BRITISH STANDARD

BS 691:1987
Incorporating Amendments Nos. 1 and 2

Specification for

Sub-normal range, ovulation and dual-scale clinical maximum thermometers (mercury-in-glass, solid stem)

ICS 11.040.50

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Laboratory Apparatus Standards Committee (LBC/-) to Technical Committee LBC/4 upon which the following bodies were represented:

British Laboratory Ware Association
British Lampblown Scientific Glassware Manufacturers Association Ltd
British Medical Association
Department of Health and Social Security
Department of Trade and Industry, National Physical Laboratory
Institute of Petroleum
Medical Sterile Products Association
Ministry of Defence

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The following BSI references relate to the work on this standard:
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Contents

Foreword

This British Standard has been prepared under the direction of the Laboratory Apparatus Standards Committee and supersedes BS 691:1979 which is withdrawn. It was first published in 1936, and was intended to specify requirements for a first grade clinical thermometer for general use. Experience showed, however, that certain of the provisions regarding dimensions and markings were too restrictive to be generally acceptable, although the specification undoubtedly played an important part in improving the quality of clinical thermometers generally.

A revised edition was issued in 1953 containing a simplified specification while at the same time retaining sufficient dimensional and other provisions to ensure a good quality instrument. Three types of cylindrical bulbs were specified, the thermometers being designated "quick", "medium" and "stubby" respectively.

Another revision was issued in 1961 in which the requirements were further simplified and the less essential ones were recommended for the guidance of manufacturers instead of being mandatory. The "medium" type of bulb was omitted as being no longer required, and the term "long" was preferred for the "quick" type, in keeping with the policy of avoiding any designation relating to measuring period (see below). A "pear-shaped" bulb was also included, this being mainly for rectal use.

Another revision was issued in 1966 in which the "pear-shaped" bulb thermometer was omitted owing to lack of demand, leaving only two types of bulb for ordinary range thermometers, namely the "long" and "stubby" types, the latter being suitable for both oral and rectal use. For rectal applications a bulb of blue glass was specified.

A subnormal range thermometer was added to this edition to cover the medical requirements associated with cases of accidental hypothermia. The British Medical Association recommended the inclusion of this type of thermometer and a specification was evolved as a result of consultation with that association and the thermometer manufacturers. Only the "stubby" type of bulb was specified for the subnormal range thermometer.

A further change in that revision was that the "lens-front" stem was specified, for ease of reading, and for the same reason the wording of the clause that specified graduation and the figuring was modified to ensure that the scale lines, the numbers, and the magnified image of the mercury column were all readily visible at the same time. Considerable attention was given to the test for the permanence of pigment, in view of the many different sterilizing solutions used in hospitals for disinfecting and storing thermometers. The phenol solution which was specified, while unlikely to be used for this purpose in practice, was shown to provide a rapid test which indicated satisfactorily the performance of the markings under most conditions of use.

Amendments to the 1966 edition were issued in 1967, 1968, 1973 and 1974.

With the publication by the International Organization of Legal Metrology (OIML) of International Recommendation No. 7 and its subsequent implementation in an EEC Directive relating to clinical maximum thermometers (76/764/EEC)[1)] it was decided to align BS 691 with that Directive, and a revision to that effect dividing the specification into the following three sections, was published in 1979.

— Section 1: Thermometers for general use;

— Section 2: Subnormal range thermometers;

— Section 3: Ovulation thermometers.

[1)] Council Directive of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass maximum reading thermometers, which was repealed by Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Technical differences between the 1966 and 1979 editions included the addition of the ovulation thermometers, an increase in the recommended overall length from 100 mm to 110 mm, the addition of a requirement for the response interval, a tightening of the accuracy requirements, and withdrawal of thermometers with Fahrenheit scales.

The 1987 edition reflected the continuous demand for clinical thermometers graduated also with the Fahrenheit scale. This edition introduces a dual-scale (Celsius and Fahrenheit) thermometer deemed not to conflict with the Council Directive 93/42/EEC of 14 June 1993.

The EEC Directive gives requirements for solid-stem and enclosed-scale types of clinical maximum reading thermometers. Requirements for the solid-stem type of clinical maximum reading thermometers, excluding the normal thermometer for general use, are given in this British Standard as amended by Amendment No. 2. Requirements for normal thermometers for general use are given in BS EN 12470-1. Requirements for the enclosed-scale clinical maximum reading thermometers are the subject of BS 6985.

