bulb shall be hemispherical at the tip.

(v) The bulb, capillary tube and mercury shall be sufficiently free from entrapped gas, debris and foreign bodies in order to ensure the correct functioning of the thermometer.

(4) *Dimensions*

The dimensional and scale requirements for solid stem type clinical thermometers, shall be as given in Table 1.

TABLE 1

DIMENSIONAL AND SCALE REQUIREMENTS FOR SOLID STEM CLINICAL THERMOMETERS

Sl. No.	*Characteristic*	*Requirements*
(1)	*(2)*	*(3)*
(i)	Scale range, °C	35.0 to 42.0 or 35.0 to 43.0
(ii)	Smallest scale division, °C	0.1
(iii)	Over all length, mm	100 to 115
(iv)	Scale length, mm	40 to 65
(v)	External diameter of stem, mm	4 to 6
(vi)	Bulb length, mm	
	(a) Oral thermometer	12 to 18
	(b) Rectal thermometer	Not more than 9
(vii)	External diameter of bulb, mm	
	(a) Oral thermometer	2.0 to 3.5
	(b) Rectal thermometer	3.0 to 6.0 (But not exceeding that of stem)
(viii)	Distance from top of the constriction to the 35.5°C mark, mm, Min.	10
(ix)	Distance from the highest graduation line to top of stem, mm, Min	8
(x)	Scale spacing, mm Min	0.5

Note : See Figure 3 in IS 8757 : 1977

(5) *Graduation and Numbering*

(i) The thermometer scale shall be sub-divided in 0.1°C as shown in Figure 55Q.

(ii) The graduation lines shall be equally spaced and at right angles to the axis of the thermometer.

(iii) All graduation lines shall be of equal and uniform thickness of not more than 1/4 of the length of the smallest scale division or 0.15 mm whichever is less.

(iv) The pattern of graduation and numbering shall be as follows:—

(a) Every tenth graduation line shall be a long line (about 2 mm) which shall be numbered.

(b) There shall be a medium line (about 1.5 mm) midway between two consecutive long lines, and

(c) There shall be four short lines (about 1 mm) equally spaced between consecutive medium and long lines.

(v) When the thermometer is held in a vertical position and viewed from the front, the left-hand ends of the graduation lines shall lie on an imaginary vertical line (see Figure 55Q).

(vi) The numbers shall be placed to the right of the axis in such a way that extension of the line to which they refer, would bisect them. The figures shall be placed parallel to the axis of the thermometer.

(vii) A distinguishing mark (say, an arrow) shall be marked at 37.0°C mark to indicate the normal temperature.

(viii) All graduation lines and numbering shall be clearly and permanently marked or etched on the stem and filled with a pigment. The marking shall pass the test for permanency given in Annex B.

Note : The pigment may be black, red, green or blue as agreed to between the purchaser and the supplier.

6. Performance requirements

(1) *Appearance*

When heated to 42°C or so the mercury column shall look like a strip of uniform width with clarity and brightness throughout.

Note : This test takes care of all visual defects, for example, twist in the glass, aberrations, cloudiness, devitrification, etc.

(2) *Ageing and Accuracy*

(i) The clinical thermometers shall meet all the requirements after ageing by natural or artificial means.

Natural Ageing involves holding the thermometers at room temperature for four months after completion of the construction. Artificial ageing method involves heat treatment of the bulb and constriction of the unfilled thermometer at a temperature and duration to be specified by the manufacture of the glass tubing.

(ii) Clinical thermometers shall after ageing ensure that their accuracy as measured by the method prescribed in Appendix C shall be ± 0.1°C for at least one year after the first official verification.

(3) *Influence of Immersion Time*

If a thermometer at temperature t_1 (15°C t_1 < 30°C) is suddenly immersed in a well-stirred water bath having a constant temperature t_2 (35.5°C < t_2 < 42°C) and is withdrawn after 20 seconds the thermometer reading, after cooling to ambient temperature (15°C to 30°C)

(i) shall comply with maximum permissible error requirement, and

(ii) shall not deviate from its stabilized reading for temperature t_2°C by more than 0.005 (t_2 - t_1)°C.

This stabilized reading is the thermometer reading obtained when the thermometer has been cooled to ambient temperature, after reaching complete thermal equilibrium with the water bath at a temperature t_2°C. This reading shall also meet the maximum permissible error requirements stipulated in paragraph 6(2)(ii).

Note : A free choice of test method is permitted, provided the law of the variation of the indication of the thermometer as a function of immersion time is known.

7. Marking and Packing

(1) *Marking*

Each clinical thermometer shall be legibly and indelibly marked on its stem with the following:—

(a) The letter °C near the top of the scales;

(b) The word Oral or Rectal, as the case may be;

(c) The manufacturer's name or his recognized trade-mark, if any;

(d) A code number to trace the batch of manufacture;

(e) A recognized mark of the verifying authority showing the year of initial verification;

(f) An indication identifying the glass used for the bulb, if the glass is not already identified by its maker; and

(g) The Standard Mark of the Bureau of Indian Standards.

(2) *Packing*

Clinical thermometers shall be securely packed, individually and collectively, in any manner acceptable to the purchaser so as to minimize the risk of damage in handling, transport and storage.

APPENDIX A

TEST FOR HARDNESS OF MAXIMUM INDICATING DEVICE

1. Apparatus

(1) *Centrifuge*—A centrifuge with radial arms 15 cm each. Each arm shall be provided with a pocket for keeping one or more clinical thermometers. Speed of the centrifuge shall be either fixed or adjustable to 600ppm.

2. Procedure

(1) Place the thermometers for sometime in water at a temperature anywhere between 42°C — 43°C. Then put them in the pockets of all the centrifuge, bulb facing outwards, that is away from the axis of the centrifuge while in rotation.

Let the centrifuge work steadily at its correct speed for at least 2 minutes. Then stop it.

Take the thermometers out of the pockets and observe the mercury column.

Thermometers shall be taken as having satisfied the requirement of this test, if the mercury rests below or at 35°C mark.

Important—It is necessary that the room temperature does not exceed 34.5°C during the test.

APPENDIX B

TEST FOR PERMANENCY OF MARKING

1. Procedure

(1) Place the thermometers in a 5 per cent (m/v) solution of phenol in water maintained at 37 ± 0.5°C for a period of 20 minutes.

(2) Wipe the thermometers dry with a piece of soft cloth and examine.

(3) The thermometers shall be considered to have passed the test if, after this treatment, the marking does not peel off anywhere.

APPENDIX C

TEST FOR ACCURACY

1. Apparatus

(1) *Comparator Bath*—Either screw type or bubbler type, as prescribed in IS 6274-1971 Method of calibrating liquid-in-glass thermometers, filled with water.

(2) *Reference Thermometers*—Calibrated reference thermometers (see schedule mark ISTI of IS 4825 : 1968)

2. Procedure

(1) After preliminary check of the clinical thermometers, carry out the accuracy test in accordance with 6.2 of IS 6274—1971 at 37.0 ± 0.5°C, 39.0 ± 0.5°C and 41.0°C ± 0.5°C respectively.

(2) The thermometers shall be considered to have passed this test if the accuracy so determined lies within limits prescribed in paragraph 6(2)(ii).

APPENDIX D

DETERMINATION OF THE MEAN DEPRESSION OF ZERO OF THERMOMETERS

1. It is not possible to determine the depression of zero of clinical thermometers (mercury-in-glass, with the maximum indicating device) covered by this specification. Therefore, special test thermometers (paragraph 2) shall be manufactured from the glass being examined in order to conduct the necessary measurements.

2. The test thermometers must meet the following requirements—

(1) Scale Range
At least from - 3.0°C to + 3.0°C.

