
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*



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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 of 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.

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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 TEMPERATURE 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:

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

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

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:	
— generation of a TECHNICAL ALARM CONDITION;	201.101.2
— not providing an OUTPUT TEMPERATURE.	201.12.1.101

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, 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+A1:2012, Clause 7 applies, except as follows:

201.7.2.1 Minimum requirements for marking on ME EQUIPMENT and interchangeable parts

Additional subclause:

201.7.2.1.101 Additional requirements for marking of the packaging

The packaging of a CLINICAL THERMOMETER and PROBE shall be marked with the following information:

- MEASURING SITE and REFERENCE BODY site;
- details to enable the OPERATOR to identify the mode of operation of the CLINICAL THERMOMETER and the contents of the packaging;

EXAMPLE This package contains a predictive thermometer that estimates the PATIENT's temperature and 10 probe covers.
- if sterile, the appropriate symbol from ISO 15223-1:2016 (see Table 201.D.2.101, Symbols 3 to 8);
- for a CLINICAL THERMOMETER or PROBE with an expiration date (use-by date), ISO 15223-1:2016, Symbol 5.1.4 (see Table 201.D.2.101, Symbol 2);
- any special storage, handling or operating instructions.

For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent.

Compliance is checked by inspection.

201.7.2.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

Additional subclause:

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

A CLINICAL THERMOMETER shall have CLEARLY LEGIBLE markings with the following information:

- a) the symbol “°C” or “°F” adjacent to the OUTPUT TEMPERATURE, if not indicated at the display. If switching between degrees Fahrenheit and degrees Celsius is possible, the respective unit of measure of the OUTPUT TEMPERATURE shall be indicated unambiguously;
- b) intended MEASURING SITE;
- c) that a new PROBE COVER shall be used prior to next measurement, if necessary, to maintain ESSENTIAL PERFORMANCE.

Compliance is checked by inspection.

201.7.4.3 Units of measurement

Additional subclause:

201.7.4.3.101 Additional requirements for unit of measure

A CLINICAL THERMOMETER shall express the temperature in either degrees Celsius, °C, or degrees Fahrenheit, °F, or both.

The CLINICAL THERMOMETER shall clearly indicate the unit of measure.

Compliance is checked by inspection and functional testing.

201.7.9 ACCOMPANYING DOCUMENT

201.7.9.1 Additional general requirements

Amendment (replace the first dash with):

- name or trade name and address of
 - the MANUFACTURER, and
 - where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale
- to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Additional requirements for instructions for use

Additional subclause:

201.7.9.2.101 Instructions for use

The instructions for use shall include the following:

- a) a summary of the USE SPECIFICATION as determined for IEC 62366-1:2015;
- b) the MEASURING SITE and REFERENCE BODY SITE of the CLINICAL THERMOMETER;

- c) if applicable, the recommended minimum measuring time and minimum time between measurements for each intended MEASURING SITE;
- d) the RATED OUTPUT RANGE for each intended REFERENCE BODY SITE;
- e) the LABORATORY ACCURACY in the RATED OUTPUT RANGE and, if equipped, the LABORATORY ACCURACY in the RATED EXTENDED OUTPUT RANGE;
- f) for CLINICAL THERMOMETERS intended to be used with a PROBE COVER:
 - 1) instructions for the application of a PROBE COVER;
 - 2) information about the behaviour of the CLINICAL THERMOMETER when used without the PROBE COVER;
- g) the information whether the CLINICAL THERMOMETER is a DIRECT MODE or an ADJUSTED MODE CLINICAL THERMOMETER;
- h) if applicable, instructions for selection and replacement of the INTERNAL ELECTRICAL POWER SOURCE;

EXAMPLE 1 Battery replacement.
- i) details of the nature and frequency of any maintenance and/or calibration needed to ensure that the CLINICAL THERMOMETER operates properly and safely;
- j) information concerning the disposal of the CLINICAL THERMOMETER and its components;

EXAMPLE 2 Battery or PROBE COVER disposal.
- k) if the CLINICAL THERMOMETER or its parts are intended for single use, information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the CLINICAL THERMOMETER or its parts would be re-used.

Compliance is checked by inspection.

Additional subclause:

201.7.9.101 Additional requirements for ACCOMPANYING DOCUMENT

Unless the CLINICAL THERMOMETER is equipped with a TEST MODE or DIRECT MODE, the ACCOMPANYING DOCUMENT shall include the correction method to derive unadjusted temperatures from OUTPUT TEMPERATURE measured in the ADJUSTED MODE.

Compliance is checked by inspection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 8 applies.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+A1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+A1:2012, Clause 11 applies, except as follows:

Additional subclause:

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT and ME SYSTEM

Amendment (add additional requirement as new first paragraph):

The surfaces of the CLINICAL THERMOMETER, PROBE and ACCESSORIES that can become contaminated with body fluids during NORMAL CONDITION or SINGLE FAULT CONDITION shall be designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in IEC 60601-1:2005+A1:2012, 11.6.7 and IEC 60601-1-11:2015, Clause 8). The CLINICAL THERMOMETER may be dismantled during the decontamination PROCESS. ACCESSORIES not intended for re-use are exempt from this requirement.

Amendment (add additional requirement and replace the compliance test):

CLINICAL THERMOMETER and PROBE ENCLOSURES shall be designed to allow for surface cleaning and disinfection to reduce to acceptable levels the RISK of infection of OPERATORS, bystanders, or the PATIENT.

Instructions for processing and REPROCESSING the CLINICAL THERMOMETER, PROBE and ACCESSORIES shall comply with ISO 17664:2004 and ISO 14937:2009 and shall be disclosed in the instructions for use.

NOTE 1 ISO 14159^[8] provides guidance for the design of ENCLOSURES.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this document could be affected by the cleaning or the disinfecting of the CLINICAL THERMOMETER, PROBE or its parts or ACCESSORIES, clean and disinfect them 100 times in accordance with the methods indicated in the instruction for use, including any cooling or drying period. After these PROCEDURES, confirm that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained. Confirm that the MANUFACTURER has evaluated the effects of multiple PROCESS cycles and the effectiveness of those cycles.

NOTE 2 Additional information regarding the order of test is found in 211.10.1.1 and 212.10.1.1.

201.11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

Amendment (add after existing text):

The ACCESSIBLE PARTS of a CLINICAL THERMOMETER, PROBE, its parts or ACCESSORIES that contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction shall be marked as containing phthalates on the device itself or on the packaging. The symbol of EN 15986:2011 (see Table 201.D.2.101, Symbol 10) may be used. If the INTENDED USE of a CLINICAL THERMOMETER, PROBE, its parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE. The instructions for use of a CLINICAL THERMOMETER, PROBE, its parts or ACCESSORIES that contain such phthalates shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Amendment (replace compliance check):

Check compliance by inspection of the instructions for use and inspection of the information provided by the MANUFACTURER for identification of the presence of substances which are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+A1:2012, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Additional subclause:

201.12.1.101 Additional requirements for accuracy of controls and instruments

When the CLINICAL THERMOMETER is not capable of indicating a temperature within the LABORATORY ACCURACY, it shall provide a TECHNICAL ALARM CONDITION or it shall not provide an OUTPUT TEMPERATURE.

NOTE 1 Possible causes include the following:

- a) low voltage of the internal electrical power source;
- b) output temperature outside the rated output range or rated extended output range.

The OUTPUT TEMPERATURE of CLINICAL THERMOMETERS should cover the minimum RATED OUTPUT RANGE from 34,0 °C to 43,0 °C.

NOTE 2 In some applications, a wider RATED OUTPUT RANGE can be needed.

NOTE 3 In some applications, a narrower RATED OUTPUT RANGE can be needed (e.g. ovulation CLINICAL THERMOMETER).

Compliance is checked by inspection and functional testing.

201.12.2 Usability

Additional subclause:

201.12.2.101 * Additional requirements for USABILITY of ME EQUIPMENT

In addition to the requirements of IEC 60601-1:2005+A1:2012, 12.2 for CLINICAL THERMOMETERS intended for use in HOME HEALTHCARE ENVIRONMENT, the display of OUTPUT TEMPERATURE shall be at least 4 mm high or optically magnified so as to appear that height.

For CLINICAL THERMOMETERS with a segmented indication display, a functional test of all segments shall be performed after activation.

Compliance is checked by inspection and inspection of the USABILITY ENGINEERING FILE.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005+A1:2012, Clause 13 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+A1:2012, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 15 applies.

201.16 ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 16 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 17 applies.

Additional subclauses:

201.101 Laboratory performance requirements**201.101.1 * General test requirements**

Laboratory performance shall be assessed in DIRECT MODE or in TEST MODE under the same conditions. If a TEST MODE or DIRECT MODE is not available, use the correction method to derive unadjusted temperatures from the OUTPUT TEMPERATURE in accordance with the ACCOMPANYING DOCUMENT.

A CLINICAL THERMOMETER intended for use with a PROBE COVER shall be tested together with the PROBE COVER as indicated in the instructions for use. A new PROBE COVER shall be used for each OUTPUT TEMPERATURE measurement.

NOTE A CLINICAL THERMOMETER OPERATING MODE whose accuracy cannot be VERIFIED by utilizing a FLUID BATH is also required to be evaluated according to 201.102.

Compliance is checked by inspection and inspection of the ACCOMPANYING DOCUMENT.

201.101.2 * LABORATORY ACCURACY

The LABORATORY ACCURACY within the RATED OUTPUT RANGE in NORMAL USE shall be within $\pm 0,3$ °C.

The LABORATORY ACCURACY, within the RATED EXTENDED OUTPUT RANGE in NORMAL USE, shall be within $\pm 0,4$ °C unless CLINICAL THERMOMETER indicates that the measured temperature is outside of the RATED OUTPUT RANGE.

If the PROBE is separable from the CLINICAL THERMOMETER, they may be tested separately.

NOTE For some applications, improved LABORATORY ACCURACY can be needed (e.g. ovulation CLINICAL THERMOMETER).

Compliance is checked with the following test.

- a) ** Utilize a REFERENCE TEMPERATURE SOURCE, which is either a FLUID BATH or a BLACKBODY radiator as described in Annex BB. Confirm that the temperature supplied by the REFERENCE TEMPERATURE SOURCE has an expanded measurement uncertainty (covering factor $k = 2$) of not greater than $0,07$ °C.*
- b) *Place the CLINICAL THERMOMETER into a climatic chamber and set the ambient temperature and humidity to approximately the mid-range of the RATED temperature and humidity as indicated in the ACCOMPANYING DOCUMENT.*
- c) *Set the temperature of the REFERENCE TEMPERATURE SOURCE to approximately the midpoint of the RATED OUTPUT RANGE. Stabilize the CLINICAL THERMOMETER at given conditions of ambient temperature and humidity for a minimum of 30 min, or longer if indicated in the ACCOMPANYING DOCUMENT.*
- d) *Measure the temperature of the REFERENCE TEMPERATURE SOURCE with both the CLINICAL THERMOMETER and a REFERENCE THERMOMETER. Document the results.*

- e) Repeat c) and d), once setting the temperature of the REFERENCE TEMPERATURE SOURCE to within 1 °C of the upper limit and once within 1 °C of the lower limit of the RATED OUTPUT RANGE.
- f) If the CLINICAL THERMOMETER is provided with an EXTENDED OUTPUT RANGE, repeat e), once setting the temperature of the REFERENCE TEMPERATURE SOURCE to within 0,5 °C of the upper limit and once within 0,5 °C of the lower limit of the RATED EXTENDED OUTPUT RANGE.
- g) Repeat c) through f) at four points, the combinations of upper and lower limits of the RATED environmental temperature and humidity ranges as indicated in the ACCOMPANYING DOCUMENT.
- h) Calculate the measurement error, e , for each individual OUTPUT TEMPERATURE measurement using Formula (1).
- i) Confirm that the measurement error meets the requirement.

The error of an individual OUTPUT TEMPERATURE measurement is indicated by Formula (1).

$$e = T_{\text{DUT}} - T_{\text{REF}} \quad (1)$$

where

T_{DUT} is the individual OUTPUT TEMPERATURE of the CLINICAL THERMOMETER under test (DUT) when measuring the REFERENCE TEMPERATURE SOURCE;

T_{REF} is the corresponding OUTPUT TEMPERATURE of the REFERENCE TEMPERATURE SOURCE measured by the REFERENCE THERMOMETER.

201.101.3 * Time response for a DIRECT MODE CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER

The transient response for a DIRECT MODE CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER shall be characterized and disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use and with the following test.

- a) Utilize two REFERENCE TEMPERATURE SOURCES, which are FLUID BATHS, BLACKBODIES or specially designed thermal sources as described in Annex BB.
- b) Set the temperature of the first REFERENCE TEMPERATURE SOURCE to approximately the middle of the RATED OUTPUT RANGE. Set the temperature of the second REFERENCE TEMPERATURE SOURCE to approximately 2 °C higher than the first REFERENCE TEMPERATURE SOURCE. Confirm that the temperature of the second REFERENCE TEMPERATURE SOURCE is within the RATED OUTPUT RANGE of the CLINICAL THERMOMETER.
- c) For 5 min, or longer if necessary to achieve thermal equilibrium, thermally couple the PROBE of the CLINICAL THERMOMETER to the first REFERENCE TEMPERATURE SOURCE. Note the time and immediately move the PROBE to the second REFERENCE TEMPERATURE SOURCE.
- d) Continuously monitor the OUTPUT TEMPERATURE until the new temperature reading remains within the LABORATORY ACCURACY limits of the second REFERENCE TEMPERATURE SOURCE and is within the LABORATORY ACCURACY of the CLINICAL THERMOMETER. Note the time.
- e) Note the difference between the two points in time and document the heating transient time.
- f) Set the temperature of the second REFERENCE TEMPERATURE SOURCE to approximately 2 °C lower than the first REFERENCE TEMPERATURE SOURCE. Confirm that the temperature of the second REFERENCE TEMPERATURE SOURCE is within the RATED OUTPUT RANGE of the CLINICAL THERMOMETER.

- g) Repeat c) and d).
- h) Note the difference between the two times and document the cooling transient time.
- i) Confirm that the transient time for both heating and cooling is less than the recommended minimum measuring time indicated in the ACCOMPANYING DOCUMENT.

201.102 * CLINICAL ACCURACY VALIDATION

201.102.1 Method

ADJUSTED MODE CLINICAL THERMOMETERS shall be VALIDATED for CLINICAL ACCURACY in each ADJUSTED MODE. The results of CLINICAL ACCURACY VALIDATION shall be disclosed in the ACCOMPANYING DOCUMENT. This disclosure shall include: the CLINICAL BIAS, Δ_{cb} , with its LIMITS OF AGREEMENT, L_A , the CLINICAL REPEATABILITY, σ_r , the REFERENCE BODY SITE and MEASURING SITE for each OPERATING MODE.

NOTE 1 CLINICAL BIAS is the mean difference between OUTPUT TEMPERATURES of the CLINICAL THERMOMETER under test (DUT) and the RCT for a specific REFERENCE BODY SITE when measured from a selected group of subjects. The CLINICAL BIAS for each OPERATING MODE of the DUT defines closeness between the DUT OUTPUT TEMPERATURE and that of the RCT.

NOTE 2 Any CLINICAL THERMOMETER OPERATING MODE whose accuracy cannot be VERIFIED by utilizing a FLUID BATH is considered an ADJUSTED MODE CLINICAL THERMOMETER.

NOTE 3 The CLINICAL THERMOMETER can have more than one OPERATING MODE with different CLINICAL ACCURACIES.

The CLINICAL ACCURACY VALIDATION shall be conducted in accordance with ISO 14155:2011.

NOTE 4 This document specifies that during a CLINICAL ACCURACY VALIDATION of a CLINICAL THERMOMETER, characteristics that represent CLINICAL ACCURACY (i.e. the CLINICAL BIAS with its LIMITS OF AGREEMENT and CLINICAL REPEATABILITY) are evaluated. These characteristics are evaluated from the same data set obtained with a CLINICAL THERMOMETER under test (DUT) and a REFERENCE CLINICAL THERMOMETER (RCT), both indicating the OUTPUT TEMPERATURE of the same REFERENCE BODY SITE.

A CLINICAL THERMOMETER intended for use with a PROBE COVER shall be tested together with the PROBE COVER as indicated in the instructions for use. A new PROBE COVER shall be used for each OUTPUT TEMPERATURE measurement.

Consider compliance with the requirements of this subclause to exist when the requirements of 201.101.2, 201.102.3, 201.102.4 and 201.102.5 have been fulfilled, by inspection of the instructions for use and with the following test.

- a) Obtain temperatures with the DUT in the OPERATING MODE being evaluated and with the PATIENT population indicated in the instructions for use according to 201.101.2. Before and after the tests, confirm the LABORATORY ACCURACY of the RCT with a REFERENCE TEMPERATURE SOURCE.
- b) Take OUTPUT TEMPERATURES from the DUT and the RCT concurrently, or sequentially, when using the same MEASURING SITE, using the measuring time as indicated in the instructions for use. Use the RCT according to its instructions for use.
- c) Perform at least three consecutive measurement PROCEDURES, as indicated in the instructions for use, with the DUT and at least one temperature with an RCT for each subject. Wait between individual measurements as indicated in the instructions for use. See also 201.101.1. For febrile subjects less than 5 years of age, only one measurement need be taken.

NOTE 5 Care should be taken to ensure that the actual temperatures of the MEASURING SITES of the DUT and RCT remain stable during a series of measurements.

d) Repeat b) and c) for each subject in the study. Take care to exclude subjects with medical conditions which might skew CLINICAL ACCURACY VALIDATION results such as inflammation at the MEASURING SITE.

EXAMPLE 1 Barbiturates, thyroid preparations, antipsychotics, recent immunizations.

Take care to exclude subjects who have taken antipyretics in the preceding 120 min.

NOTE 6 Studies show that PATIENT temperature is reasonably stable 120 min after taking common antipyretics^{[9][10]}.

EXAMPLE 2 Aspirin, acetaminophen, ibuprofen.

201.102.2 * Human subject population requirements

The total number of febrile subjects shall be not less than 30 % and not greater than 50 % of all subjects in the selected age group.

NOTE 1 The first temperature out of three measurements is used in calculation of CLINICAL BIAS and LIMITS OF AGREEMENT. All three OUTPUT TEMPERATURE measurements are used in calculation of the CLINICAL REPEATABILITY.

NOTE 2 For the purpose of CLINICAL ACCURACY VALIDATION, a febrile subject is defined as a subject having

- an elevated core or rectal temperature of 38,0 °C (100,4 °F) or higher as measured by an RCT,
- an elevated sublingual temperature of 37,5 °C (99,5 °F) or higher as measured by an RCT, or
- an elevated axillary temperature of 37,2 °C (99,0 °F) or higher as measured by an RCT.

CLINICAL ACCURACY VALIDATION shall be carried out on all age groups indicated in the instructions for use as indicated in the USE SPECIFICATION. The minimum number of subjects in the CLINICAL ACCURACY VALIDATION shall be not less than 105. The number of subjects in each age group shall be sufficiently large to minimize the effect of random components of measurement error. The age groups shall be developed with the guidelines of Table 201.102. Subjects may be PATIENTS. The minimum number of subjects in an age group shall be at least 35, and at least 15 in subgroup A1 or A2 if subgroup A is not explicitly excluded in the instructions for use.

Table 201.102 — Subject age groups

Age group	Age ^[11]
A1	0 up to 3 months
A2	3 months up to 1 year
B	older than 1 year and younger than 5 years
C	older than 5 years

201.102.3 * CLINICAL BIAS calculation

To evaluate the CLINICAL BIAS for the OPERATING MODE being evaluated, use the first CLINICAL THERMOMETER under test (DUT) OUTPUT TEMPERATURE out of three and the corresponding RCT OUTPUT TEMPERATURE from each subject in a test group. The CLINICAL BIAS for the specified REFERENCE BODY SITE and age group is calculated from Formula (2).

$$\Delta_{cb} = \frac{\sum_{i=1}^n (T_{DUT,i} - T_{RCT,i})}{n} \quad (2)$$

where

- i is the index number for an individual subject;
- n is the total number of subjects per MEASURING SITE and age group;
- $T_{DUT,i}$ is the i th observed OUTPUT TEMPERATURE from the DUT;
- $T_{RCT,i}$ is the i th observed OUTPUT TEMPERATURE from the RCT.

201.102.4 * LIMITS OF AGREEMENT calculation

To calculate the LIMITS OF AGREEMENT, L_A , use Formula (3).

$$L_A = 2 \times \sigma_{\Delta_{cb}} \quad (3)$$

where

$\sigma_{\Delta_{cb}}$ is calculated using Formula (4).

To calculate the deviation, $\sigma_{\Delta_{cb}}$, use the first measurement of the CLINICAL THERMOMETER under test (DUT) OUTPUT TEMPERATURE out of three measurements and the corresponding RCT OUTPUT TEMPERATURE of each subject for the OPERATING MODE being evaluated using Formula (4).

$$\sigma_{\Delta_{cb}} = \sqrt{\frac{\sum_{i=1}^n [(T_{DUT,i} - T_{RCT,i}) - \Delta_{cb}]^2}{n - 1}} \quad (4)$$

where

- i is the index number for an individual subject;
- n is the total number of subjects per MEASURING SITE and age group;
- $T_{DUT,i}$ is the i th OUTPUT TEMPERATURE indicated by the DUT;
- $T_{RCT,i}$ is the i th OUTPUT TEMPERATURE indicated by the RCT;
- Δ_{cb} is the CLINICAL BIAS as calculated in Formula (2).

201.102.5 * CLINICAL REPEATABILITY calculation

An ADJUSTED MODE CLINICAL THERMOMETER that makes continuous estimates of the REFERENCE BODY SITE temperature shall be exempt from the requirements of this subclause.

CLINICAL REPEATABILITY, for a particular OPERATING MODE, is determined for the subject population of all age groups given in Table 201.102 combined. Febrile subjects less than 5 years of age may be excluded.

CLINICAL REPEATABILITY is calculated by a pooled standard deviation of triplicate measurements over the entire population of subjects. First, calculate the standard deviation, σ_j , of the three OUTPUT TEMPERATURE measurements ($T_{1,j}$, $T_{2,j}$ and $T_{3,j}$) for each subject j using Formula (5).

$$\sigma_j = \sqrt{\frac{\sum_{i=1}^m (T_{\text{DUT},i} - \overline{T_{\text{DUT},j}})^2}{m-1}} \quad (5)$$

where

$T_{\text{DUT},i}$ is the i th OUTPUT TEMPERATURE (e.g. 1, 2 or 3) indicated by the DUT;

$\overline{T_{\text{DUT},j}}$ is the average of the OUTPUT TEMPERATURES on subject j ;

m is the number of OUTPUT TEMPERATURE measurements on the subject.

NOTE m is typically equal to 3.

Then calculate a pooled standard deviation (the CLINICAL REPEATABILITY), σ_r , for all subjects using Formula (6).

$$\sigma_r = \sqrt{\frac{\sigma_1^2 + \sigma_2^2 + \dots + \sigma_j^2 + \dots + \sigma_N^2}{N}} \quad (6)$$

where

N is the total number of subjects of all age groups in a study.

201.103 * PROBES, PROBE CABLE EXTENDERS and PROBE COVERS

201.103.1 General

All PROBES, PROBE CABLE EXTENDERS and PROBE COVERS shall comply with the requirements of this document, whether they are produced by the MANUFACTURER of the CLINICAL THERMOMETER or by another entity ("third party manufacturer" or healthcare provider) or are REPROCESSED.

MANUFACTURERS of a PROBE, PROBE CABLE EXTENDER and PROBE COVER, including a REPROCESSED PROBE, PROBE CABLE EXTENDER and PROBE COVER, shall conduct tests to VERIFY that all CLINICAL THERMOMETER specifications are met with each MODEL OR TYPE REFERENCE of CLINICAL THERMOMETER with which the PROBE, PROBE CABLE EXTENDER or PROBE COVER is intended to be used. The ACCOMPANYING DOCUMENT of PROBES, PROBE CABLE EXTENDERS and PROBE COVERS, including those that are REPROCESSED, shall list all CLINICAL THERMOMETERS with which compatibility is claimed.

It is the responsibility of the MANUFACTURER of a PROBE, PROBE CABLE EXTENDER and PROBE COVER, including a REPROCESSED PROBE, PROBE CABLE EXTENDER and PROBE COVER, to have their PROCESSES VALIDATED to VERIFY that any new or REPROCESSED product complies with the requirements of this document.

Compliance is checked by the tests of this document.

201.103.2 Labelling

The MODEL OR TYPE REFERENCE of at least one CLINICAL THERMOMETER shall be included in the ACCOMPANYING DOCUMENT provided with each PROBE, PROBE CABLE EXTENDER and PROBE COVER, compliant with 201.103.1.

Statements shall be included in the ACCOMPANYING DOCUMENT of each PROBE, PROBE CABLE EXTENDER and PROBE COVER to the effect that

- a) they are designed for use with specific thermometer or monitoring equipment,
- b) the operator is responsible for checking the compatibility of the thermometer or monitoring equipment, probe, probe cable extender and probe cover before use, and
- c) incompatible components can result in degraded performance.

Additional information is found in 201.103.1.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENT.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.4.3.1 Configurations

Amendment (add after the last dash of 4.3.1):

- if applicable, attachment of ACCESSORIES as necessary to achieve the BASIC SAFETY and ESSENTIAL PERFORMANCE of the CLINICAL THERMOMETER;

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Amendment [add note to list element b)]:

NOTE The requirements of this document are not considered deviations or allowances.

Addition:

202.8.1.101 Additional general requirements

The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE, shall not be allowed:

- component failures;
- changes in programmable parameters or settings;
- reset to default settings;
- change of OPERATING MODE;
- change in LABORATORY ACCURACY at any point in the RATED OUTPUT RANGE and in the RATED EXTENDED OUTPUT RANGE greater than permitted in 201.101.2 without the generation of either a TECHNICAL ALARM CONDITION or an indication of abnormal operation.

The CLINICAL THERMOMETER may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing), which does not require OPERATOR intervention and that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

In the event of disruption during IMMUNITY tests, the CLINICAL THERMOMETER shall recover from any disruption within 30 s.

206 Usability

IEC 60601-1-6:2010+A1:2013 applies except as follows:

For a CLINICAL THERMOMETER, the following shall be considered PRIMARY OPERATING FUNCTIONS:

- a) observing the OUTPUT TEMPERATURE;
- b) properly positioning CLINICAL THERMOMETER or PROBE at the MEASURING SITE;
- c) starting the CLINICAL THERMOMETER from power off;
- d) turning off the CLINICAL THERMOMETER;
- e) performing a basic pre-use functional check of the CLINICAL THERMOMETER.

The following functions, if available, also shall be considered PRIMARY OPERATING FUNCTIONS:

- f) performing a basic pre-use functional check of the ALARM SIGNALS;
- g) configuring the ACCESSORIES including connection of the detachable parts to the CLINICAL THERMOMETER;
- h) REPROCESSING the ACCESSORIES;
- i) setting the OPERATOR-adjustable controls:
 - switching between MEASURING SITES;
 - setting CLINICAL THERMOMETER control parameters;
 - setting ALARM LIMITS;
 - inactivating ALARM SIGNALS.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006+A1:2012 applies except as follows:

208.6.1.2 Determination of ALARM CONDITIONS and assignment of priority

Amendment (add prior to the compliance check):

A CLINICAL THERMOMETER need not have a PHYSIOLOGICAL ALARM CONDITION.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015 applies except as follows:

211.4.2.3.1 Continuous operating conditions

Amendment (replace the first dash with):

- a temperature range of at least +15 °C to +40 °C;

211.10.1.1 General requirements for mechanical strength

Amendment (add as the first paragraph):

The tests of IEC 60601-1-11:2015, Clause 10 and IEC 60601-1:2005+A1:2012, 15.3 shall be performed on the same sample of the CLINICAL THERMOMETER after the cleaning and disinfection PROCEDURES of 201.11.6.6 of this document have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use. If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested. A separate sample of the CLINICAL THERMOMETER may be used for each specified PROCEDURE.

212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

IEC 60601-1-12:2014 applies except as follows:

212.10.1.1 General requirements for mechanical strength

Amendment (add as the first paragraph):

The tests of IEC 60601-1-12:2014, Clause 10 and IEC 60601-1:2005+A1:2012, 15.3 shall be performed on the same sample of the CLINICAL THERMOMETER after the cleaning and disinfection PROCEDURES of 201.11.6.6 of this document have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use. If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested. A separate sample of the CLINICAL THERMOMETER may be used for each specified PROCEDURE.

Annexes

IEC 60601-1:2005+A1:2012, annexes apply, except as follows:

Annex C (informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows:

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS, or their parts

Addition:

201.C.1.101 Marking on the outside of a CLINICAL THERMOMETER or its parts

Additional requirements for marking on the outside of a CLINICAL THERMOMETER or its parts are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a CLINICAL THERMOMETER or its parts

Description of marking	Subclause
Containing phthalates, if applicable	201.11.7
Intended MEASURING SITE	201.7.2.101 b)
On the packaging, any special storage, handling or operating instructions	201.7.2.1.101 e)
On the packaging, appropriate sterility symbol, if applicable	201.7.2.1.101 c)
On the packaging, containing phthalates, if applicable	201.11.7
On the packaging, expiration date, if applicable	201.7.2.1.101 d)
On the packaging, MEASURING SITE	201.7.2.1.101 a)
On the packaging, REFERENCE BODY SITE	201.7.2.1.101 a)
On the packaging, mode of operation of CLINICAL THERMOMETER	201.7.2.1.101 b)
On the packaging, contents of package	201.7.2.1.101 b)
Symbol “°C” or “°F”, as appropriate	201.7.2.101 a)
That a new PROBE COVER shall be used prior to the next measurement, if applicable	201.7.2.101 c)
Clearly indicate the units of measurement	201.7.4.3.101

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

201.C.4.101 ACCOMPANYING DOCUMENTS, general, of a CLINICAL THERMOMETER

Additional requirements for ACCOMPANYING DOCUMENTS, general, of a CLINICAL THERMOMETER are found in Table 201.C.102.

