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)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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.

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, Clause 1 applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT. This standard specifies the general and technical requirements for electrical CLINICAL THERMOMETERS. This standard 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 standard does not apply to auxiliary equipment.

ME EQUIPMENT that measures a temperature not as a primary purpose, but as a secondary function, is outside the scope of this standard.

EXAMPLE 1 Swan-Ganz thermodilution determination of cardiac output is not in the scope of this standard.

EXAMPLE 2 A Foley catheter that includes a temperature PROBE is in the scope of this standard.

EXAMPLE 3 PATIENT heating ME EQUIPMENT that includes a skin temperature measurement such as infant incubators, heating blankets, heating pads and heating mattresses are not in the scope of this standard, unless they indicate a temperature of a REFERENCE BODY SITE in which they are in the scope of this standard.

Requirements for ME EQUIPMENT intended to be used for non-invasive human febrile temperature screening of groups of individuals under indoor environmental conditions are given in IEC 80601-2-59:2008 and such ME EQUIPMENT is not covered by this standard.

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 standard are not covered by specific requirements in this standard except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005, 4.2.

201.1.2 Object

Replacement:

The object of this particular standard 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. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of a CLINICAL THERMOMETER.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in IEC 60601-1:2005, Clause 2, as well as Clause 2 of this particular standard.

IEC 60601-1-3 does not apply.

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 particular standard takes priority over IEC 60601-1.

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

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard 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 standard.

“Addition” means that the text of this particular standard 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 particular standard.

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 6060-1-3, etc.

The term “this standard” is used to make reference to the IEC 60601-1, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, 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 particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 43.

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

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2006, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability*

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*

Addition:

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
Amendment 1:2008

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

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

201.3 Terminology and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-6:2006, IEC 60601-1-8:2006, and the following definitions apply.

NOTE An alphabetized index of defined terms is found beginning on page 45.

Additions:

201.3.201
***** ADJUSTED MODE
OPERATING MODE where the OUTPUT TEMPERATURE is calculated by adjusting the signal from the input SENSOR

EXAMPLE Adjustments can include one or more of the following: variations in the SENSOR'S rate of response, ambient temperature, measured temperature, and the thermal, physiological, or anatomical properties of both the MEASURING SITE and the REFERENCE BODY SITE.

NOTE For the purposes of this particular standard, emissivity is considered a thermal or physiological property of the MEASURING SITE, i.e. any CLINICAL THERMOMETER utilizing radiance that is dependant on emissivity is considered to operate in an ADJUSTED MODE.

201.3.202
BLACKBODY
REFERENCE TEMPERATURE SOURCE of infrared radiation made in the shape of a cavity and characterized by precisely known temperature of the cavity walls and having an effective emissivity at the cavity opening as close as practical to unity

201.3.203
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

201.3.204
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 LIMITS OF AGREEMENT can also be described as clinical uncertainty.

201.3.205
CLINICAL REPEATABILITY
σ_r
pooled standard deviation (over a selected group of subjects) of changes in multiple OUTPUT TEMPERATURES taken from the same subject from the same MEASURING SITE with the same CLINICAL THERMOMETER by the same OPERATOR within a relatively short time

201.3.206
* CLINICAL THERMOMETER
ME EQUIPMENT used for measuring at the MEASURING SITE and indicating the temperature at the REFERENCE BODY SITE

NOTE The MEASURING SITE can be the same as REFERENCE BODY SITE.

201.3.207
* 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

201.3.208
EXTENDED OUTPUT RANGE
OUTPUT TEMPERATURE range having one or both limits that are outside of the RATED OUTPUT RANGE

201.3.209
FLUID BATH
REFERENCE TEMPERATURE SOURCE containing fluid at a uniform temperature

EXAMPLES Water, oil and air.

201.3.210
LABORATORY ACCURACY
closeness of agreement between the OUTPUT TEMPERATURE of a thermometer and the true value of the measurand

NOTE LABORATORY ACCURACY is sometimes referred to as maximum permissible error.

201.3.211
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 subjects

NOTE LIMITS OF AGREEMENT can also be described as clinical uncertainty.

201.3.212
MEASURING SITE
part of a PATIENT where the temperature is measured

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

201.3.213
OPERATING MODE
state of a CLINICAL THERMOMETER that gives an OUTPUT TEMPERATURE of an intended REFERENCE BODY SITE

201.3.214
OUTPUT RANGE
span between the lowest and highest temperature limits where a CLINICAL THERMOMETER indicates OUTPUT TEMPERATURE within the specified characteristics of LABORATORY ACCURACY

201.3.215
OUTPUT TEMPERATURE
temperature indicated by a thermometer

NOTE Methods of indication can include printed, spoken, displayed and remotely displayed.

201.3.216
PROBE
part of a CLINICAL THERMOMETER that provides a thermal coupling between the SENSOR and the PATIENT

NOTE Thermal coupling can be contact or non-contact.

201.3.217
PROBE CABLE EXTENDER
cable that connects a CLINICAL THERMOMETER to a PROBE

NOTE 1 Not every CLINICAL THERMOMETER utilizes a PROBE CABLE EXTENDER.

NOTE 2 A PROBE CABLE EXTENDER can be an APPLIED PART.

201.3.218
PROBE COVER
disposable or reusable ACCESSORY of a CLINICAL THERMOMETER that provides a sanitary barrier between the PROBE and the PATIENT

201.3.219
* REFERENCE BODY SITE
part of a PATIENT to which the OUTPUT TEMPERATURE refers

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

201.3.220
REFERENCE CLINICAL THERMOMETER
RCT
CLINICAL THERMOMETER having established CLINICAL ACCURACY and LABORATORY ACCURACY, which is used for CLINICAL ACCURACY VALIDATION of another CLINICAL THERMOMETER

201.3.221
REFERENCE TEMPERATURE SOURCE
source of a thermal energy whose temperature is measured by a REFERENCE THERMOMETER

EXAMPLES BLACKBODY, FLUID BATH.

201.3.222
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 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.

201.3.223
REPROCESSING
any activity, not specified in the ACCOMPANYING DOCUMENT, that renders a used product ready for re-use

NOTE 1 The term "REPROCESSED" is used to designate the corresponding status.

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

NOTE 3 Such activities can occur in healthcare facilities.

201.3.224
SENSOR
part of the CLINICAL THERMOMETER that converts thermal energy into an electrical signal

201.3.225
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 The TEST MODE can be used for the determination of the LABORATORY ACCURACY of the CLINICAL THERMOMETER.

NOTE 2 The TEST MODE can be the DIRECT MODE of the CLINICAL THERMOMETER.

201.4 General requirements

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

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Additional subclause:

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

When performing the RISK MANAGEMENT PROCESS required by IEC 60601-1:2005, 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.

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Accuracy of the CLINICAL THERMOMETER or at least one of the following:	201.101.2
— generation of a TECHNICAL ALARM CONDITION;	201.12.1.101
— not providing an OUTPUT TEMPERATURE;	
— marking the ambient temperature operating range.	201.4.101

Additional subclause:

201.4.101 Environmental conditions of use

A CLINICAL THERMOMETER intended for home healthcare use shall operate in NORMAL USE over the ranges of

— an ambient temperature operating range from 15 °C to 35 °C; and

— a relative humidity range of 15 % to 85 % (non-condensing);

or the CLINICAL THERMOMETER shall be marked with the limited environmental operation range and the instructions for use shall disclose the warning of the consequences of operation outside of that range.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005, Clause 5 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, Clause 7 applies, except as follows: