INTERNATIONAL STANDARD

ISO 80601-2-56

Second edition
2017-03

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 performances essentielles des thermomètres médicaux pour mesurer la température de corps

Reference number
ISO 80601-2-56:2017(E)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This second edition cancels and replaces the first edition (ISO 80601-2-56:2009), which has been technically revised. It also incorporates the Amendments IEC 60601-1:2005/AMD1:2012, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-8:2006/AMD1:2012, as well as IEC 60601-1-12, the second edition of IEC 60601-1-11 and the fourth edition of IEC 60601-1-2.

The most significant changes are the following modifications:

— change in the clinical evaluation exclusion criteria related to antipyretics;

— deletion of Annex CC as this material is covered by IEC 60601-1-9[1];

and the following additions:

— disclosure requirement for a summary of the USE SPECIFICATION;

— tests for mechanical strength (via IEC 60601-1-11 and IEC 60601-1-12);

— tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11 and IEC 60601-1-12);

— tests for cleaning and disinfection PROCEDURES (via IEC 60601-1-11 and IEC 60601-1-12).

Introduction

This document 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, febrile or hypothermic 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[2]. 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 document 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.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, 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 DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

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

— "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 document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— “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.

Medical electrical equipment —

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

201.1 * Scope, object and related standards

IEC 60601-1:2005+A1:2012, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT. This document specifies the general and technical requirements for electrical CLINICAL THERMOMETERS. This document applies to all electrical CLINICAL THERMOMETERS that are used for measuring the BODY TEMPERATURE of PATIENTS.

CLINICAL THERMOMETERS can be equipped with interfaces to accommodate secondary indicators, printing equipment, and other auxiliary equipment to create ME SYSTEMS. This document does not apply to auxiliary equipment.

ME EQUIPMENT that measures a BODY TEMPERATURE is inside the scope of this document.

This document does not specify the requirements for screening thermographs intended to be used for the individual non-invasive human febrile temperature screening of groups of individual humans under indoor environmental conditions, which are given in IEC 80601-2-59[4].

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+A1:2012, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601–1:2005+A1:2012, 4.2.

201.1.2 Object

Replacement:

The object of this particular document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for a CLINICAL THERMOMETER, as defined in 201.3.206, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the CLINICAL THERMOMETER and the ACCESSORIES needs to be safe and effective. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in IEC 60601-1:2005+A1:2012, Clause 2, as well as 201.2 of this document.

IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 208, 211 and 212, respectively. IEC 60601-1-3[5] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a document takes priority over IEC 60601-1 and its collateral standards.

For brevity, IEC 60601-1:2005+A1:2012 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the IEC 60601-1 or applicable collateral standard is replaced completely by the text of this particular document.

"Addition" means that the text of this document is additional to the requirements of the IEC 60601-1 or applicable collateral standard.

"Amendment" means that the clause or subclause of the IEC 60601-1 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101, Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the IEC 60601-1:2005+A1:2012, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, the section, clause or subclause of the IEC 60601-1 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the IEC 60601-1 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005+A1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability +Amendment 1:2013*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems +Amendment 1:2012*

Addition:

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance +Amendment 1:2012*

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-8:2006+A1:2012, IEC 62366-1:2015 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An alphabetized index of defined terms is found beginning in Annex DD.

IEC 60601-1:2005+A1:2012, Clause 3 applies, except as follows:

Additions:

201.3.201

*** ADJUSTED MODE**

OPERATING MODE where the OUTPUT TEMPERATURE is calculated by adjusting the signal from the input SENSOR

Note 1 to entry: For the purposes of this document, emissivity is considered a thermal or physiological property of the MEASURING SITE, i.e. any CLINICAL THERMOMETER utilizing radiance that is dependent on emissivity is considered to operate in an ADJUSTED MODE.

201.3.202

BLACKBODY

REFERENCE TEMPERATURE SOURCE of infrared radiation characterized by precisely known temperature and having an effective emissivity close to one

201.3.203

BODY TEMPERATURE

all temperatures of the human body except SKIN TEMPERATURE

201.3.204

CLINICAL ACCURACY

closeness of agreement between the OUTPUT TEMPERATURE of a CLINICAL THERMOMETER and the true value of the temperature of the REFERENCE BODY SITE that the CLINICAL THERMOMETER purports to represent

201.3.205

CLINICAL BIAS

Δ_{cb}

mean difference between OUTPUT TEMPERATURES of a CLINICAL THERMOMETER and a REFERENCE CLINICAL THERMOMETER for the intended REFERENCE BODY SITE with specified LIMITS OF AGREEMENT when measured from selected group of subjects

Note 1 to entry: LIMITS OF AGREEMENT can also be described as clinical uncertainty.

201.3.206

CLINICAL REPEATABILITY

σ_r

pooled standard deviation (over a selected group of subjects) of changes in multiple OUTPUT TEMPERATURES taken from the same subject at the same MEASURING SITE with the same CLINICAL THERMOMETER by the same OPERATOR within a relatively short time

201.3.207

*** CLINICAL THERMOMETER**

ME EQUIPMENT used for measuring at the MEASURING SITE and indicating the temperature at the REFERENCE BODY SITE

Note 1 to entry: The MEASURING SITE can be the same as the REFERENCE BODY SITE.

201.3.208

*** DIRECT MODE**

OPERATING MODE of a CLINICAL THERMOMETER where the OUTPUT TEMPERATURE is an unadjusted temperature that represents the temperature of the MEASURING SITE to which the PROBE is coupled

201.3.209

EXTENDED OUTPUT RANGE

OUTPUT TEMPERATURE range having one or both limits that are outside of the RATED OUTPUT RANGE

201.3.210

FLUID BATH

REFERENCE TEMPERATURE SOURCE containing fluid at a uniform temperature

EXAMPLE Water, oil and air.