Table 201.C.102 — Accompanying documents, general, of a clinical thermometer

Description of marking	Subclause
Correction method to derive the unadjusted temperature from the OUTPUT TEMPERATURE measured in the ADJUSTED MODE, if applicable	201.7.9.101
Correction method to derive the unadjusted temperature from the OUTPUT TEMPERATURE, if applicable	201.101.1
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, all CLINICAL THERMOMETERS with which compatibility is claimed	201.103.1
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, a statement to the effect that it is designed for use with specific thermometer or monitoring equipment	201.103.2 a)
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, a statement to the effect that the OPERATOR is responsible for checking the compatibility of the thermometer or monitoring equipment, probe, probe cable extender and probe cover before use	201.103.2 b)
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, a statement to the effect that incompatible components can result in degraded performance	201.103.2 c)
For a PROBE, PROBE CABLE EXTENDER and PROBE COVER, the MODEL OR TYPE REFERENCE of at least one CLINICAL THERMOMETER	201.103.2
For an ADJUSTED MODE CLINICAL THERMOMETER, the results of the CLINICAL ACCURACY VALIDATION	201.102.1
Name and address of the MANUFACTURER and where the MANUFACTURER does not have an address within the locale, an authorized representative	201.7.9.1

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use*Addition:***201.C.5.101 ACCOMPANYING DOCUMENTS, instructions for use of a CLINICAL THERMOMETER**

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of a CLINICAL THERMOMETER are found in Table 201.C.103.

Table 201.C.103 — ACCOMPANYING DOCUMENTS, instructions for use of a CLINICAL THERMOMETER

Description of marking	Subclause
A summary of the USE SPECIFICATION	201.7.9.2.101 a)
Characteristics and technical factors known to the MANUFACTURER that could pose a RISK if a single use CLINICAL THERMOMETER or its parts would be re-used	201.7.9.2.101 k)
Details of the nature and frequency of any maintenance and/or calibration needed to ensure that the CLINICAL THERMOMETER operates properly and safely	201.7.9.2.101 i)
For a CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER, the transient response	201.101.3
For a CLINICAL THERMOMETER, its parts or ACCESSORIES that contain phthalates, information on RESIDUAL RISKS for treatment of children or that of pregnant or nursing women and, if applicable, on appropriate precautionary measures	201.11.7
Information about the behaviour of the CLINICAL THERMOMETER when used without the PROBE COVER, if applicable	201.7.9.2.101 f) 2)
Information concerning the disposal of the CLINICAL THERMOMETER and its components	201.7.9.2.101 j)
Instructions for application of a PROBE COVER, if applicable	201.7.9.2.101 f) 1)
Instructions for processing and REPROCESSING the CLINICAL THERMOMETER and its ACCESSORIES	201.11.6.6
Instructions for selection and replacement of the INTERNAL ELECTRICAL POWER SOURCE, if applicable	201.7.9.2.101 h)
LABORATORY ACCURACY in the RATED OUTPUT RANGE	201.7.9.2.101 e)
LABORATORY ACCURACY in the RATED EXTENDED OUTPUT RANGE if applicable	201.7.9.2.101 e)
MEASURING SITE and REFERENCE BODY SITE	201.7.9.2.101 b)
RATED OUTPUT RANGE for each intended REFERENCE BODY SITE	201.7.9.2.101 d)
Recommended minimum measuring time and minimum time between measurements, if applicable	201.7.9.2.101 c)
RESIDUAL RISKS associated with changing environmental conditions	201.4.2.101
Whether the CLINICAL THERMOMETER is a DIRECT MODE or an ADJUSTED MODE CLINICAL THERMOMETER	201.7.9.2.101 g)

Annex D (informative)

Symbols on marking

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

Addition:

Table 201.D.2.101 — Additional symbols on marking

No.	Symbol	Reference	Title
1		ISO 7000-1051 Symbol 5.2.6 ISO 15223-1:2016	Do not re-use
2	 (YYYY-MM)	ISO 7000-2607 Symbol 5.1.4 ISO 15223-1:2016	Use by date
3		ISO 7000-2499 Symbol 5.2.1 ISO 15223-1:2016	Sterile
4		ISO 7000-2500 Symbol 5.2.2 ISO 15223-1:2016	Sterilized using aseptic processing techniques
5		ISO 7000-2501 Symbol 5.2.3 ISO 15223-1:2016	Sterilized using ethylene oxide

No.	Symbol	Reference	Title
6		ISO 7000-2502 Symbol 5.2.4 ISO 15223-1:2016	Sterilized using irradiation
7		ISO 7000-2503 Symbol 5.2.5 ISO 15223-1:2016	Sterilized using steam or dry heat
8		ISO 7000-2608 Symbol 5.2.6 ISO 15223-1:2016	Do not resterilize
9		ISO 7000-2606 Symbol 5.2.8 ISO 15223-1:2016	Do not use if package is damaged
10		ISO 7000-2725 EN 15986:2011	Contains or presence of xxx Where PHT is used for phthalate

Annex AA (informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of ISO 80601-2-56 and is intended for those who are familiar with the subject of ISO 80601-2-56 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses and subclauses in ISO 80601-2-56. The numbering is, therefore, not consecutive.

Subclause 201.1 Scope, object and related standards

This document addresses a range of MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) generally known as CLINICAL THERMOMETERS. This ME EQUIPMENT has been widely used to measure PATIENT temperature during monitoring and treatment of disease. Examples of applications include detection of fever, determination of the time of ovulation, monitoring of a physiological response to various medications and PROCEDURES, effects of exercise and physical work, and evaluation of mental state.

CLINICAL THERMOMETERS are designed and fabricated as PORTABLE, transit-operable, or HAND-HELD ME EQUIPMENT for home healthcare and clinical use, or as parts of the STATIONARY ME EQUIPMENT. The requirements and test PROCEDURES of this document have been developed with the intent to make them applicable to a broad range of present and future CLINICAL THERMOMETER technologies, while assuring that every CLINICAL THERMOMETER that conforms to this document provides an acceptable degree of diagnostic value and acceptable RISK. There are several RISKS associated with use of this type of ME EQUIPMENT. An obvious RISK is a misdiagnosis. For example, a false negative or false positive detection of a fever which leads to a wrong treatment of a PATIENT. Another RISK is a possible injury of a PATIENT or OPERATOR by the CLINICAL THERMOMETER or its components. RISK CONTROL is the main purpose of this document, which describes the requirements and PROCEDURES that assure acceptable levels of CLINICAL ACCURACY and functionality, and which should be maintained over the EXPECTED SERVICE LIFE of the CLINICAL THERMOMETER.

Definition 201.3.201 ADJUSTED MODE

The OUTPUT TEMPERATURE indicated by a CLINICAL THERMOMETER is not necessarily the same as the temperature of the SENSOR that is thermally coupled to the MEASURING SITE. In the DIRECT MODE, the OUTPUT TEMPERATURE indicated by a CLINICAL THERMOMETER is the same as the temperature of the SENSOR that is thermally coupled to the MEASURING SITE. Often, DIRECT MODES are inconvenient. For example, the time response for an accurate measurement might be too slow or it might be impossible to place the SENSOR close to the desired body site.