(2) Scale Interval
0.02°C, 0.05°C or 0.1°C

(3) The scale spacing must be at least 1.0 mm.

(4) The expansion chamber must be large enough to allow the thermometers to be heated to 400°C without damage.

(5) The thermometers must be properly stabilized by the manufacturer and must meet the requirements of the stabilization test (see paragraph 3).

3. The proper stabilization of each test thermometer must be tested in accordance with the following provisions:—

(1) The thermometer is heated in a test bath (liquid bath or metal block type oven) from ambient temperature up to 350°C ± 10°C and keep at this temperature for at least five minutes. It is then cooled to 50°C in the test bath, which decreases in temperature by 10 to 15°C/h.

(2) When the thermometer has reached a temperature of 50°C, it is removed from the test bath and its 0°C correction value (K_1) is determined with the help of a zero point (0°C) ice bath, which consists of a Dewar flask filled with finely crushed ice covered over with water. The water used to make the ice and the water in which ice is submerged must be pure. Its electrical conductivity must not exceed 10–3 S.m1 at 20°C. The ice must be carefully tamped so that there are no air bubbles in the ice-water mixture. It must be compacted as much as possible both prior to measurement and periodically during measurement.

It is recommended that a water purifier, a refrigerator with ice trays and an ice crusher be employed for preparing the ice-water mixture.

(3) The thermometer is then heated a second time to 350°C ± 10°C in the test bath and kept at this temperature for 24 hours. It is then cooled to 50°C, as before {paragraph 3(1)}.

(4) When the thermometer has reached a temperature of 50°C, it is removed from the test bath and its 0°C correction value (K_2) is determined once more.

(5) K_2 must not differ from K_1 by more than 0.15°C. Thermometers which do not meet this requirement must not be used to determine the depression of zero.

4. The mean depression of zero is determined in accordance with the following provisions:—

(1) At least three test thermometers must be used. They must be manufactured from the glass being tested, must have met the requirements of the stabilization test (paragraph 3), and not have been heated above the ambient temperature once value K_2 has been determined [paragraph 3(4)].

(2) Each of these thermometers must be tested at least three times in accordance with the provisions of [paragraphs 4(2)(i), 4(2)(ii) and 4(2)(iii) below].

(i) The thermometer is kept in a test bath at 100°C ± 1.0°C for 30 minutes. It is then removed from the bath and allowed to cool in air. While it is cooling to ambient temperature, its bulb must not come into contact with other objects.

(ii) The 0°C correction of the thermometer is determined not later than 15 minutes after the thermometer has been removed from the test bath. The correction value obtained is designated by the symbol K_3.

(iii) The thermometer is then kept for one week at a temperature between 20°C and 25°C. At the end of the week the 0°C correction is determined. This correction value is designated K_4. The procedures described in paragraphs 4(2)(i) and 4(2)(ii) are then repeated, and a 0°C correction value, designated K_5, is obtained.

(iv) The procedures described in paragraph 4(2)(iii) are repeated to obtain a series of n differences $K_2 - K_3$, $K_4 - K_5$, $K_{2n} - K_{2n+1}$. These are the values of the thermometer's depression of zero from the first, second and *n* the series of measurements, respectively.

(v) When *n* series of measurements have been made with *m* test thermometers, the following expression is obtained for the mean depression of zero of these thermometers.

$$\frac{1}{mn}\sum_{i=1}^{i=m}\left[\left(k_2^{(i)}-k_3^{(i)}\right)+\left(k_4^{(i)}-k_5^{(i)}\right)+\left(k_{2n}^{(i)}-k_{2n+1}^{(i)}\right)\right]$$

which must not exceed 0.07°C {paragraph 7(2)(ii)}

In accordance with the provisions of paragraphs 4(1) and 4(2), the conditions m 3 and n 3 must be met for *m* and *n*, and the standard deviation of the mean depression of zero determined in accordance with the aforementioned provisions, must not exceed ± 0.01°C.

(vi) If a more accurate value for the mean depression of zero is required, at least five series of measurements on at least five test thermometers must be carried out.

PART B

CLINICAL THERMOMETER—ENCLOSED SCALE TYPE

Scope : This Part specifies the requirements and methods of test for enclosed scale type clinical thermometers having a maximum indicating device.

1. Terminology

(1) For the purpose of this standard the definitions given in IS 2627-1979 Glossary of terms relating to liquid-in-glass thermometers as revised from time to time, in addition to the following, shall apply.

(2) *Glass tubes*—Sheath tubes, capillary tubes and bulb tubes.

2. Type

The thermometers shall be of the enclosed-scale mercury-in-glass type.

3. Temperature Scale

The thermometers shall have a translucent paper or plastic material strip duly graduated in degrees Celsius (°C) and shall have a range from 35 to 42°C or 35 to 43°C.

4. Immersion

Thermometers shall be calibrated for total vertical/horizontal immersion.

5. Requirements

(1) *Patterns*—There shall be two patterns of bulb, namely, oral and rectal as follows:

(c) Oral-for thermometers for use in mouth, and

(d) Rectal-for thermometers for use in rectum.

Note 1 : Oral thermometers may also be used in armpit or groin.

Note 2: Rectal thermometers may also be used in the mouth, armpit or groin after proper disinfection

(2) *Materials*

(I) *Glass tubing*—The thermometers shall be made from glass tubing conforming to IS 4529-1968 Specification for glass tubes for medical thermometers.

(ii) *Thermometric liquid*—The thermometric liquid shall be pure, dry mercury.

(iii) *Strip*—The strip bearing the scale shall be of a translucent or plastic material suitable for the temperature to be read.

(3) *Construction*

(i) The thermometer sheath shall be in alignment with the bulb and it shall be round or oval.

(a) The free end of the sheath shall be finished smooth, preferably hemispherical in shape as shown in Figure 2

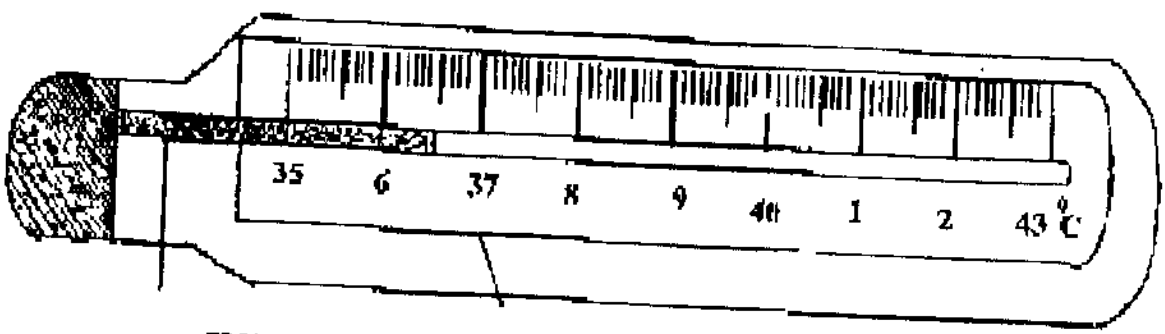


FIGURE-2 CLINICAL THERMOMETER : ENCLOSED SCALE TYPE

(ii) *Maximum Indicating device (constriction)*—The thermometers shall have a maximum indicating devices (constriction) constructed in the capillary, between the mercury bulb and the scale in order to prevent the mercury in the stem from returning to the bulb on cooling.

(a) The maximum indicting device shall pass the hardness test prescribed in Appendix A when an acceleration of 600 m/sec^2 is applied at the closed end of the bulb for a period of at least 2 minutes.

(iii) *Bulb*—The bulb of the oral thermometers shall be cylindrical with a smooth rounded end and shall be in alignment with the sheath. The bulb of the rectal thermometers shall be pear-shaped.

(a) The diameter of bulb and the joint of bulb with sheath shall no where

exceed that of the sheath. The joint shall be smooth and regular.

(b) The bulb shall be hemispherical at the tip.

(iv) *Strip bearing the scale*—It shall be placed tightly against the capillary tube inside the sheath and shall be firmly and securely fastened at the top of the thermometer in such a way that it can freely expand in length. The fixing shall not obscure the scale.

Note : A suitable method of fixing is by fusing a glass tube or rod to the sheath and to the upper end of the strip bearing the scale.

(v) *Capillary tube*—The capillary tube shall be smooth and uniform.

(4) *Dimensions*—The dimensional and scale requirements for clinical thermometers, enclosed scale shall be as given in Table 2.

TABLE 2

DIMENSIONAL AND SCALE REQUIREMENTS FOR CLINICAL THERMOMETERS, ENCLOSED SCALE

Sl. No.	Characteristic	Requirements
(1)	(2)	(3)
(i)	Scale range, °C	35 to 42 or 35 to 43
(ii)	Smallest scale division, °C	0.1
(iii)	Over all length, mm, Max	120
(iv)	Scale length, mm	45 to 65
(v)	External diameter of sheath, mm (round or oval), max	12
(vi)	External diameter of capillary, mm	2 ± 0.2
(vii)	External diameter of the bulb, mm	4 ± 0.5
(viii)	Bulb length, mm, max	21
(ix)	Thickness of strip, mm	0.6 ± 0.1
(x)	Distance above the constriction upto the 35°C mark, mm, Min	10
(xi)	Distance from the highest graduation line to top of sheath, mm, Min	8

(5) *Graduation and Figuring*

(i) The thermometer scale shall be sub-divided in 0.1°C as shown in Figure 55R.

(ii) The graduation lines shall be of black pigment, marked permanently on the strip. They shall be equally spaced and at right angles to the axis of the thermometer.

(iii) All graduation lines shall be of equal and uniform thickness of not more than 0.2 mm.

(d) Every tenth graduation line shall be a long line (about 2 mm) which shall be figured.

(e) There shall be a medium line (about 1.5 mm) midway between two consecutive long lines, and

(f) There shall be four short lines (about 1 mm) equally spaced between consecutive medium and long lines.

(iv) When the thermometer is held in a vertical position and viewed from the front, the left-hand ends of the graduation lines shall lie on an imaginary vertical line (see Figure 55R).

(v) The figures shall be placed to the right of the axis in such a way that extension of the line to which they refer, would bisect them. The figures shall be placed parallel to the axis of the thermometer.

(vi) A distinguishing mark (say, an arrow) shall be marked at 37.0°C mark to indicate the normal temperature.

(vii) All graduation lines and figures shall be clearly visible.

6. Performance requirements

(1) *Appearance*—When heated to 42°C or so the mercury column shall look like a strip of uniform width with clarity and brightness throughout.

Note : This test takes care of all visual defects, for example, twist in the glass, aberrations, cloudiness, devitrification, etc.

(2) *Ageing and Accuracy*—Clinical thermometers shall be adequately aged to ensure that their accuracy as measured by the method prescribed in Appendix B shall be ± 0.1°C for at least one year after the first official verification.

(3) *Time of Response*—The time of response of clinical thermometers, as checked by the method prescribed in Appendix C shall not exceed 8.0 seconds.

When the temperature is rising very slowly at a uniform rate, the jumping of the meniscus of the thermometric liquid does not exceed one-half of the smallest scale division.

7. Marking and Packing

(1) *Marking*—Each clinical thermometer shall be legibly and indelibly marked on its stem with the following:—

(a) The letter °C near the top of the scales;

(b) The word Oral or rectal as the case may be;

(c) The manufacturer's name or his recognized trade-mark, if any;

(d) A code number to trace the batch of manufacture; and

(e) A recognized mark of the verifying authority showing the year of initial verification;

(f) The Standard Mark of the Bureau of Indian Standards.

(2) *Packing*—Clinical thermometers shall be securely packed, individually and collectively, in any manner acceptable to the purchaser so as to minimize the risk of damage in handling, transport and storage.

APPENDIX A

TEST FOR HARDNESS OF MAXIMUM INDICATING DEVICE

1. Apparatus

(1) *Centrifuge*—A centrifuge with radial arms 15 cm each. Each arm shall be provided with a pocket for keeping one or more clinical thermometers. Speed of the centrifuge shall be either fixed or adjustable to 600 rpm.

2. Procedure

(1) Place the thermometers for some time in water at a temperature anywhere between 42 and 43°C.

(2) Then put them in the pockets of all the centrifuge, bulb facing outwards, that is away from the axis of the centrifuge while in rotation.

(3) Let the centrifuge work steadily at its correct speed for at least 2 minutes. Then stop it.

(4) Take the thermometers out of the pockets and observe the mercury column.

(5) Thermometers shall be taken as having satisfied the requirement of this test, if the mercury rests below or at 35°C mark.

Important—It is necessary that the room temperature does not exceed 34.5°C during the test.

APPENDIX B

TEST FOR ACCURACY

1. Apparatus

(1) *Comparator Bath*—Either screw type or bubbler type, as prescribed in IS 6274-1971 Method of calibrating liquid-in-glass thermometers, filled with water.

(2) *Reference Thermometers*—Calibrated reference thermometers [see Schedule Mark 8 and 9 of the IS 4825-1982 specification of liquid-in-glass solid-stem reference thermometers (first revision)].

2. Procedure :

(1) After preliminary check of the clinical thermometers, carry out the accuracy test in accordance with 6.2 of IS 6274-1971 at 37.6 ± 0.5°C, 39.0 ± 0.5°C and 41 ± 0.5°C respectively.

(2) The thermometers shall be considered to have passed this test if the accuracy so determined lies within limits prescribed in paragraph 6(2).

APPENDIX C

TEST OF TIME OF RESPONSE

1. Apparatus

Same as in paragraphs 1(1) and 1(2) of Appendix B provided that some automatic arrangement is made to switch off stirring at the instant the bulb of thermometers under test touch the water surface and to switch it again immediately after the thermometers are taken out of the water.

2. Procedure

(1) Set the comparator bath at a temperature of 41 ± 0.5°C. Note the temperature on the reference thermometer.

(2) Shake down the clinical thermometers under test to maximum extent.

Note : Centrifuge mentioned under para 1(1) of Annexure A may be used for this purpose, if required.

(3) Plunge the clinical thermometers into the bath upto 35°C mark. Take out suddenly after 7.5 to 8.0 seconds wipe and dry. Take their readings.

(4) Thermometers shall be considered to have passed this test, if they indicate temperature within ± 0.1°C of the comparator bath temperature noted in paragraph 2(1) of this Appendix.

Important—It is necessary that the room temperature does not exceed 34.5°C during the test.

PART C

CLINICAL ELECTRICAL THERMOMETERS WITH MAXIMUM DEVICE

1. Scope

(1) This Part specifies the metrological and technical requirements for clinical electrical thermometers with a maximum device. Such instruments are designed to measure human or animal body temperature. They indicate a maximum temperature measured after a steady state is reached or predicted after a time specific to the design of the instrument. Until the maximum temperature is indicated, the actual temperature may be indicated by the thermometer.

(2) The measuring range of clinical thermometer shall be either of 35°C to 42°C or 35°C to 43°C. Two accuracy classes, class I and class II, are covered by this specification.

(3) This specification applies to battery-powered instruments which provide a digital indication of temperature.

(4) Clinical electrical thermometers designed to measure skin temperature are not covered by this specification.

(5) This specification does not exclude the use of any contract device based on other measurement principles that meets equivalent performance standards in determining maximum body temperature at specified time intervals.

2. Terminology

(1) A clinical electrical thermometer, as covered by this specification is a contact thermometer comprising a temperature probe and an indicating unit, and that is designed to measure human or animal body temperature.

(2) A temperature probe is the component of a thermometer of which part is applied to a body cavity or tissue with which it establishes thermal equilibrium. It comprises a temperature sensor with associated parts including coverage, seals, inner leads, and connecting plug, where appropriate.

Notes : 1. A body or tissue may be the mouth (sublingual), rectum, or armpit.

2. The part of the probe in contact with a body cavity or tissue is called the 'applied part'.

3. An indicating unit is the component of a thermometer that process the output signal of the temperature sensor and displays the measured temperature.

4. A maximum device is the component of a thermometer that monitors over a specified time the temperature measured by a probe in contact with a body cavity or tissue, at which it indicates the maximum temperature and maintains the indication until reset by the user.

5. Predicting clinical electrical thermometer calculates the maximum temperature of a probe in contact with a body cavity or tissue, without waiting for thermal equilibrium to occur, by using heat transfer data and a mathematical algorithm.

3. Description of the instrument

(1) A complete thermometer consists of a temperature probe connected to any indicating unit.

The instrument may be of the following type:—

—indicating unit that is compatible with the characteristic response of a probe.

4. Metrological requirements

(1) *Unit of measurement-measuring range-scale interval*

(a) The unit of temperature shall be the degree Celsius °C.

(b) The measurement range shall be a minimum of 35°C to 43°C or 35°C to 42°C. Greater measuring ranges may be sub-divided into partial ranges; however, the range 35°C to 42°C shall be continuous.

(c) The scale interval or digital increment shall not exceed—

- 0.01°C for class I thermometers,
- 0.1°C for class II thermometers.

(2) *Maximum permissible errors*

(a) The maximum permissible error under reference conditions for the temperature range 32.0°C to 42.0°C for the two accuracy classes covered shall be as follows:—

Maximum permissible errors (range 32.0°C to 42.0°C)

Accuracy class	*Complete thermometer*	*Indicating unit*	*Temperature probe*
Class I	± 0.15°C	± 0.05°C	± 0.1°C
Class II	± 0.2°C	± 0.1°C	± 0.1°C

(b) Outside the temperature range 32°C to 42°C, the maximum errors shall be at twice the values specified in paragraph 4(2)(a).

(3) *Reference conditions*

The reference conditions for the requirements of paragraph 4(2) shall be:

- ambient temperature of 27°C ± 5°C
- relative humidity to 50% ± 20%
- the instrument operating within the specified range of battery voltage (specified power supply conditions).

(4) *Time response*

The thermometer shall be submitted by the manufacturer to a testing laboratory to determine its time response. The test shall be based on any analysis of a significant sample of human subjects.

The difference between the displayed calculated temperature and the corresponding measured temperature at thermal equilibrium of calculating (predicting) thermometer shall not exceed 0.2°C.

5. Technical requirements

(1) *Temperature probe*

(i) For an interchangeable probe of the resistance type, the manufacturer shall specify the maximum power that may be supplied to the probe by an indicating unit; this power shall not cause energy dissipation (I^2R) giving rise to any increase in temperature by more than 0.02°C when immersed in a reference water bath maintained at a temperature range of 36.9°C to 37.1°C.

Note :(1) For a description of the reference water bath, see Annexure A.

(2) A test of this requirement is only applicable to inter-changeable probes submitted for pattern approval without a specific indicating unit. When a probe is submitted with an associated indicating unit, the requirement in 5(2)(7) applies.

(ii) The thermal stability of the probe, after exposure for 100 hours at 80°C ± 2°C or 300 hours at 55°C ± 2°C, shall be such that the requirement for maximum permissible errors specified in paragraph 4(2) is met.

(iii) The electrical insulation of the probe shall be sufficient to prevent a change in indicated temperatures greater than ± 0.02°C when the probe is immersed in an electrically conducting liquid having an insulation resistance of 80 MW at 20°C. This insulation includes that between the inner lead wires, that between the wires and the surface of the probe, and that encasing and protecting connections and transitions.

(iv) The locations of the sensors in the probe shall be such that, when the probe is immersed to depths greater than 50 mm from its tip in a reference water bath at a temperature does not vary by more than 0.05°C from that indicated at a depth of 50 mm.

(v) The probe shall be strong enough to withstand mechanical stresses expected under normal conditions of the use.

(vi) If the probe is inter-changeable, it shall be fitted with either a plug-in or quick disconnectable electrical connector. The contact resistance of the connector or the insulation resistance between the circuits of the connector or to ground shall not cause a variation in the indicated temperature greater than 0.02°C.

Note : The connectors may not be required to be water resistant.

(vii) The probe shall meet the requirements for maximum permissible errors specified in paragraph 4(2) when the applied part has been subjected to the cleaning in and disinfecting procedure specified by the manufacturer.

Notes : (1) For small compact thermometers this applies to the complete instrument.

(2) The materials of the probe that come into contact with the body should be selected for compatibility with body tissue.

(viii) The output signal of the probe shall not vary by more than ± 0.05°C when the temperature of the cable connecting it to an indicating unit varies by 20°C.

(2) *Indicating unit*

(i) When connected to a resistance-type temperature probe, the indicating unit shall provide an energizing potential sufficiently low so that energy dissipation (1^2 R) in the probe shall not cause an increase in indicated temperature of over 0.01°C when the probe is immersed in a reference water bath at a temperature within the specified measuring range.

(ii) The indicating unit shall not indicate a temperature when connected to a battery charger.

(iii) The digital display of temperature shall be at least 4 mm in height or it shall be optically magnified so as to appear at least 4 mm in height.

(iv) The indicating unit shall provide a clear indicating or warning signal when the measured temperature is outside the specified measuring range.

(v) The indicating unit shall include a self-checking device that meets the requirements of the paragraph 4(2). This device, which may be manual or automatic, shall input a predetermined electrical signal. Failure shall be clearly indicated.

Note : This device checks only the operation of the indicating unit and does not ensure that a temperature measurement is correct. It provides a means of detecting a faulty operation caused by a defective component or other disturbance.

(vi) In the case of a predicting thermometer, the indicating unit shall provide a means of displaying the measured temperature after reaching the thermal equilibrium.

(3) *Complete thermometer*

Note : The reference thermometer is that indicated (either before the test, or before and after the test, as appropriate) by the thermometer probe immersed in the reference water bath according to the paragraph 1 of Annexure A, the temperature being held constant within the working range of the thermometer.

(i) The thermometer shall provide a clear indication or warning signals when the battery voltage is outside the specified limits and it shall meet the requirement specified in paragraph 4(2) when the voltage is within these limits.

(ii) The indicated temperature shall not vary by more than ± 0.1°C from the reference temperature when the temperature of the thermometer casing varies from 10°C to 40°C.

(iii) The indicated temperature shall not vary more than ± 0.1°C from the reference temperature after a thermal shock resulting from an abrupt change in temperature from -5°C to+50°C.

(iv) The indicated temperature shall not vary by more than ± 0.1°C from the reference temperature after storage for 24 hours at -20°C ± 2°C and at 60°C ± 2°C.

(v) The indicated temperature shall not vary by more than ± 0.1°C from the reference temperature after storage at a relative humidity of 91% to 95% at a temperature constant within ± 2°C in the range 20°C to 32°C.

(vi) The indicated temperature shall not vary by more than ± 0.3°C from the reference temperature during exposure to electromagnetic field having a frequency between 150 kHz and 500 MHz and a field strength of 10V/m.

