SLOVENSKI STANDARD

SIST EN ISO 80601-2-56:2013

01-januar-2013

Nadomešča:

SIST EN 12470-3:2000+A1:2009

SIST EN 12470-4:2001+A1:2009

SIST EN 12470-5:2003

Elektromedicinska oprema - 2-56. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kliničnih termometrov za merjenje telesne temperature (ISO 80601-2-56:2009)

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2009)

Appareils électromédicaux - Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux performances essentielles des thermomètres médicaux pour mesurer la température de corps (ISO 80601-2-56:2009)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-56:2012**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN ISO 80601-2-56:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-56

October 2012

ICS 11.040.55

Supersedes EN 12470-3:2000+A1:2009, EN 12470-4:2000+A1:2009, EN 12470-5:2003

English Version

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)

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This European Standard was approved by CEN on 16 September 2012.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

The text of ISO 80601-2-56:2009 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO 80601-2-56:2012 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

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 April 2013, and conflicting national standards shall be withdrawn at the latest by October 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12470-4:2000+A1:2009, EN 12470-5:2003, EN 12470-3:2000+A1:2009.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-56:2009 has been approved by CEN as a EN ISO 80601-2-56:2012 without any modification.

Annex ZA
(informative)

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

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 Union 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 on medical devices

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed.
201.11	7.3	Only the part of the first sentence relating to design is addressed.
201.7.9.2.14.101	7.5	Only the third paragraph of ER 7.5 is addressed.
201.11, 201.103	7.6	
201.11	8.1	The part of ER 8.1 relating to easy handling is not addressed.
201.11	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137.
201.7.2.1.101	8.7	
201.4, 201.4.2.101, 201.7, 201.7.9.2.101 e), 201.16, 201.101.1, 201.102.1, 201.103, 201.103.2	9.1	
201.9, 201.12.1.101, 201.12.2, 201.15, 202	9.2	The 4th indent of ER 9.2 is not addressed.
201.11, 201.13	9.3	
201.7.9.2.101 d), 201.12, 201.101, 201.102, 201.103	10.1	
201.12.2	10.2	
201.7	10.3	

Table ZA.1 (*continued*)

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
202	11.3.1	
201.14	12.1	
201.14	12.1 a)	
201.12	12.4	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.11, 201.15	12.7.4	
201.11, 201.15	12.7.5	
201.7, 201.12.2, 201.15, 206	12.9	
201.7, 201.7.2.1, 201.7.2.1.101, 201.7.2.2, 201.7.9	13.1	The requirement for information on the sales packaging is not addressed.
201.7, 201.7.2.1, 201.8, 201.9	13.2	
201.7, 201.7.9.1	13.3 a)	
201.7, 201.7.2.1.101 b)	13.3 b)	
201.7.2.1.101 c)	13.3 c)	
201.7	13.3 d)	This ER is only covered if the batch number is preceded by the word LOT.
201.7.2.1.101 d)	13.3 e)	
201.7.2.1.101, 201.7.2.1.101 e)	13.3 f)	
201.7, 201.7.2.1.101 f)	13.3 i)	
201.7	13.3 j)	
201.7	13.3 k)	
201.7.2.1.101 c)	13.3 m)	Presumption of conformity is only provided if symbols 4 to 7 are utilized.
201.7, 201.7.9.1, 201.16	13.6 a)	
201.7.9.2.101 c), 201.7.9.2.101 d)	13.6 b)	
201.7, 201.7.9.2.101 e), 201.16	13.6 c)	
201.7, 201.7.9.2.101 g), 201.16	13.6 d)	
201.7, 201.16	13.6 f)	
201.7, 201.7.2.9.2.101 j), 201.11, 201.16	13.6 h)	The requirement for information on the packaging is not addressed.

Table ZA.1 (*continued*)

Clause(s)/sub-clause(s) of this International standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7	13.6 i)	
201.7.2.9.2.101 i)	13.6 n)	
201.7.2.9.2.101 d)	13.6 p)	
201.7.2.9.2.101 k)	13.6 q)	

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

INTERNATIONAL STANDARD

ISO 80601-2-56

First edition
2009-10-01

Medical electrical equipment —

Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

Appareils électromédicaux —
Partie 2-56: Exigences particulières relatives à la sécurité fondamentale et aux perfomances essentielles des thermomètres médicaux pour mesurer la température de corps

Reference number
ISO 80601-2-56:2009(E)

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Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 80601-2-56 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* in cooperation with Subcommittee 62D, *Electrical equipment*, of Technical Committee IEC/TC 62: *Electrical equipment in medical practice*.

ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

— *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

— *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

— *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

— *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

— *Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*

IEC 80601-2-30: *Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*, IEC 80601-2-35: *Particular requirements for basic safety and essential performance of blankets, pads and mattresses intended for heating in medical use*, IEC 80601-2-58: *Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*, IEC 80601-2-59: *Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening* and IEC 80601-2-60: *Particular requirements for basic safety and essential performance of dental equipment* are published by IEC.

Introduction

In this International Standard, the following print types are used.

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this International Standard, the term

— "clause" means one of the 20 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this International Standard are by number only.

In this International Standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This international standard deals with electrical CLINICAL THERMOMETERS, either already available or that will come available in the future.

The purpose of a CLINICAL THERMOMETER is to assess the true temperature of a REFERENCE BODY SITE. The temperature of the PATIENT'S body is an important vital sign in assessing overall health, typically in combination with blood pressure and pulse rate. Determining whether a PATIENT is afebrile or febrile is an important purpose of a CLINICAL THERMOMETER, since being febrile suggests that the PATIENT is ill.

There are different temperatures at each REFERENCE BODY SITE according to the balance between the production, transfer, and loss of heat.[38] CLINICAL ACCURACY of a CLINICAL THERMOMETER is VERIFIED by comparing its OUTPUT TEMPERATURE with that of a REFERENCE THERMOMETER, which has a specified uncertainty for measuring true temperature. For an equilibrium CLINICAL THERMOMETER, the CLINICAL ACCURACY can be sufficiently determined under laboratory conditions that create an equilibrium state between the two thermometers.

For a CLINICAL THERMOMETER that operates in the ADJUSTED MODE, laboratory VERIFICATION alone is not sufficient because the adjustment algorithm for deriving the OUTPUT TEMPERATURE includes the characteristics of the PATIENT and the environment.[3] Therefore the CLINICAL ACCURACY of a CLINICAL THERMOMETER that operates in the ADJUSTED MODE has to be VALIDATED clinically, using statistical methods of comparing its OUTPUT TEMPERATURE with that of a REFERENCE CLINICAL THERMOMETER which has a specified CLINICAL ACCURACY in representing a particular REFERENCE BODY SITE temperature.

For a CLINICAL THERMOMETER that operates in the ADJUSTED MODE, the LABORATORY ACCURACY is VERIFIED in a DIRECT MODE and the CLINICAL ACCURACY is VALIDATED in the ADJUSTED MODE (OPERATING MODE) with a sufficiently large group of human subjects.

The intention of this International Standard is to specify the requirements and the test procedures for the VERIFICATION of the LABORATORY ACCURACY for all types of electrical CLINICAL THERMOMETERS as well as for the VALIDATION of the CLINICAL ACCURACY of a CLINICAL THERMOMETER that operates in the ADJUSTED MODE.