For some CLINICAL THERMOMETERS, the OUTPUT TEMPERATURE can be the result of a signal adjustment or conversion^[12] and so the mode of operation is called the ADJUSTED MODE. For example, an infrared PROBE can be placed in an ear canal but the digital display (OUTPUT TEMPERATURE) indicates an estimated sublingual temperature of the PATIENT. ADJUSTED MODE CLINICAL THERMOMETERS compensate for

limitations of DIRECT MODE CLINICAL THERMOMETERS by using signal processing algorithms to estimate temperature from measured values, though there is often a corresponding reduction in CLINICAL ACCURACY. This document requires both clinical VALIDATION and laboratory VERIFICATION for all types of ADJUSTED MODES.

Examples of two common types of ADJUSTED MODES follow.

Time adjustment

The first type is the case of a predictive intermittent CLINICAL THERMOMETER that displays an OUTPUT TEMPERATURE before reaching thermal equilibrium, so the displayed OUTPUT TEMPERATURE is an estimate of the “would-be” equilibrium temperature by computation, therefore generally reducing the measurement time. This type of ADJUSTED MODE is used to reduce the measurement time, e.g. from minutes to several seconds. It takes about 5 min for a sublingual CLINICAL THERMOMETER and about 10 min for an axillary (under the armpit) CLINICAL THERMOMETER to achieve thermal equilibrium, while a predictive intermittent CLINICAL THERMOMETER can produce an OUTPUT TEMPERATURE in less than 20 s.

For a predictive intermittent CLINICAL THERMOMETER, the rate of change of the SENSOR'S output is measured and used to predict (anticipate) the final equilibrium temperature which is never reached during the time of measurement^[13]. Figure AA.101 illustrates this type of adjustment.

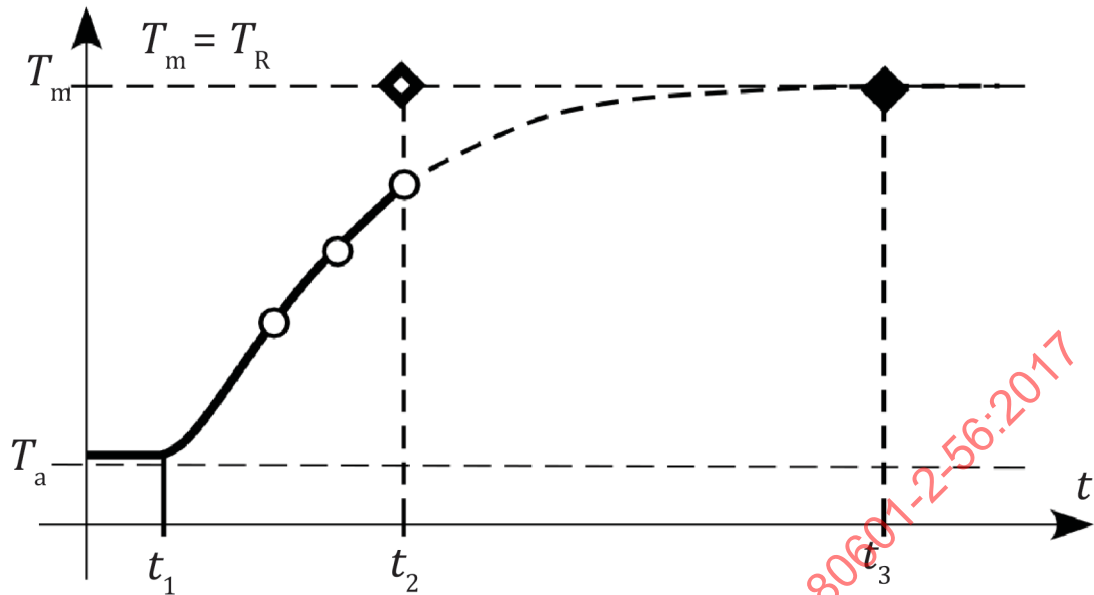
Location adjustment

The second type of ADJUSTED MODE performs a positional dependent adjustment to another position that is different from the MEASURING SITE. This position can be a physiological offset with the aim of providing for convenient temperature measurement of a desired body site that is different from the MEASURING SITE or can be a temperature inside the patient directly below the SENSOR.

EXAMPLE 1 A constant-heat flow CLINICAL THERMOMETER such as a sublingual equilibrium CLINICAL THERMOMETER.

EXAMPLE 2 A radiance ear canal CLINICAL THERMOMETER that estimates the temperature at a different body site by calculation.

EXAMPLE 3 A heat-flow sensor at the forehead.

**Key**

T_a is the ambient temperature

T_m is the MEASURING SITE temperature

T_R is the REFERENCE BODY SITE temperature

t_1 is the time of thermal coupling

t_2 is the time when the temperature at the MEASURING SITE is estimated

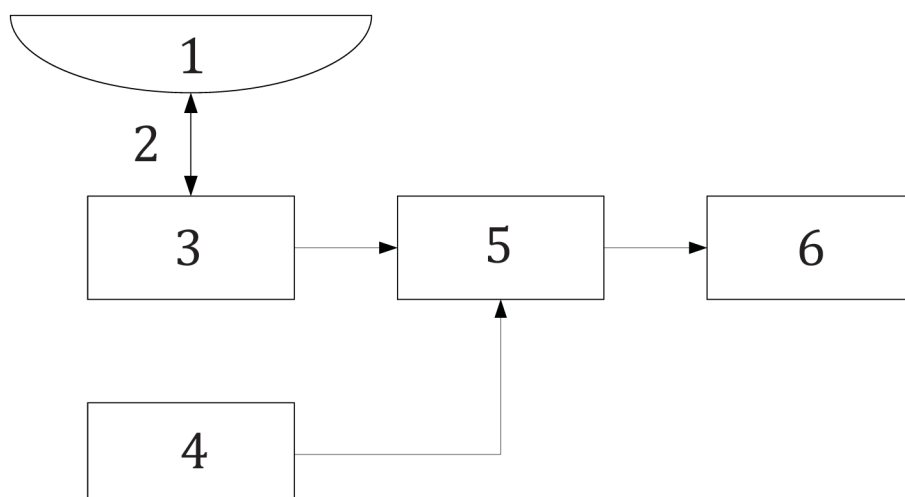
t_3 is the time when achieving thermal equilibrium could have been reached

NOTE The MEASURING SITE is the same as the REFERENCE BODY SITE.

Figure AA.101 — Example of temperature time adjustment for a predictive intermittent CLINICAL THERMOMETER

Definition 201.3.206 CLINICAL THERMOMETER

Any CLINICAL THERMOMETER (see Figure AA.102) contains at least two essential components: a SENSOR (for example, a thermistor or a thermopile) and an output means (for example, a digital display, speaker or printer). A SENSOR is usually incorporated inside or positioned near the PROBE. The PROBE can be attached directly to the ENCLOSURE of a CLINICAL THERMOMETER or connected to it by a cable. To measure temperatures, the PROBE is placed so that the SENSOR is thermally coupled to the MEASURING SITE. The SENSOR converts thermal energy into an electrical signal from which an output representation of the temperature is derived. Other auxiliary components and a signal processing circuit can also be included. The auxiliary components and processing circuit can include the ambient temperature SENSOR, optical components, microcontroller, power supply and other components. A microcontroller uses a software that processes the signals that are received from the SENSOR according to an algorithm that displays OUTPUT TEMPERATURE in the appropriate format.



Key

- 1 MEASURING SITE
- 2 thermal coupling (contact or non-contact)
- 3 SENSOR
- 4 auxiliary components
- 5 processing circuit
- 6 output means that indicates OUTPUT TEMPERATURE

Figure AA.102 — General structure of a CLINICAL THERMOMETER

Definition 201.3.207 DIRECT MODE

A DIRECT MODE CLINICAL THERMOMETER (or the TEST MODE of an ADJUSTED MODE CLINICAL THERMOMETER) is a CLINICAL THERMOMETER whose OUTPUT TEMPERATURE is intended to represent the true temperature of the MEASURING SITE or object, which is thermally coupled to the SENSOR. In other words, the actual temperature detected by the SENSOR is displayed as the OUTPUT TEMPERATURE; whatever is measured is indicated.

Definition 201.3.219 REFERENCE BODY SITE

A CLINICAL THERMOMETER measures and indicates temperatures of a specific organ or area of a PATIENT'S body called a "*body site*". The site where the temperature is actually measured (MEASURING SITE) and the site for which the temperature is indicated (REFERENCE BODY SITE) are not necessarily the same. For example, a measurement can be made sublingually, while the OUTPUT TEMPERATURE indicates a temperature that corresponds to the rectum. Thus, two types of "*body sites*" should be considered.

- The MEASURING SITE is a place on or inside the body of the PATIENT where the PROBE is positioned and to which the SENSOR is thermally coupled.
- The REFERENCE BODY SITE is the part of the body of the PATIENT whose temperature is directly measured or calculated and indicated by the output means of a CLINICAL THERMOMETER.

For the purpose of detecting fever, BODY TEMPERATURES historically have been measured by contact CLINICAL THERMOMETERS in the sublingual, rectal, or axillary (under the armpit) MEASURING SITES which were the same as the REFERENCE BODY SITES. However, most externally accessible MEASURING SITES have not represented the body core temperature with a specific quantitative relationship. Thus, during surgical PROCEDURES and intensive care, temperatures often are measured by invasive PROBES in recognized core temperature MEASURING SITES (e.g. pulmonary artery, distal oesophagus and urinary bladder). These PROBES are normally combined with invasive devices, for example, a Foley catheter.

Although this document does not deny the use of new REFERENCE BODY SITES, new REFERENCE BODY SITES should be scientifically and clinically evaluated for a particular medical purpose. For ADJUSTED MODE CLINICAL THERMOMETERS, this document does require clinical VALIDATION with an existing REFERENCE CLINICAL THERMOMETER. This requirement means that the OUTPUT TEMPERATURE of a new CLINICAL THERMOMETER has to reference a REFERENCE BODY SITE utilized by an existing VALIDATED CLINICAL THERMOMETER.

Subclause 201.4.3.101 Additional requirements for ESSENTIAL PERFORMANCE

CLINICAL THERMOMETERS span the range from invasive ME EQUIPMENT with sophisticated ALARM SYSTEMS that continually monitor critically ill PATIENTS to simple, inexpensive home healthcare environment ME EQUIPMENT. Every CLINICAL THERMOMETER measures or estimates the temperature of a REFERENCE BODY SITE for the purpose of diagnosing or monitoring. These purposes can be the detection of fever, determination of the moment of ovulation, monitoring of the physiological response to medication and PROCEDURES, detection of life-threatening situations (e.g. malignant hyperthermia, sepsis) and many other applications.

This document considers it an unacceptable RISK for a CLINICAL THERMOMETER to present an OUTPUT TEMPERATURE that is not accurate without indicating that it is not accurate. Methods of indicating this degraded performance include generating a TECHNICAL ALARM CONDITION or not providing an OUTPUT TEMPERATURE. Additionally, to allow for affordable home healthcare CLINICAL THERMOMETERS, this document permits the permissible operating temperature range to be marked on the CLINICAL THERMOMETER.

Subclause 201.11.6.6 Additional requirements for USABILITY of ME EQUIPMENT

The CLINICAL THERMOMETER, the PROBE and the ACCESSORIES should not be operated or used if their condition could compromise the health or safety of the PATIENT using them or the employees or third parties supplying them. Among other reasons, this means that the CLINICAL THERMOMETER, the PROBE and the ACCESSORIES cannot be operated or used if there is a potential RISK of the PATIENT becoming infected from the CLINICAL THERMOMETER, the PROBE or the ACCESSORIES.

All CLINICAL THERMOMETERS, PROBES and ACCESSORIES are a potential source of infection in humans. Any CLINICAL THERMOMETERS, PROBES or ACCESSORIES that have been used by a PATIENT are potentially contaminated with reproductive human pathogenic microorganisms until proven otherwise. Appropriate procedures for handling and processing are essential to protect the next person handling, or the next PATIENT using, the CLINICAL THERMOMETER, PROBE or ACCESSORIES. Hence, any CLINICAL THERMOMETERS, PROBES and ACCESSORIES that have been used need processing, following the MANUFACTURER'S instructions, prior to re-use by another PATIENT.

CLINICAL THERMOMETERS, the PROBES and the ACCESSORIES if specified for re-use and the number of re-uses are not limited by the specification provided by the MANUFACTURER. They will be cleaned and disinfected several thousand times during their useful lives. When compliance with this document could be affected by the cleaning or the disinfecting of the CLINICAL THERMOMETER, the PROBE and the ACCESSORIES, an appropriate number of cycles should be required to demonstrate the resistance to the methods specified by the MANUFACTURER. Considering on one hand the test effort for thousands of test cycles necessary with regards to the expected number of applications and on the other hand the usually predicted test results if a reasonable number of cycles has been applied to the CLINICAL THERMOMETER, the PROBE and the ACCESSORIES, the committee considered a pragmatic number of 100 cleaning and disinfection cycles as appropriate to demonstrate the resistance to the methods specified by the MANUFACTURER.

Subclause 201.12.2.101 Additional requirements for USABILITY of ME EQUIPMENT

CLINICAL THERMOMETERS that are intended for home healthcare use (e.g. the PATIENT can be the OPERATOR) need to be readable by OPERATORS that have impaired vision. Additionally, CLINICAL THERMOMETERS that utilize a segmented display need an effective functional test that ensures that all segments are functioning. This ensures that the OPERATOR can distinguish between numbers such as 4 and 9, 5 and 6, or 1 and 7.

Subclause 201.101.1 General test requirements

An ultimate goal of a CLINICAL THERMOMETER is to assess the true temperature of a REFERENCE BODY SITE. Thus, CLINICAL ACCURACY of such a CLINICAL THERMOMETER can only be assessed by comparing its OUTPUT TEMPERATURE with that of another thermometer (REFERENCE THERMOMETER) when temperatures are taken concurrently from the same object or the same subject. The methods of assessment are not the same for DIRECT MODE and ADJUSTED MODE CLINICAL THERMOMETERS. They also can be different for CLINICAL THERMOMETERS with invasive and non-invasive PROBES.

For all CLINICAL THERMOMETERS whose PROBES have negligible thermal contact with the environment (zero-heat-flow thermometers) and whose OUTPUT TEMPERATURES are not adjusted, a laboratory assessment of performance is sufficient. This is done by performing temperature measurements with the CLINICAL THERMOMETER by employing a REFERENCE TEMPERATURE SOURCE and comparing the OUTPUT TEMPERATURE of the CLINICAL THERMOMETER with the temperature of the REFERENCE TEMPERATURE SOURCE. This laboratory assessment is described in 201.101.

For all other CLINICAL THERMOMETERS (ADJUSTED MODE), additional clinical VALIDATION with subjects is required, because the measured temperature is modified to indicate the OUTPUT TEMPERATURE. The modification is a function of the physiological and anatomical properties of an average subject as well as of the environmental conditions. Thus, to assess the effectiveness of such a CLINICAL THERMOMETER, it is compared with another CLINICAL THERMOMETER whose CLINICAL ACCURACY has already been established (i.e. a REFERENCE CLINICAL THERMOMETER). The CLINICAL ACCURACY VALIDATION is described in 201.102.

Table AA.101 summarizes the types of required testing for certain CLINICAL THERMOMETERS.