Measuring period. The term "½ min" or "1 min" are sometimes used to distinguish the different sizes of bulbs of clinical thermometers not made in accordance with this British Standard. Experience has shown that these terms bear no relation to the actual time required for the thermometer to take up the deep body temperature; this time depends on the physical condition of the patient, the skill with which the thermometer is placed in position, the initial temperature of the thermometer and other factors.

For this reason, no "measuring period" indication is permitted on British Standard clinical thermometers. To avoid possible misunderstanding on this point, it is specified that a printed slip which includes the explanatory wording given in clause **13** shall accompany every British Standard clinical thermometer (except those supplied in bulk to hospitals and similar institutions).

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 12, an inside back cover and a back cover.

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1 Scope

This British Standard specifies requirements for three types of mercury-in-glass clinical maximum thermometers of the solid-stem type, intended for the measurement of deep body temperature of human beings.

The types are as follows:

a) subnormal temperature range thermometers;

b) ovulation thermometers;

c) dual-scale (i.e. Celsius and Fahrenheit) thermometers intended for general use.

NOTE 1 Requirements for normal thermometers for general use are given in BS EN 12470-1.

NOTE 2 The titles of the publications referred to in this standard are listed on the inside back cover.

2 Temperature scales

The thermometers shall be graduated in accordance with the Celsius scale as defined in the current definition of the International Temperature Scale adopted by the General Conference of Weights and Measures (CGPM).

The dual-scale thermometers shall, in addition, be graduated in accordance with the Fahrenheit scale.

3 Type of thermometer

British Standard clinical thermometers shall be of the mercury-in-glass type with a solid stem of "lens-front" section and shall be provided with an enamel back.

The thermometers shall be provided with a maximum reading device that prevents the mercury column from falling when the mercury in the bulb returns to the surrounding temperature.

4 Scale ranges and scale intervals

4.1 Scale ranges

The scale ranges shall not exceed the ranges specified in Table 1, and shall include scale lines at the temperatures, specified in Table 1 for the thermometer type concerned.

4.2 Smallest scale divisions

The smallest scale divisions shall be as specified in Table 1 for the thermometer type concerned.

4.3 Linear scale equivalent

The distance representing one Celsius degree on the scales shall be not less than the lengths specified in Table 1 for the thermometer type concerned.

5 Material

5.1 Glass: general requirements

The thermometers shall be made of suitable thermometric glasses selected and processed so that the finished instruments shall have the following characteristics.

a) Stress in the glass of the bulb and stem shall be reduced to a level sufficient to minimize the possibility of fracture as a result of mechanical or thermal shock.

b) When tested in accordance with BS 3473-2, the quantity of alkali obtained in solution from 1 g of the glass shall not exceed 263.5 4 μg of Na_2O, i.e. the glass shall be a class 3 glass.

5.2 Glass for the bulb

5.2.1 *Zero point depression*. When determined by the method given in Appendix A, the glass from which the bulb is made shall have a depression of zero not exceeding 0.05 °C after exposure to a temperature of 100 °C.

5.2.2 *Rectal use*. Any thermometer intended for rectal use shall be of the "stubby" type (see **6.1.2**) identified preferably by having a bulb of blue glass but alternatively by means of readily-visible permanent blue colouration introduced at the top of the thermometer and above the highest scale line.

5.2.3 *Stabilization*. The bulb glass shall be stabilized by a suitable heat treatment.

5.3 Liquid filling

Mercury shall be used.

In order to ensure that the thermometer functions correctly, the mercury, together with the bulb, and capillary tube shall be free of gas, glass fragments, foreign bodies and moisture.

6 Manufacture

6.1 General requirements

6.1.1 *Freedom from faults*. The thermometer shall be free from faults that are likely to interfere with its proper functioning or to mislead the user, including flaws in the glass, errors in dividing or figuring, constructional defects or gas trapped in the bulb and/or mercury column.

6.1.2 *Bulb pattern*. The bulb shall be of either the "long" or "stubby" pattern for the thermometer type concerned, ensuring that at the join with the stem the diameter does not reduce to create a pear shape. (See Table 1.)

The diameter of the bulb shall be not greater than the distance between the front and back surfaces of the lens in the stem cross section (see Figure 3).

6.1.3 *Bulb alignment*. The bulb shall be in alignment with the stem.

6.1.4 *Ends*. The ends of the thermometer shall be smoothly rounded.

Table 1 — Requirements for thermometer types

Clause	Requirement	Thermometer type			
		Subnormal	Ovulation	Dual-scale	
4.1	Scale range (max.),	16 °C	4 °C	8 °C and 15 °F	
	Scale lines at:	25 °C and 40 °C	35 °C and 38 °C	35 °C and 42 °C	95 °F and 108 °F
4.2	Smallest scale division	0.2 °C	0.1 °C max.	0.1 °C and 0.2 °F	
4.3	Linear scale equivalent per °C, min.	2 mm	8 mm	5 mm	
6.2.1	Constriction test temperature min.	40 °C	38 °C	40 °C	
7.2	Scale lines at:	1 °C	0.5 °C and 1 °C	0.5 °C and 1 °C	1 °F and 2 °F
	Length constraint	Longer than those at 0.2 °C	Longer than those at the smallest scale division	Longer than those at 0.1 °C	Longer than those at 0.2 °F
7.3	Scale lines numbered at:	Preferably every 5 °C	Every 1 °C	Every 1 °C and every 2 °F	
	Distinguishing mark	No	No	Yes	
7.4	Number of fully-figured scale lines	All	At least two	At least two on each scale	
7.8	Nominal height of numerals	2 mm	2 mm	1.75 mm	
9	Maximum permissible error	± 0.30 °C	± 0.10 °C	± 0.10 °C – 0.15 °C	
10	Overall length	110^{+2}_{-5} mm	110^{+2}_{-5} mm	110^{+2}_{-5} mm	
	Minimum stem diameter	4 mm	4 mm	4 mm	
6.1.2	Bulb pattern	**"Stubby"**	**"Long"**	**"Long"**	**"Stubby"**
10	Bulb length	9 mm max.	15 mm max.	12 mm to 18 mm	9 mm max.
	Bulb diameter	2.5 mm to 5.0 mm	3.5 mm to 5.5 mm	2.0 mm to 3.5 mm	2.5 mm to 5 mm

6.1.5 *Surface condition*. The surface of the stem and bulb shall be free of cavities that are likely to harbour micro-biological contamination.

6.2 Constriction

6.2.1 *Temperature indication*. There shall be a constriction in the bore below the lowest scale range such that when the thermometer, at ambient temperature, is held in a vertical position with the bulb downwards, after exposure to a temperature of at least that given in Table 1 for the thermometer concerned, it shall indicate the temperature to which it was exposed within the limits of the maximum permissible error specified in clause **9**.

6.2.2 *Return of mercury column*. To ensure that the mercury shakes through the constriction without undue effort when the thermometer is being reset, the mercury column shall pass completely below the lowest scale line when the thermometer is subjected to an acceleration of 600 m/s^2 at the base of the bulb after heating to a temperature of at least 37 °C and returning to normal room temperature.

7 Scale lines and figuring (see Figure 1)

7.1 Marking and thickness

The scale lines shall be either clearly etched or otherwise durably marked (see clause **8**) and shall be of a uniform thickness not less than 0.15 mm and not greater than 0.25 mm.

7.2 Length

The scale lines at the temperature positions given in Table 1 shall be subjected to the constraints given in Table 1, according to the thermometer type concerned.

NOTE For types A and B it is recommended that the scale lines at each 1 °C and 0.5 °C (if applicable) position should be nominally 2 mm in length and that those at the smallest scale division should be nominally 1.5 mm in length.

NOTE For type C it is recommended that the scale lines at each 1 °C, 0.5 °C and 1 °F should be nominally 1.5 mm in length and those of the smallest scale division should be nominally 0.75 mm in length.

7.3 Numbering

The scale lines shall be numbered at each of the temperature positions given in Table 1 for the thermometer type concerned. If so indicated in Table 1, the scale lines shall be either augmented or replaced at 37 °C (98.6 °F) by a distinguishing mark (e.g. an arrow) to denote "normal" deep body temperature.

7.4 Figuring

The number of scale lines that shall be fully figured is given in Table 1 for the thermometer type concerned. Partial figuring (e.g. the numeral "6" to represent 36 °C) shall be permitted for the remainder.

7.5 Orientation

The scale lines shall be at right angles to the axis of the thermometer.

7.6 Extent

Except for the dual-scale type thermometer, one end of each of the longest scale lines shall extend as closely as practicable to the magnified image of the mercury column.

NOTE It is recommended that those ends of the shortest scale lines that are closer to the mercury column should not be separated from the nearer edge of the image of the magnified mercury column by more than half the magnified width of the mercury column (see Figure 2).

