# SLOVENSKI STANDARD
# SIST EN 12470-1:2000

**01-julij-2000**

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**Klinični termometri – 1. del: Zaprti stekleni termometri s tekočimi kovinami**

Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device

Medizinische Thermometer - Teil 1: Mit metallischer Flüssigkeit gefüllte Glasthermometer mit Maximumvorrichtung



Thermometres médicaux - Partie 1: Thermometres a dilatation de liquide métallique dans une gaine de verre, avec dispositif a maximum



**Ta slovenski standard je istoveten z:** **EN 12470-1:2000**

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**ICS:**

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| 11.040.55 | Diagnostična oprema | Diagnostic equipment |

**SIST EN 12470-1:2000** **en**

# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

**EN 12470-1**

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English version

# Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device

Thermomètres médicaux - Partie 1: Thermomètres à dilatation de liquide métallique dans une gaine de verre, avec dispositif à maximum

Medizinische Thermometer - Teil 1: Mit metallischer Flüssigkeit gefüllte Glasthermometer mit Maximumvorrichtung

This European Standard was approved by CEN on 13 May 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

**Central Secretariat: rue de Stassart, 36 B-1050 Brussels**



Ref. No. EN 12470-1:2000 E

## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2000, and conflicting national standards shall be withdrawn at the latest by July 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

For A-deviations, see annex ZB.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This European Standard applies to clinical thermometers which are used for measuring the body temperature of humans.

EN 12470 consists of the following Parts under the general title 'Clinical thermometers':

Part 1: Metallic liquid-in-glass thermometers with maximum device

Part 2 : Phase change-type (dot matrix) thermometers

Part 3 : Performance of compact electrical thermometers (non-predictive and predictive) with maximum device



Part 4 : Performance of electrical thermometers for continuous measurements

Part 5 : Performance of infra-red ear thermometers (with maximum device)



Annexes A, B, C, ZA and ZB are informative.

## 1 Scope

This Part of EN 12470 specifies performance requirements and test methods for clinical liquid-in-glass thermometers with maximum device and applies only to thermometers filled with metallic liquid.

NOTE 1: Note that in some European countries the use of mercury is prohibited in clinical thermometers.

NOTE 2: Substances other than metallic liquids can be used in the manufacturing of liquid-in-glass thermometers. No reference is made to these in this European standard because there is no experience of clinical thermometers which use other substances.

This European Standard does not apply to clinical thermometers designed for special applications (e.g. thermometers for premature babies, ovulation thermometers) which, owing to their measurement range, scale interval or maximum permissible error, fall outside the scope of this standard.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publication. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

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| EN 980 | *Graphical symbols for use in the labelling of medical devices* |
| EN 1041 | *Information supplied by the manufacturer with medical devices* |
| ISO 719 | *Glass - Hydrolytic resistance of glass grains at 98 degrees C - Method of test and classification* |
| ISO 2859-2: 1985 | *Sampling procedures for inspection by attributes - Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection* |

## 3 Definitions

For the purposes of this Part of EN 12470, the following definitions apply:

**3.1 correction :** Value added algebraically to the uncorrected result of a measurement to compensate for systematic error.

**3.2 error :** Result of measurement minus a true value of the measurand.

**3.3 maximum device :** Device which prevents the liquid column from falling when the temperature of the liquid in the bulb returns to the ambient temperature.

**3.4 scale panel (enclosed-scale type):** Panel to which the scale is fixed longitudinally behind the capillary tube.

**3.5 Stabilized thermometer reading:** Result given by a thermometer which, after attaining thermal equilibrium with a water bath of a temperature within the thermometers measuring range, has been removed from the water bath and cooled to a temperature of between 15°C and 30°C.

**3.6 zero point correction :** Correction of the reading of the thermometer at 0°C.

NOTE: $K = 0°C - t_1$

**3.7 zero point depression :** Change of zero point correction after heating and fast cooling of the thermometer.

## 4 Unit

The unit of temperature shall be the degree Celsius, symbol °C.

## 5 Types of thermometer



The types of metallic liquid-in-glass thermometers with maximum device shall be:

a) solid-stem, or
b) enclosed-scale

## 6 Requirements

### 6.1 Scale

#### 6.1.1 *Measuring range and scale interval*

The thermometer shall cover the minimum range from 35,5 °C to 42,0 °C with a scale interval of 0,1 °C.

Testing shall be performed by visual inspection.

#### 6.1.2 *Scale marks and numbering*

##### 6.1.2.1 *General*

The scale marks shall be uniformly spaced and of uniform width.

The scale marks and numbers shall be at right angles to the axis of the thermometer and shall be visible at the same time as the liquid column.

Testing shall be performed by visual inspection.

##### 6.1.2.2 *Scale spacing*

The distance between adjacent scale marks shall be at least 0,5 mm for solid-stem thermometers and at least 0,6 mm for enclosed-scale thermometers.

Testing shall be performed using an appropriate device, which magnifies the scale by at least x 4.

##### 6.1.2.3 *Width and length of the scale marks*

The scale marks shall be durably marked and shall be of uniform width not exceeding one-quarter of the length of a scale spacing plus 0,05 mm for solid-stem thermometers, or one-fifth of the length of a scale spacing plus 0,05 mm for enclosed-scale thermometers.



Scale marks representing whole degrees and half degrees shall be longer than the other scale marks.



Testing shall be performed using an appropriate device, which magnifies the scale by at least x 4.

##### 6.1.2.4 *Numbering*

Scale marks representing whole degrees shall be numbered.

NOTE. The scale mark representing the temperature of 37°C can be rendered conspicuous by means of a different colour from that used for the numbering and/or by additional marking.

Testing shall be performed by visual inspection.

**6.1.2.5** *Special requirements for solid-stem thermometers*

The scale shall be indelibly marked directly on the thick-walled capillary stem.

When tested in accordance with 7.2, the appearance of the scale lines shall not be significantly affected.

**6.1.2.6** *Special requirements for enclosed-scale thermometers*

The thermometer shall have a separate scale panel adjacent to the capillary tube. The capillary tube and the scale panel shall be enclosed in a transparent tube impermeably fixed to the bulb and forming a protection sheath.

The scale shall be marked on a scale panel fixed longitudinally behind the capillary tube.

Testing shall be performed by visual inspection.

**6.1.2.7** *Resistance to breakage of enclosed-scale thermometers*

The thermometer shall not break when subjected to a force of at least 50N in accordance with 7.8.

**6.2 Material**

**6.2.1** ***Thermometer bulb***

**6.2.1.1** *General*

The thermometer bulb shall be made of a type of glass which satisfies the requirements specified in 6.2.1.2 and 6.2.1.3. This glass shall be clearly and indelibly identified by either:

a) an integral mark introduced by the glass manufacturer in such a way as to be clearly recognizable on the bulb after manufacture of the thermometer or;

b) by a mark chosen by the glass manufacturer and affixed by the thermometer manufacturer and clearly indicating the type of glass used.



**6.2.1.2** *Hydrolytic resistance*

When tested in accordance with ISO 719 the quantity of alkali obtained in solution from 1 g of the glass shall not exceed 263,5 µg of $Na_2O$.

**6.2.1.3** *Zero point depression*

When tested in accordance with the method given in 7.3, the glass shall have an average zero point depression not exceeding 0,05°C.

#### 6.2.2 *Maximum device and capillary*

The glass used for the maximum device and the capillary shall have the same hydrolytic resistance as the glass for the thermometer bulb.

#### 6.2.3 *Scale panel of enclosed-scale thermometer*

The scale panel of enclosed-scale thermometers shall be of opal glass, metal or another material of a dimensional stability such that, when tested in accordance with 7.4, the length of the scale sample after heating shall not differ from that before heating by more than 0,2%.

#### 6.2.4 *Thermometric liquid filling*

The metallic liquid filling used in the thermometer shall have the purity, properties and characteristics that will enable the finished thermometers to comply with all requirements specified in this European Standard.

The bulb, the capillary tube and the liquid column of the finished thermometer shall be free of gas, water, glass fragments or other foreign material.

Testing shall be performed by visual inspection using an appropriate device which magnifies by at least x 4.

### 6.3 Manufacture

#### 6.3.1 *Freedom from defects*

The thermometer and its surface shall be free from defects that are likely to interfere with its proper functioning or to mislead the user, e.g. errors in graduation, flaws in the glass and constructional defects.

Testing shall be performed with an appropriate device, which magnifies the scale by at least x 4.



#### 6.3.2 *Capillary tube*

The capillary tube shall ensure that the entire length of the liquid column and the meniscus are clearly visible from at least one angle. It shall be prismatic in form and have a magnifying effect, or shall be so designed as to ensure consistent ease of reading.



Testing shall be performed by visual inspection.

#### 6.3.3 *Thermometer ends*

The ends of the thermometer shall be smoothly rounded in order to prevent tissue damage during use.

Testing shall be performed by visual and tactile inspection.

### 6.3.4 *Liquid column*

When the thermometer is heated slowly, the liquid column shall rise uniformly without appreciable surges.

NOTE: Surges larger than half a scale interval are considered as defects.

Testing shall be performed by visual inspection.

When tested in accordance with 7.6, the liquid column shall fall below the lowest numbered scale mark.

The thermometer shall not break when subjected to this test.

### 6.3.5 *Scale panel of enclosed-scale thermometer*

The scale panel shall be either directly fixed to the capillary tube or be in direct contact with the capillary tube and fixed sufficiently firmly in the sheath to prevent any displacement with respect to the capillary tube. The scale panel shall be so positioned as to ensure that any displacement can be easily detected either by means of an indelible mark on the sheath level with a numbered scale mark or by some equivalent means. The marking shall be in accordance with 6.1.2.3 and shall be placed at 38°C with a lateral tolerance of one-fifth of a scale spacing. The sheaths of enclosed-scale thermometers shall be free of moisture, liquid, glass fragments and foreign material.

Testing shall be performed by visual inspection.