(vii) The indicated temperature shall not vary by more than ± 0.1°C from the reference temperature after fall on to a hard surface from a height of 1m from three different orientations.

(viii) Small and compact complete thermometers shall be water resistant.

6. Practical Instructions

(1) Manufacturers shall provide an operating manual, or instructions, including the following information:—

- description of appropriate uses and means of applications,
- identification of the specified temperature measuring range of the complete thermometer taking into account, if applicable, the specified measuring ranges of both the interchangeable probes and the indicating unit,
- instructions and precautions for cleaning and disinfecting the complete thermometer or the inter-changeable probes,
- identification of components and suitable inter-changeable parts such as probes and

batteries, including nominal voltage, if applicable,

- minimum time for achieving thermal equilibrium,
- description of transition from the predicted temperature-measuring mode into the actual temperature-measuring mode,
- instruction for the self-checking device,
- information on the correct environmental conditions of use, storage, and transport of the thermometer.

(2) Specific information should be provided by the manufacturer, on request, regarding possible sub-standard performance if used under the following conditions:—

- outside the prescribed environmental temperature and humidity range,
- after an accidental mechanical shock.

7. Metrological controls

(1) *Pattern evaluation*

(i) Manufacturers shall provide the following information:—

- location of sensor from tip of probe,
- description and principles of measurements of complete thermometer,
- description of electrical principles and of any necessary equipments provided,
- description of test for self-checking device,
- specified working range for battery,
- nominal and specified temperature measuring ranges,
- nominal values of calibrations data for type of temperature probe, as applicable,
- precautions for cleaning and disinfecting complete thermometer or temperature probes, as appropriate, including test results as specified in paragraph 3 of Annexure B,
- indicating on instrument if a displayed value is calculated,
- test results,
- results of clinical test of time responses [paragraph 4(4) and Annex D],
- operating manual and/or instructions (see clause 6).

(ii) Thermometers shall be subjected to the following tests:—

Note : Requirements for the reference water bath and the test for maximum permissible errors are provided in Annexure A. The performance requirements for the instrument and its major components are provided in paragraphs 4 and 5. Where appropriate, an additional description of required tests is provided in Annexure B.

Probe

- maximum permissible errors [4(2) and paragraph 2(2)(i) of Annexure A]
- long-term thermal stability [5(1)(ii)]
- electrical insulation and water resistance [5(1)(iii) and paragraph 2 of Annexure B].
- location of sensor [5(1)(iv)]
- mechanical strength [5(1)(v)]
- electrical contact resistance of connector [5(1)(vi)]
- cleaning and disinfecting [5(1)(vii) and paragraph 3 of Annexure B]
- stability with changes in temperature of cables [5(1)(viii)]

Indicating unit

- maximum permissible errors [4(2) and Annexure A]
- power provided to probe [5(2)(i) and paragraph 1 of Annexure B]
- indication when connected to battery charger [5(2)(ii)]
- indication if the thermometer is outside the specified measuring range [5(2)(iv)]
- self-checking device [5(2)(v)]
- display of predicting thermometer [5(2)(vi)]

Complete thermometer

- maximum permissible errors [4(2) and Annexure A]
- low battery indication [5(3)(i) and paragraph 4 of Annexure B]
- ambient temperature [5(3)(ii) and paragraph 6 of Annexure B]

- thermal shock [5(3)(iii) and paragraph 6 of Annexure B]
- storage temperatures [5(3)(iv)]
- humidity [5(3)(v) and paragraph 7 of Annexure B]
- electromagnetic radiation interference [5(3)(vi) and paragraph 8 of Annexure B]
- mechanical shock [5(3)(vii) and paragraph 9 of Annexure B]
- water resistance of small compact thermometers [5(3)(viii) and Annexure C]
- instructions and precautions for cleaning and disinfecting the complete thermometer or the inter-changeable probes,
- identification of components and suitable inter-changeable parts such as probes and batteries, including nominal voltage, if applicable,
- minimum time for achieving thermal equilibrium by an indicating energy dissipation requirements [5(1)(a) and paragraph 1 of Annexure B]

(iii) A report of the results of tests required in paragraphs 7(1)(ii) and 7(1)(iii) shall be prepared.

(2) *Marks and labels*

(i) Manufacturers shall provide a space for marks and labels.

(ii) Manufacturers shall affix on the thermometer or indicating unit, if separate, the following marks or labels:—

- name and address of manufacturer or supplier, and/or trademark,
- model or type designation, and serial or lot number,
- temperature values or indications given by the self-checking device,
- indication of the orientation or position in sue, where appropriate,
- indication if a displayed value is calculated.

(iii) Inter-changeable temperature probes shall bear the following marks or labels:—

- name and address of manufacture and/or trademark,
- type designation,
- serial or lot number, or relevant manufacturing production data.

(iv) A single-use temperature probe shall be sealed in a package on which the information specified in paragraph 7(2)(iii) and the measuring range shall be indicated. In addition, sufficient space on the package shall be provided for the application of official approval marks. It shall be clear if the package has been opened and the instructions shall stipulate that the user only opens the package immediately before use.

(v) The testing laboratory shall permit the application in a conspicuous place, of the following:—

- pattern approval mark or label, on each complete thermometer or indicating unit and associated temperature probe(s).
- indication of the specified temperature measuring range if the total range of the thermometer is greater.

(3) *Verification*

(i) The laboratory shall examine the information provided by manufacturers as specified in paragraph 6.

(ii) The laboratory shall examine the instrument's pattern approval certificate mark(s) or label(s).

(iii) The laboratory shall carry out any of the tests indicated in paragraph 7(1)(ii) that may be critical for the designated application of the instrument.

Note : The tests indicated in paragraph 2 of Annexure A may be sufficient for verification.

(iv) The laboratory shall provide a verified instrument with a mark or label.

(v) The water resistance of small and compact complete thermometers shall be examined by means of the procedure described in paragraph 2 of Annexure C.

(vi) The laboratory shall indicate the period of validity of the verification.

ANNEXURE A

ESTABLISHING REFERENCE TEMPERATURES AND DETERMINING MAXIMUM PERMISSIBLE ERRORS

(Mandatory)

1. Reference temperatures

(1) A well-regulated and stirred water bath containing at least one litre in volume shall be used

to establish reference temperatures over the measuring range for conducting various performance tests on an instrument. The bath shall be controlled to a temperature stability of better than ± 0.02°C over the specified temperature range and shall not have a temperature gradient greater than ± 0.01°C within its working space at a specified temperature. This temperature gradient shall be assured under all conditions and methods of loading temperature probes.

Note : The water bath described above is referred to as a "reference water bath" in this specification.

(2) A reference thermometer with an expanded uncertainty not greater than 0.03°C (calculated for a coverage factor k = 3) shall be used to determine the temperature of the water bath. The calibration shall be traceable to national measurement standards.

2. Determining maximum permissible errors

(1) *Complete thermometer*

(i) The temperature probe of a complete thermometer shall be immersed in a reference water bath at a constant temperature until temperature equilibrium is established. The temperature indicated by the thermometer shall be compared to that indicated by the reference thermometer. The bath temperature shall then be increased or decreased, the temperature equilibrium re-established, and the measurement process repeated. The difference between the measured and reference temperatures shall meet the requirements for maximum permissible errors as specified in paragraph 4(2).