7.7 Alignment

Those ends of the scale lines that are farther from the magnified image of the mercury column shall finish on a line parallel with the axis of the thermometer.

Dual-scale thermometers are exempt from this requirement.

7.8 Numerals

When the thermometer is viewed in a horizontal position with the bulb to the viewer's left (see Figure 1 for the preferred style of scale lines and figuring), the numerals shall be upright and shall be so placed that they would be bisected by their corresponding scale lines if these were extended. They shall be either clearly etched or otherwise permanently marked, shall have the nominal height given in Table 1 for the thermometer type concerned, and shall be visible at the same time as the magnified image of the mercury column.

NOTE Two short lines, both parallel to the axis, or other suitable marks, may be provided to assist the user to locate the mercury column more readily.

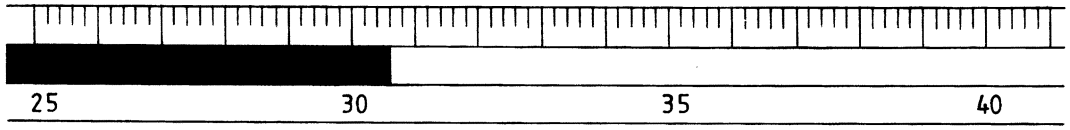
8 Permanence of pigment

The appearance of the scale lines and figuring shall not be significantly affected when the stem of the thermometer is immersed for 20 min in a 50 g/L aqueous phenol solution at 38 °C and then wiped dry.

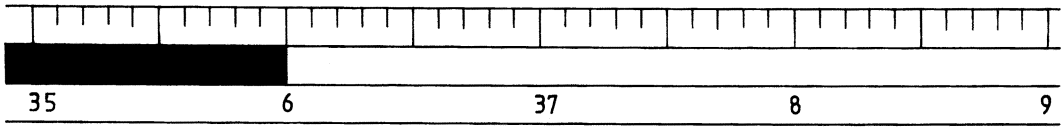
NOTE In order to assess compliance with the requirements of clause **8**, it is recommended that for large batches a single sampling plan for normal inspection at general inspection level I, as given in BS 6001-1:1999 and shown in Table 2, is used together with an acceptable quality level (AQL) of 0.10, provided that the sample is selected at random from the whole batch. If one or more thermometers from the sample is significantly affected the whole batch should be rejected.

Table 2 — Size of sample

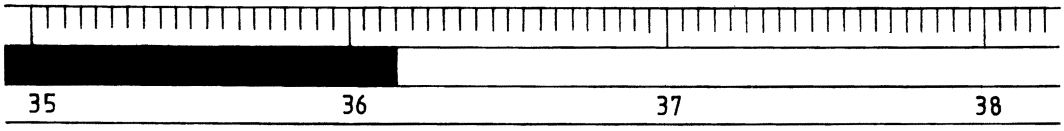
Batch size			Number sampled and tested
1 201	to	3 200	125
3 201	to	10 000	125
10 001	to	35 000	125
35 001	to	150 000	200



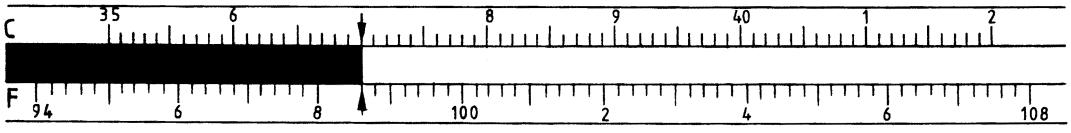
(a) Subnormal range thermometer



(b) Ovulation thermometer, divided to 0.1 °C



(c) Ovulation thermometer, divided to 0.05 °C



(d) Dual scale thermometer, divided to 0.1 °C and 0.2 °F

NOTE 1 In order to avoid overcrowding of numerals, some partial figuring is permitted for general use thermometers and ovulation thermometers to improve the clarity of reading (see **7.4**).

