SLOVENSKI STANDARD
SIST EN 12470-3:2000/kprA1:2009

01-april-2009

Klinični termometri - 3. del: Delovanje zaprtih trdnih električnih termometrov (brez umerjanja ali z njim)

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

Medizinische Thermometer - Teil 3: Elektrische (extrapolierende und nicht extrapolierende) Kompaktthermometer mit Maximumvorrichtung

Thermomètres médicaux - Partie 3: Performances des thermomètres électriques compacts (à comparaison et à extrapolation) avec dispositif à maximum

Ta slovenski standard je istoveten z: **EN 12470-3:2000/prA1**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 12470-3:2000/kprA1:2009 **en,fr**

EUROPEAN STANDARD

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FINAL DRAFT
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English Version

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

Thermomètres médicaux - Partie 3: Performances des thermomètres électriques compacts (à comparaison et à extrapolation) avec dispositif à maximum

Medizinische Thermometer - Teil 3: Elektrische (extrapolierende und nicht extrapolierende) Kompaktthermometer mit Maximumvorrichtung

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A1, if approved, will modify the European Standard EN 12470-3:2000. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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 CEN Management Centre has the same status as the official versions.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 12470-3:2000/prA1:2009) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document 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, see informative Annex ZA, which is an integral part of this document.

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 measurement

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

1 Modification to Clause 2, Normative references

Replace the title of EN 980 with the following: "*Symbols for use in the labelling of medical devices".*

Replace the title of EN 60601-1 with the following: "*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*".

2 Modification to 6.1, Probe cover

Add the following new sentence:

"If the probe cover is a single use device, it shall bear an indication on the probe cover or on its packaging, which is consistent across the European Community, that it is intended for single use only."

3 Modification to 8.1, General

Add the following new sentence:

"The manufacturer shall state the date of issue or the latest revision of the instruction for use."

4 Modification to 8.2, Marking

Add the following new item d):

"d) the name and address of the authorised representative where the manufacturer does not have a registered place of business in the community."

5 Modification to 8.3, Instructions for use

Add the following new items m) and n):

"m) the name and address of the authorised representative where the manufacturer does not have a registered place of business in the community;

n) information of known characteristics and technical factors that could pose a risk if the device were to be re-used".

6 Modification to Annex ZA

Replace the existing Annex ZA with the following:

"

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
2	1, Dash 1 and dash 2	For EN 60601-1 based standards, ER is covered by normative reference to EN 60601-1-6
4	10.3	
6	1, 2, 3, 4, 5	
6.1	13.3 f)	
6.2	10.1	
6.2.6	9.2	
6.3	9.2, 10.1	
6.3.5	9.2	
6.3.7	7.6	
6.4.1.1	10.1, 12.2	
6.4.1.2	10.2	
6.4.2	7.5	
6.5	9.2	
6.6.1	9.2, 12.7.1	
6.6.2	9.2	
7	1, 2, 3, 4, 5	
7.2, 7.3, 7.4, 7.5	7.1	
7.6, 7.7, 7.8, 7.9, 7.10, 7.11	9.2, 10.1	
7.12	7.6, 9.2, 10.1	
7.13	9.2, 10.1, 12.2	
8.1	12.9, 13.1, 13.6 q)	
8.2	12.9, 13.1	
8.2 a)	10.3	
8.2 b)	13.3 i), 13.3 j)	
8.2 c)	13.3 k)	

8.2 d)	13.3 a)	
8.3	13.1, 13.6 a), 13.6 b)	
8.3 b)	13.3 n)	
8.3 d)	8.1, 13.6 h)	
8.3 e)	13.6 p)	
8.3 f)	13.6 d)	
8.3 m)	13.3 a)	
8.3 n)	13.6 h)	
	6a	This Essential Requirement is not addressed in this European Standard
	7.1, Dash 3	The modification of this Essential Requirement is not addressed in this European Standard
	7.4	The modification of this Essential Requirement is not addressed in this European Standard
	12.1a	This Essential Requirement is not addressed in this European Standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."