(ii) The number of measurements at different temperatures depends on the measuring range of the instrument; however, measurements shall be carried out for at least the following number of temperatures within the measuring range:—

Measuring range	*Number of temperatures*
≤ 10°C	3
≥ 10°C	5

(2) *Inter-changeable and single-use probe*

(i) An inter-changeable or single-use probe shall be immersed in a reference water bath as specified in paragraph 2(1)(i) of Annexure A measured physical property of the probe shall be converted to a temperature value by using an appropriate instrument to measure a change in that property as a function of temperature. For a resistance-type probe, an appropriate instrument for measuring its output signal may be an ohm meter that can apply power to the probe at a level below the limit specified in paragraph 5(2)(i) and the temperature value is obtained from the manufacturer's data of resistance versus temperature. The expanded measurement uncertainty of the appropriate instrument shall not be greater than a value equivalent to 0.01°C (calculated for a coverage factor k = 3), referring to the manufacturer's data at a temperature of 37°C. The calibration shall be traceable to national measurement standards. Each temperature value obtained for the probe in this way shall be compared to that indicated by the reference thermometer in the bath. The difference between these temperature values shall meet the requirements for maximum permissible errors as specified in paragraph 4(2).

(ii) The number of measurements required shall be the same as specified in paragraph 2(1)(ii) of Annexure A.

(3) *Indicating unit*

(i) The performance of an indicating unit shall be tested using a device that simulates the relevant physical properties of the appropriate probe type. The expanded measurement uncertainty of the simulating device shall not be greater than a value equivalent to 0.01°C (calculated for a coverage factor k = 3), referring to the manufacturer's data at a temperature of 37°C. The calibration shall be traceable to national measurement standards.

Note : For example, a calibrated decade resistance box may be used to provide a variable resistance to simulate a resistance-type probe. Values of resistance for input to the indicating unit over its specified measuring range shall be selected from the manufacturer's data of resistance versus temperature. Similarly, variable voltage sources may be used to simulate a thermocouple.

(ii) The difference between the temperatures displayed by the indicating unit and the corresponding simulated values of

temperature shall meet the requirements for maximum permissible errors specified in paragraph 4(2).

(iii) The number of measurements shall be the same as specified in paragraph 2(1)(ii) of Annexure A.

ANNEXURE B

BRIEF DESCRIPTION OF INSTRUMENT PERFORMANCE TESTS

(Mandatory)

1. Energy dissipation of a resistance-type interchangeable probe

(1) The probe shall be placed in a reference water bath as specified in paragraph 1(1) of Annexure A at a temperature of 37°C ± 1°C. Measurements shall be carried out at three or more DC currents with the highest power being 2mW. For each applied current, the voltage and current shall be measured.

(2) The equivalent resistance values shall be calculated and then converted to temperature values using the manufacturer's characteristic (resistance versus temperature) table for the probe type. A linear (least-squares fit) curve of temperature as a function of applied power shall be drawn. From this curve, power corresponding to the maximum energy dissipation that will cause a change in indicated temperature by 0.01°C for reusable, interchangeable, or single-use probes shall be determined. This value is the maximum power that may be provided by an indicating unit for the type of probe tested and the manufacturer's specified value shall be equal to or less than the value determined.

2. Electrical insulation resistance of the probe

(1) The resistance of the temperature probe shall be determined at one or more temperatures using the procedure specified in paragraphs 2(1)(i) or 2(2)(ii) of Annexure A. The probe shall then be immersed to a length equal to that intended to be in contact with the body, or 50 mm, whichever is greater, in a physiological saline solution (9.5g of NaCl per litre of distilled water).

(2) After at least one minute, the resistance between the electrical connections of the probe taken together and an electrode immersed in the physiological saline solution shall be measured using an instrument that applies a voltage of 10 V ± 1 V between the probe connections and the electrode. The resistance measured shall be greater than the shunt resistance that would correspond to a change in indicated temperature of 0.02°C.

(3) The probe shall be left in the physiological saline solution for 24 hours, after which its resistance shall be re-measured as specified in paragraph 2(1) of Annexure B. The difference in indicated temperature between measurements shall not be greater than 0.02°C.

3. Cleaning and disinfecting the probe

(1) The applied part of the temperature probe or of the complete compact thermometer shall be cleaned and disinfected twenty times according to the manufacturer's instructions.

(2) After cleaning and disinfecting as specified in paragraph 3(1) of Annexure B, the requirements of paragraph 4(2) shall be met.

4. Low battery indication

Note : Paragraphs 4 to 9 of Annexure B it is to be understood that the temperature indication of a complete thermometer shall be generated within the measuring range by inserting the probe in a reference water bath or in another bath with similar qualities. The temperature indication of an indicating unit designed for use with interchangeable probes shall be generated by replacing the probe by an auxiliary device, such as an appropriate precision resistor simulating the temperature of a resistance probe. The reference temperature indication is that obtained under the reference conditions described in paragraph 4(3).

(1) The battery shall be replaced by a variable DC voltage source.

(2) The voltage of the source shall be reduced unit a low battery indication or warning signal is activated at the level specified by the manufacturer. The test shall be carried out at three different temperatures; 37°C ± 1°C, and the lower and upper limits of the measuring range.

5. Ambient temperature

(1) The complete thermometer or indicating unit shall be placed in a test chamber, and the temperature of the chamber varied from 10°C to 40°C with each temperature setting constant within ± 2°C. Sufficient time shall be allowed at each temperature setting to permit the complete thermometer or indicating unit to reach thermal equilibrium with the chamber.

(2) At each temperature tested, the requirements specified in paragraph 4(2) shall be met.

6. Thermal shock

(1) The indicating unit shall be placed in a test chamber at - 5°C ± 2°C.

(2) After thermal equilibrium has been established, the complete thermometer or indicating

unit shall be placed in a test chamber at 50°C ± 2°C until thermal equilibrium has been established and all traces of condensed moisture have evaporated.

(3) The process described in paragraphs 6(1) and 6(2) of Annexure B shall be performed five times.

(4) The indicating unit shall be allowed to achieve thermal equilibrium at room temperature after which the indicated temperature shall not change by more than ± 0.1°C as a result of exposure to the thermal shocks described in paragraphs 6(1) and 6(2) by Annexure B.

Note : Thermal equilibrium may be achieved more quickly and completely by opening the casing of the thermometer, if possible.

7. Humidity

(1) The complete thermometer or indicating unit shall be stabilized at a temperature t within the range 20°C to 32°C for 4 hours or more. During this time, t shall remain constant within ± 2°C.

(2) After achieving a stable temperature as specified in paragraph 7(1) of Annexure B, the complete thermometer or indicating unit shall be placed in a humidity test chamber containing air at a temperature between t and t + 4°C and a relative humidity between 91% and 95% for a period of 48 hours.

(3) After exposure as specified in paragraph 7(2) of Annexure B, the complete thermometer or indicating unit shall be removed from the test chamber and allowed to stabilize at room temperature for 48 hours. The indicated temperature shall not vary by more than ± 0.1°C as a result of this test.

8. Electro-magnetic radiation interference

(1) The complete thermometer or indicating unit shall be exposed to an electromagnetic field with a field strength of 10 V/m at frequencies between 150 kHz and 500 MHz modulated by a 1 kHz sine wave and 80% amplitude modulation.

(2) The specific field strength shall be established prior to testing and without the instrument being placed in the electro-magnetic field. The field strength may be generated as follows :—

- a strip line for low frequencies (below 3 MHz) or in some cases 150 MHz) for small instruments,
- dipole antennas, or antennas with circular polarization, placed 1m from the instrument at higher frequencies.

(3) The field shall be generated with two orthogonal polarizations and then slowly scanned through the frequency range. Antennas with circular polarization may be used to generate the electro-magnetic field without a change in their positions. The test shall be carried out in a shielded enclosure to comply with international laws prohibiting interference with radio communications, but care shall be taken to minimize reflections.

(4) During the test, the requirements specified in paragraph 5(3)(vi) shall be met.