Figure 1 — Examples of preferred style of graduation and numbering

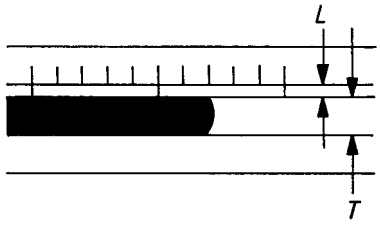


Figure 2 — Examples of graduation showing the position of the scale lines relative to the enlarged image of the mercury column where L is less than 0.5 T (see 7.6)

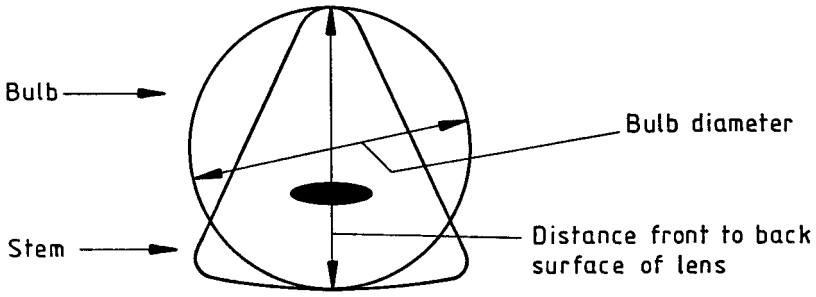


Figure 3 — Maximum bulb diameter

9 Maximum permissible errors

After immersion in a testing bath at any temperature within the range of the thermometer, followed by return to an ambient temperature of between 15 °C and 30 °C, the temperature shown shall be that of the testing bath to within the limits given in Table 1 for the thermometer type concerned. In the case of the dual scale type, the reading on the Fahrenheit scale shall in addition be within 0.1 °F of the comparable equivalent reading on the Celsius scale.

10 Dimensions

The recommended dimensions shall be as specified in Table 1 for the thermometer type and bulb pattern concerned.

11 Influence of immersion time

NOTE This is a laboratory test and there is no direct relationship to the measuring period in medical use.

When the thermometer, at an ambient temperature (t_1) of between 15 °C and 30 °C is suddenly immersed for 20 s in a vigorously stirred water bath at a constant temperature (t_2) between 35.5 °C and 42 °C, withdrawn and cooled to ambient temperature, the reading:

a) shall be within the limits of the maximum permissible error;

b) shall not differ by more than 0.005 ($t_2 - t_1$) from the stabilized reading for temperature t_2.

12 Inscriptions

12.1 Each thermometer shall have the following information permanently and legibly marked on it:

a) the symbol "°C" and, on dual scale thermometers only, the symbol "°F", in both cases adjacent to the relevant scale;

b) the manufacturer's name or mark;

c) the number of this British Standard, i.e. BS 691[2)];

d) the identification of the bulb glass, e.g. coloured stripe or stripes on the bulb or an approved abbreviation on the stem;

e) if required, the vendor's name or readily identifiable mark;

f) if required, an identification number.

12.2 *Text deleted*

12.3 A "measuring period" indication shall not be marked on the thermometer.

13 Accompanying slip

Except for those supplied in bulk to hospitals and similar institutions, no clinical thermometer complying with the requirements of this British Standard shall be distributed or sold unless accompanied by a printed slip bearing the manufacturer's name, address and guarantee of accuracy together with the following wording.

"Notes on the use of thermometers complying with BS 691, *Specification for sub-normal range, ovulation and dual-scale clinical maximum thermometers (mercury-in-glass, solid stem).*

The time taken for a clinical thermometer to indicate the deep body temperature depends much more on the patient, on his or her condition and on the method of using the thermometer than on the thermometer itself. To avoid the danger of misleading the user, therefore, British Standard thermometers do not carry any inscription for the time required to take a temperature. No error will be caused by leaving the thermometer longer than necessary to reach a maximum temperature but, with too short a time, it will indicate too low a temperature. When the thermometer is used in the mouth, about 2 min to 4 min will probably be sufficient.

In high or low ambient air temperature conditions, a thermometer used in the mouth will give a misleading value for deep body temperature, even after 4 min. This is due to the effect of the external air temperature on the temperature of the tissues of the mouth.

All thermometers specified in BS 691 are constructed with a solid stem of "lens-front" section. By slowly rotating the thermometer about its long axis, a position will be obtained where a magnified image of the mercury column is aligned with the scale lines, thus assisting the user to read the temperature or to interpolate between scale lines.

[2)] Marking BS 691 on or in relation to a product is a claim by the manufacturer that the product has been manufactured to the requirements of the standard. The accuracy of such a claim is therefore solely the manufacturer's responsibility. Enquiries as to the availability of third party certification should be addressed to the appropriate certification body.

It should be noted that the value now recommended by the British Medical Association to represent the "normal" deep-body temperature is 37 °C (98.6 °F). Whilst this value is the generally recognized "normal" temperature it should be emphasized that it is the "average" temperature of deep-body tissues for most healthy people at rest in a neutral temperature environment.