201.3.211

LABORATORY ACCURACY

closeness of agreement between the OUTPUT TEMPERATURE of a thermometer and the true value of the measurand

Note 1 to entry: LABORATORY ACCURACY is sometimes referred to as maximum permissible error.

201.3.212

LIMITS OF AGREEMENT

L_A

the magnitude of a potential disagreement between outputs of two CLINICAL THERMOMETERS equal to double the standard deviation of OUTPUT TEMPERATURE differences when used on the same human subject

Note 1 to entry: LIMITS OF AGREEMENT can also be described as clinical uncertainty.

201.3.213

MEASURING SITE

part of a PATIENT where the temperature is measured

EXAMPLE Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin.

201.3.214

OPERATING MODE

state of a CLINICAL THERMOMETER that gives an OUTPUT TEMPERATURE of an intended REFERENCE BODY SITE

201.3.215

OUTPUT RANGE

span between the lowest and highest limits of OUTPUT TEMPERTURE where a CLINICAL THERMOMETER indicates OUTPUT TEMPERATURE within the specified characteristics of LABORATORY ACCURACY

201.3.216

OUTPUT TEMPERATURE

temperature indicated by a thermometer

Note 1 to entry: Methods of indication can include printed, spoken, displayed and remotely displayed.

201.3.217

PROBE

part of a CLINICAL THERMOMETER that provides a thermal coupling between the SENSOR and the PATIENT

Note 1 to entry: Thermal coupling can be contact or non-contact.

201.3.218

PROBE CABLE EXTENDER

cable that connects a CLINICAL THERMOMETER to a PROBE

Note 1 to entry: Not every CLINICAL THERMOMETER utilizes a PROBE CABLE EXTENDER.

Note 2 to entry: A PROBE CABLE EXTENDER can be an APPLIED PART.

201.3.219

PROBE COVER

disposable or reusable ACCESSORY of a CLINICAL THERMOMETER that provides a sanitary barrier between the PROBE and the PATIENT

201.3.220

*** REFERENCE BODY SITE**

part of a PATIENT to which the OUTPUT TEMPERATURE refers

EXAMPLE Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin.

201.3.221

REFERENCE CLINICAL THERMOMETER

RCT

CLINICAL THERMOMETER having established CLINICAL ACCURACY and LABORATORY ACCURACY, which is used for CLINICAL ACCURACY VALIDATION of another CLINICAL THERMOMETER

201.3.222

REFERENCE TEMPERATURE SOURCE

source of a thermal energy whose temperature is measured by a REFERENCE THERMOMETER

EXAMPLE Blackbody, fluid bath.

201.3.223

REFERENCE THERMOMETER

equilibrium thermometer of a contact type for laboratory application whose calibration is traceable to a national standard of temperature, with a specified accuracy and associated uncertainty

Note 1 to entry: An equilibrium thermometer can also be described as a zero-heat-flow thermometer.

EXAMPLE Platinum resistance thermometer with calibration traceable to a national standard of temperature.

201.3.224

REPROCESSING

any activity, not specified in the ACCOMPANYING DOCUMENT, that renders a used product ready for re-use

Note 1 to entry: The term "REPROCESSED" is used to designate the corresponding status.

Note 2 to entry: Such activities are often referred to as refinishing, restoring, recycling, refurbishing, repairing or remanufacturing.

Note 3 to entry: Such activities can occur in healthcare facilities.

201.3.225

SENSOR

part of the CLINICAL THERMOMETER that converts thermal energy into an electrical signal

201.3.226

SKIN TEMPERATURE

temperature of the skin of the PATIENT at a point on which the sensing device intended to measure the temperature is placed

[SOURCE: IEC 60601-2-19:2009, 3.8.5, modified — replaced "infant" with "PATIENT" and "infant skin temperature" with "the sensing device intended to measure the temperature is placed"]

201.3.227

TEST MODE

state of a CLINICAL THERMOMETER where the OUTPUT TEMPERATURE represents the temperature measured by the SENSOR and is not adjusted for a REFERENCE BODY SITE or the rate of response of the SENSOR

Note 1 to entry: The TEST MODE can be used for the determination of the LABORATORY ACCURACY of the CLINICAL THERMOMETER.

Note 2 to entry: The TEST MODE can be the DIRECT MODE of the CLINICAL THERMOMETER.

201.3.228

VALIDATION

confirmation, through the provision of OBJECTIVE EVIDENCE, that the requirements for a specific INTENDED USE or application have been fulfilled

Note 1 to entry: The term "VALIDATED" is used to designate the corresponding status.

Note 2 to entry: The use conditions for VALIDATION can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

201.4 General requirements

IEC 60601-1:2005+A1:2012, Clause 4 applies, except as follows:

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Additional subclause:

201.4.2.101Additional requirements for RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

When performing the RISK MANAGEMENT PROCESS required by IEC 60601-1:2005+A1:2012, 4.2, the analysis shall consider the RISKS of changing environmental conditions for the CLINICAL THERMOMETER and provide guidance regarding the RESIDUAL RISKS in the instruction for use.

NOTE PORTABLE CLINICAL THERMOMETERS can undergo changing environmental conditions that can affect the LABORATORY ACCURACY.

Compliance is checked by inspection of the instructions for use and the RISK MANAGEMENT FILE.