9. Mechanical shock

(1) The complete thermometer or indicating unit shall be allowed to fall from a height of 1m on to a hard surface (for example, a block of hard wood of density greater than 700 kg/m3 and of suitable size lying flat on a rigid base). The drop shall be performed once for three different orientations of the complete thermometer or indicating unit.

(2) After the test, the requirements specified in paragraph 5(3)(vii) shall be met.

ANNEXURE C

TEST OF WATER RESISTANCE OF COMPLETE THERMOMETERS

(Mandatory)

1. Pattern approval

(1) A total of 10 samples shall be tested.

(2) The battery casing shall be opened and closed several times before the tests if the thermometer is equipped with replaceable batteries.

(3) The thermometer shall be totally immersed in an equivalent physiological solution (9.5g NaCl per litre of distilled water) to a depth of 15 cm and at temperatures of 50°C and 20°C for the following periods of time and in the sequence indicated :—

- 1 hour at 50°C ± 2°C
- 1 hour at 20°C ± 2°C
- 24 hours at 50°C ± 2°C
- 24 hours at 20°C ± 2°C

(4) The indicated values shall be measured at two or more temperatures near the lower and upper limit of the measuring range before the first immersion and after the second and last immersion. The thermometers shall have reached equilibrium with room temperature before recording the indicated values. After the last immersion, the thermometers shall be stored for 14 days in air at room temperature before taking the last measurement.

(5) The test may be discontinued if it is obvious that water has penetrated into the casing of a thermometer.

(6) The thermometer pattern shall be declared to be water resistant if, for nine out of ten thermometers, the difference in indicated

temperatures for any individual thermometer is less than—

- 0.04°C for thermometers with a minimum digital increment of 0.01°C (class I),
- 0.1°C for thermometers with a minimum digital increment of 0.1°C (class II).

2. Verification

(1) The thermometers shall be totally immersed in an equivalent physiological solution at a temperature of 50°C ± 2°C to a depth of 15 cm for one hour, after which they shall be immersed for another hour under same conditions but at a temperature of 20°C ± 2°C. Before the first immersion and after the second immersion, the indicated values shall be measured at two temperatures.

(2) A thermometer shall be accepted if the performance requirements specified in paragraph 1(6) are met.

ANNEXURE D

CLINICAL TEST OF RESPONSE TIME

(Mandatory)

1. Non-predicting clinical electrical thermometers

The minimum time for achieving thermal equilibrium at each appropriate body site shall be determined on the basis of testing at least ten persons.

2. Predicting (calculating) clinical electrical thermometers

(1) The difference between the displayed calculated temperature and the corresponding measured temperature at thermal equilibrium of a calculating (predicting) thermometer shall be determined on the basis of testing at least 100 persons. The predicted temperature of each person at an appropriate body site shall be determined by the method specified by the manufacturer. After the predicted indication, the thermometer shall remain at the site for measuring and indicating the actual temperature of its sensor. The total time allowed shall be sufficient to attain thermal equilibrium. The difference in the first and second indicated temperatures for 95% of the persons tested shall not be more than 0.2°C.

(2) If an oral (sublingual) test has been carried out, the minimum number of persons required for rectal measurement shall be twenty.

PART VII

MANOMETERS OF INSTRUMENTS FOR MEASURING ARTERIAL BLOOD PRESSURE (SPHYGMOMANOMETARS)

PART VII-A

NON-INVASIVE MECHANICAL SPHYGMOMANOMETERS

1. Scope

This Part specifies general performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive mechanical sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure. The application of the cuff is not limited to a particular extremity of the human body (e.g. the upper arm).

Within the scope of this specification are sphygmomanometers with a mechanical pressure sensing element and display, used in conjunction with a stethoscope or other manual methods for detecting Korotkoff sounds and for cuff inflation.

Note : Luer locks shall not be used with these devices.

2. Terminology

(1) Bladder :

The inflatable component of the cuff is called bladder.

(2) Pressure in a blood vessel :

It refers to pressure in the arterial system of the body.

(3) Cuff :

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

(4) Diastolic blood pressure (value) :

The minimum value of the arterial blood pressure as a result of relaxation of the systemic ventricle is called diastolic blood pressure.

Note : Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

(5) *Mean arterial blood pressure (value)* :

It is the value of the integral of one cycle of the blood pressure curve divided by the time of one heart beat period.

Note : Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

(6) *Non-invasive blood pressure measurement* :

Indirect measurement of the arterial blood pressure without arterial puncture is called non-invasive blood pressure measurement.

(7) *Pneumatic system* :

A system that includes all pressurized and pressure-controlling parts such as cuff, tubing, connectors, valves, transducer and pump is called pneumatic system.

(8) *Sleeve* :

It is essentially inelastic part of the cuff that encloses the bladder.

(9) *Sphygmomanometer* :

It is an instrument used for the non-invasive measurement of the arterial blood pressure.

(10) *Systolic blood pressure (value)* :

The maximum value of the arterial blood pressure as a result of the contraction of the systemic ventricle is called systolic blood pressure.

Note : Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

(11) Mechanical sphygmomanometer :

The sphygmomanometer which uses either a mercury or an aneroid manometer or another mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff, is called mechanical sphygmomanometer.

(12) Auscultatory method :

It is that technique whereby sounds (known as Korotkoff sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with the systolic blood pressure and the disappearance of sounds with the diastolic blood pressure in adults. In children under age of 13, "k4" (i.e. 4th phase Korotkoff sound) may be appropriate.

(13) Deflation valve :

The valve used for controller exhaust of the pneumatic system during measurement.

(14) Rapid exhaust valve :

The valve used for rapidly exhausting the pneumatic system.

(15) Tamper proofing :

It is that means of preventing the user from gaining easy access to the measuring mechanism of the device.

3. Description of the category of instrument

The basic components of a sphygmomanometer are a cuff and bladder that can be wrapped around a patient's limb, a manual system for applying and releasing pressure to the bladder, and a means of measuring and displaying the instantaneous pressure in the bladder. Mechanical sphygmomanometers, which use either mercury or an aneroid manometer or another mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.

Notes : Components of these devices are manometer, cuff, valve for deflation (often in combination with rapid exhaust valve), hand pump or electro-mechanical pump and connection hoses. These devices may also contain electro-mechanical components for pressure control.

4. Units of measurement

The blood pressure shall be indicated either in kilo-Pascal (kPa) or in millimetres of mercury (mmHg).

5. Metrological requirements

(1) Maximum permissible errors of the cuff pressure indication

(I) *Under ambient conditions*

For any set of conditions within the ambient temperature range of 15°C to 25°C and the relative humidity range of 20% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use. Testing shall be carried out in accordance with paragraph 1 of Annexure A.

(II) *Under storage conditions*

The sphygmomanometer shall maintain the maximum permissible error requirements specified in this paragraph 5(1)(i) after storage for 24 h at a temperature of –20°C and for 24h at a temperature of 70°C and a relative humidity of 85% (non-condensing). Testing shall be carried out in accordance with paragraph 3 of Annexure A.

(III) *Under varying temperature conditions*

For the ambient temperature range of 10°C to 40°C and the relative humidity of 85% (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed ± 0.4 kPa (± 3 mmHg). Testing shall be carried out in accordance with paragraph 2 of Annexure A.

6. Technical requirements

(1) Technical requirements for the cuff and bladder

The cuff shall contain a bladder. For

reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents.

Note : 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. Use of the wrong size can affect the accuracy of the measurement.

(2) Technical requirements for the pneumatic system

(i) *Air leakage*

Air leakage shall not exceed a pressure drop of 0.5 kPa/min (4 mmHg/min).

Testing shall be carried out in accordance with paragraph 4 of Annexure A.