BS 691 specifies requirements for three models of clinical maximum thermometers, for specialized purposes. These are:

a) thermometers covering the range 25 °C to 40 °C, for measuring subnormal temperatures (as in hypothermia);

b) ovulation thermometers, covering the range 35 °C to 38 °C, for use as an aid to conception or contraceptive purposes. As these thermometers are used in general for detecting small temperature changes over a period of time, care should be taken to ensure that the sequence of readings is made with the same instrument and using the same procedure throughout.

It is recommended that these thermometers be used in conjunction with charts and information obtainable from thermometer manufacturers and local Marriage Guidance and Family Planning Authorities;

c) dual scale thermometers covering the ranges 35 °C to 42 °C and 95 °F to 108 °F, for general use.

In accordance with HM Government's policy on metrication, thermometers with Fahrenheit scales only are no longer specified in BS 691, having been withdrawn in 1979."

Appendix A Determination of the average zero point depression

A.1 Construction of test thermometers

Using the glass under consideration for the bulb, construct test thermometers with the following specifications:

scale range at least:	– 3.0 °C to + 3.0 °C;
scale interval:	0.02 °C, 0.05 °C or 0.1 °C;
distance between consecutive scale lines:	at least 1.0 mm;
expansion chamber:	of sufficient volume for the thermometer to be heated to 400 °C without damage;
stabilization:	thermometers stabilized (see **A.2**).

A.2 Confirmation of stabilization

A.2.1 Heat the thermometer in a liquid bath or metal block oven from room temperature to 350 ± 10 °C and keep it at this temperature for at least 5 min.

A.2.2 Cool the thermometer at a rate between 10 °C/h and 15 °C/h to 50 °C.

A.2.3 Remove the thermometer from the bath or oven, determine the correction[3)] at a temperature of 0 °C and record its value (K_1).

A.2.4 Heat the thermometer again to a temperature of 350 ± 10 °C, and keep it at this temperature for 24 h.

A.2.5 Cool the thermometer as in **A.2.2**.

A.2.6 Redetermine the correction as in **A.2.3** and record its value (K_2).

A.2.7 If the difference between K_1 and K_2 exceeds 0.15 °C, reject the samples, carry out the stabilization of fresh samples and repeat the procedure in **A.2.1** to **A.2.6**. If the difference between K_1 and K_2 is 0.15 °C or less carry out the depression of zero test as in **A.3**.

A.3 Depression of zero test

A.3.1 Select m stabilized test thermometers (where m is not less than 3), tested according to **A.2**, which have not subsequently been heated above room temperature, and carry out the following procedure (see **A.3.2** to **A.3.5**) for each of the thermometers in the batch.

A.3.2 Heat the thermometer to a temperature of 100 ± 1.0 °C, keep it at this temperature for 30 min, remove it from the test bath and allow it to cool to room temperature without the bulb touching any object. Determine the correction at a temperature of 0 °C within 15 min of its removal from the test bath and record its value (K_3).

A.3.3 Keep the thermometer at a temperature of between 20 °C and 25 °C for seven days, determine the correction at a temperature of 0 °C and record its value (K_4).

A.3.4 Repeat the procedure in **A.3.2** and determine K_5; repeat the procedure in **A.3.3** and determine K_6; repeat the procedure in **A.3.2** and determine K_7.

A.3.5 Further repetitions of the procedure in **A.3.3** and **A.3.2** may be carried out to obtain corrections up to K_{2n} and K_{2n+1}, where n (the number of zero depressions obtained) is greater than 3.

[3)] The algebraic difference between the temperature 0 °C and the temperature indicated by the thermometer, i.e. correction = 0 − indicated temperature.

A.4 Expression of results

A.4.1 Calculate the average depression of zero from the following expression

$$\frac{1}{mn}\sum_{i=1}^{i=m}(K_{2i}-K_{3i})+(K_{4i}-K_{5i})+(K_{6i}-K_{7i})+\ldots$$

$$\ldots+(K_{2ni}-K_{2n+1\,i})$$

where

i is the number of the test thermometer;

m is the total number of test thermometers;

n is the number of zero depressions obtained.

A.4.2 If the standard deviation of the mn values of zero depression obtained is less than 0.01 °C, report the average depression of zero as calculated in **A.4.1**.

Publications referred to

BS 3473-2, Chemical resistance of glass used in the production of laboratory glassware — Part 2: Method for determination of hydrolytic resistance of glass grains at 98 °C.

BS 6001-1:1999, Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.

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