(ii) *Pressure reduction rate*

Manually operated deflation valves shall be capable of adjustment to a deflation rate from 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s). Manually operated deflation valves shall be easily adjusted to these values. Deflation valves shall be tested in accordance with paragraph 5 of Annexure A.

(iii) *Rapid exhaust*

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

Testing shall be carried out in accordance with paragraph 6 of Annexure A.

(3) Technical requirements for the pressure indicating devices

(i) *Nominal range and measuring range*

The nominal range shall be equal to the measuring range.

The nominal range for the cuff gauge pressure shall extend from 0 kPa to at least 35 kPa (0 mmHg to at least 260 mmHg).

(ii) *Analogue indication*

(a) Scale

The scale shall be designed and arranged so that the measuring values can be read clearly and are easily recognized. Testing shall be carried out by visual inspection.

(b) First scale mark

The graduation shall begin with the first scale mark at 0 kPa (0 mmHg).

Testing shall be carried out by visual inspection.

(c) Scale interval

The scale interval shall be—

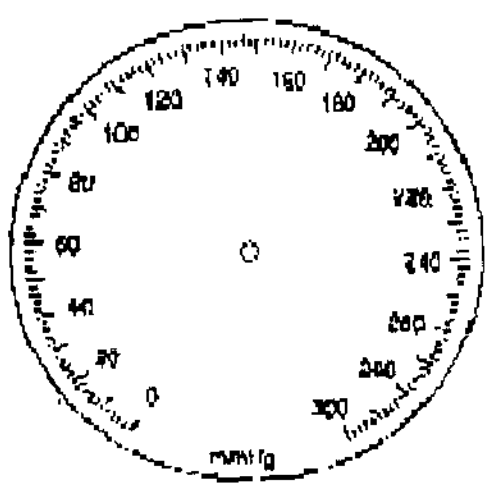
- 0.2 kPa for a scale graduated in kPa; or
- 2 mmHg for a scale graduated in mmHg. Each fifth scale mark shall be indicated by greater length and each tenth scale mark shall be numbered. An example of a scale in mmHg is given in Figure 1. Testing shall be carried out by visual inspection.

(d) Scale spacing and thickness of the scale marks

The distance between adjacent scale marks shall be not less than 1.0 mm. The thickness of the scale marks shall not exceed 20% of the smallest scale spacing.

All scale marks shall be of equal thickness.

Testing shall be carried out in accordance with paragraph 7 of Annexure A.



(Figure 1 Example of an aneroid manometer scale division in mmHg without a tolerance zone at zero)

(4) Additional technical requirements for mercury manometers

(i) *Internal diameter of the tube containing mercury*

The nominal internal diameter of the mercury tube shall be at least 3.5 mm. The tolerance on diameter shall not exceed ± 0.2 mm.

Testing shall be carried out in accordance with paragraph 8 of Annexure A.

(ii) *Portable devices*

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

Testing shall be carried out by visual inspection.

(iii) *Devices to prevent mercury from being spilled during use and transport*

A device shall be placed in the tube to prevent mercury from being spilled during use and transport (for example: stopping device, locking device, etc.). This device shall be such that when the pressure in the system drops rapidly from 27 kPa to 0 kPa (from 200 mmHg to 0 mmHg), the time taken for the mercury column to fall from 27 kPa to 5 kPa (from 200 mmHg to 40 mmHg) shall not exceed 1.5 s. This time is known as the "exhaust time".

Testing shall be carried out in accordance with paragraphs 9 and 10 of Annexure A.

(iv) *Quality of the mercury*

(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.

(v) *Graduation of the mercury tube*

Graduations shall be permanently marked on the tube containing mercury.

If, numbered at each fifth scale mark, the numbering shall be alternately on the right and left-hand side of, and adjacent to, the tube.

Testing shall be carried out by visual inspection.

(5) Additional technical requirements for aneroid manometers

(i) *Scale mark at zero*

If a tolerance zone is shown at zero it shall not exceed ± 0.4 kPa (± 3 mmHg) and shall be clearly marked.

A scale mark at zero shall be indicated.

Note : Graduations within the tolerance zone are optional.

Testing shall be carried out by visual inspection.

(ii) *Zero*

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

Neither the dial nor the pointer shall be adjustable by the user. Testing shall be carried out by visual inspection.

(iii) *Pointer*

The pointer shall cover between 1/3 and 2/3 of the length of the shortest scale mark of the scale. At the place of indication it shall be not thicker than the scale mark. The distance between the pointer and the dial shall not exceed 2 mm. Testing shall be carried out by visual inspection.

(iv) *Hysterisis error*

The hysterisis error throughout the pressure range shall be within the range 0 kPa to 0.5 kPa (0 mmHg to 4 mmHg). Testing shall be carried out in accordance with paragraph 11 of Annexure A.

(v) *Construction and materials*

The construction of the aneroid manometer and the material for the elastic sensing elements shall ensure an adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature. After 10,000 alternating pressure cycles the change in the pressure indication of the aneroid manometer shall be not more than 0.4 kPa (3 mmHg) throughout the pressure range.

Testing shall be carried out in accordance with paragraph 12 of Annexure A.

(6) Safety requirements

(i) *Resistance to vibration and shock*

The sphygmomanometer shall comply with the requirements of paragraph 5(1)(i).

(ii) *Mechanical safety*

It shall be possible to abort the blood pressure measurement at any time by activating the manual rapid exhaust valve, which shall be easily accessible.

(iii) *Tamper proofing*

Tamper proofing of the manometer shall be achieved by requiring the use of a tool or breaking a seal.

Testing shall be carried out by visual inspection.

7. Metrological controls

(1) Model approval

At least three samples of a new type of sphygmomanometer shall be tested. The tests to verify conformity to metrological and technical requirements shall be carried out according to Annexure A.

(2) Verification

(i) *Initial verification*

At initial verification the requirements of paragraphs 5(1)(i), 6(2)(i) and 6(4)(iv) shall be fulfilled.

Testing shall be carried out according to paragraphs 1, 4 and 11 of Annexure A.

(ii) *Subsequent verification*

Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repair. Requirement of paragraphs 5(1)(i) and 6(2)(i) shall be fulfilled and tests must be carried out according to paragraph 1 of Annexure A.

(3) Sealing

(i) Control marks will be put on lead seals for which corresponding punched screws shall be attached whenever necessary. These seals shall prevent, without destruction of the control marks:

- in the case of mercury manometers: the separation of reservoir and scale;
- in the case of all other manometers: the opening of the casing.

(ii) If the construction of the instrument guarantees security against any interference, the metrological control marks or the security marks may be attached in form of labels.

(iii) All seals shall be accessible without using a tool.

(4) Marking of the device

The device shall be marked with the following information:—

- name and/or trademark of manufacturer;
- serial number and year of fabrication;
- measuring range and measuring unit;
- model approval number;
- centre of the bladder, indicating the correct position for the cuff over the artery; and
- marking on the cuff indicating the limb circumference for which it is appropriate in paragraph 6(1).
- The following additional markings are required for mercury manometers:—
- indication of the internal nominal diameter and the tolerance of the tube containing mercury in paragraph 6(4)(i).

(5) Manufacturer's information

(i) The manufacturer's instruction manual shall contain the following information:—

(a) explanation of the operating procedures which are important for correct application (such as the selection of the appropriate cuff size, positioning of the cuff and adjustment of the pressure reduction rate);

(b) a warning to users of equipment intended for use in environments employing intravascular fluid systems not to connect the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used;

(c) methods for cleaning reusable cuffs;

(d) nature and frequency of the maintenance required to ensure that the device operates correctly and safely at all times; it is recommended that the performance should be checked at least every 2 years and after maintenance and repair, by re-verifying at least the requirements in paragraphs 5(1)(i), 6(2)(i) (testing