For some CLINICAL THERMOMETERS, the ACCOMPANYING DOCUMENT indicates the use of a new PROBE COVER for every new measurement. The purpose of the PROBE COVER is to minimize the RISK of cross-contamination between PATIENTS and to prevent soiling of the components of the CLINICAL THERMOMETER (e.g. by dust, faeces or ear wax adhering to the PROBE). Additionally, improper application of the PROBE COVER to the CLINICAL THERMOMETER critically affects the measurement result and care should be taken to properly mount or apply the PROBE COVERS to CLINICAL THERMOMETERS according to the PROCEDURE indicated in the ACCOMPANYING DOCUMENT.

The disposable PROBE COVERS for some radiance (infrared) ear CLINICAL THERMOMETERS (IRETs) are made from a polymeric material. The PROBE COVER acts as a relatively strong filter in the mid-infrared spectral range. Consistent thermal and optical characteristics of these disposable PROBE COVERS influence the overall accuracy of an IRET^[14]. Disposable PROBE COVERS for CLINICAL THERMOMETERS utilizing predictive algorithms can also affect performance. Minor variations in thickness or thermal coefficient influence the accuracy of these CLINICAL THERMOMETERS. The variability of the performance of PROBE COVERS influences the expanded measurement uncertainty and has to be carefully considered. These can be important considerations for any CLINICAL THERMOMETERS.

Table AA.101 — Required tests for CLINICAL THERMOMETERS

Type of CLINICAL THERMOMETER	LABORATORY ACCURACY VERIFICATION		CLINICAL ACCURACY VALIDATION		
	RATED OUTPUT RANGE	RATED EXTENDED OUTPUT RANGE ^a	CLINICAL BIAS	LIMITS OF AGREEMENT	CLINICAL REPEATABILITY
Intermittent or continuous CLINICAL THERMOMETER in DIRECT MODE: for example, a thermometer with invasive catheter PROBE; or a “pencil” contact thermometer for which the MEASURING SITE and REFERENCE BODY SITE are the same, e.g. sublingual, rectal, axillary (under armpit).	✓	✓	No	No	No
Intermittent CLINICAL THERMOMETER in ADJUSTED MODE: for example, a “pencil” predictive thermometer for which the MEASURING SITE and REFERENCE BODY SITE are not the same, e.g. sublingual, rectal, axillary (under armpit); an infrared thermometer for which the MEASURING SITE is skin or the ear canal (tympanic membrane); or a contact thermometer for which the MEASURING SITE is skin with a different REFERENCE BODY SITE.	✓	✓	✓	✓	✓
Continuous CLINICAL THERMOMETER in ADJUSTED MODE: for example, a contact thermometer for which the MEASURING SITE and REFERENCE BODY SITE are different.	✓	✓	✓	✓	No
^a If any.					

Subclause 201.101.2 LABORATORY ACCURACY

The environmental conditions of ambient temperature and relative humidity can affect the performance of a CLINICAL THERMOMETER. Within the RATED range of such conditions, the CLINICAL THERMOMETER is required to meet the requirements while being tested in a laboratory. Table AA.102 provides suggested combinations of REFERENCE TEMPERATURE SOURCE temperature, operating temperature and relative humidity at which the CLINICAL THERMOMETER can be tested.

Continuous CLINICAL THERMOMETERS that are DIRECT MODE CLINICAL THERMOMETERS are intended to monitor temperatures over time. They are well coupled to the MEASURING SITE and have a CLINICAL ACCURACY that is equivalent to their LABORATORY ACCURACY. As a result, such CLINICAL THERMOMETERS are permitted to have a larger LABORATORY ACCURACY specification.

Table AA.102 — Example combinations of operating conditions and REFERENCE temperature for testing the LABORATORY ACCURACY

REFERENCE temperature
Upper limit of RATED OUTPUT RANGE $-0,5\text{ °C} \pm 0,5\text{ °C}$
Midpoint of RATED OUTPUT RANGE $\pm 1\text{ °C}$
Lower limit of RATED OUTPUT RANGE $+0,5\text{ °C} \pm 0,5\text{ °C}$
Operating conditions
Upper limit of RATED ambient temperature range $-0,5\text{ °C} \pm 0,5\text{ °C}$ Upper limit of RATED humidity range $-5\% \pm 5\%$
Upper limit of RATED ambient temperature range $-0,5\text{ °C} \pm 0,5\text{ °C}$ Lower limit of RATED humidity range $+5\% \pm 5\%$
Midpoint of RATED ambient temperature range $\pm 5\text{ °C}$ Midpoint of RATED ambient humidity range $\pm 20\%$
Lower limit of RATED ambient temperature range $+0,5\text{ °C} \pm 0,5\text{ °C}$ Upper limit of RATED humidity range $-5\% \pm 5\%$
Lower limit of RATED ambient temperature range $+0,5\text{ °C} \pm 0,5\text{ °C}$ Lower limit of RATED humidity range $+5\% \pm 5\%$

The REFERENCE TEMPERATURE SOURCE is used to check the LABORATORY ACCURACY of the CLINICAL THERMOMETER. The largest permitted LABORATORY ACCURACY is $0,3\text{ °C}$ for a CLINICAL THERMOMETER that does not operate in the ADJUSTED MODE. In VERIFICATION, the expanded uncertainty of the measurement is usually considered to be small enough if it does not exceed $1/3$ of the LABORATORY ACCURACY^[15]. In the case of CLINICAL THERMOMETERS, this requires an uncertainty of the REFERENCE TEMPERATURE SOURCE at a coverage factor $k = 2$ of $0,3\text{ °C}/3 = 0,1\text{ °C}$ or less. The acceptance band has to be reduced by the uncertainty of the reference thermometer.

Subclause 201.101.3 Time response for a CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER

The ability of a CLINICAL THERMOMETER to track changing PATIENT temperature can be assessed by its response to a rapid change in the REFERENCE TEMPERATURE SOURCE. Depending on the type of a continuous PROBE, the REFERENCE TEMPERATURE SOURCE can be a FLUID BATH (e.g. water bath), a BLACKBODY, or another type of heat source, for example, a thermally controlled plate. The test is performed by quickly transferring a PROBE from one REFERENCE TEMPERATURE SOURCE to another REFERENCE TEMPERATURE SOURCE that has a different temperature. The faster the OUTPUT TEMPERATURE approaches the REFERENCE TEMPERATURE SOURCE temperature, the better the temperature tracking ability of a CLINICAL THERMOMETER.

Previous standards for CLINICAL THERMOMETERS required a transient response test for intermittent CLINICAL THERMOMETERS. These tests do not appear in this document because ADJUSTED MODE CLINICAL ACCURACY tests will uncover problems with response time. If the CLINICAL THERMOMETER is slow to respond relative to the time disclosed in the instructions for use, that source of error would appear in the resulting CLINICAL BIAS with associated LIMITS OF AGREEMENT and/or CLINICAL REPEATABILITY.

Subclause 201.102 CLINICAL ACCURACY VALIDATION

While laboratory testing is sufficient for a DIRECT MODE CLINICAL THERMOMETER, it is not enough for an ADJUSTED MODE CLINICAL THERMOMETER because adjustment algorithms are specific for the anatomical and

physiological properties of PATIENTS and the environment. These properties cannot be closely simulated by any known laboratory REFERENCE TEMPERATURE SOURCE, setting or instrument. Thus, the CLINICAL ACCURACY of an ADJUSTED MODE CLINICAL THERMOMETER is required to be additionally VALIDATED with actual subjects (PATIENTS). Since all subjects are different, statistical methods are employed to compare the OUTPUT TEMPERATURES of the CLINICAL THERMOMETER under test (DUT) for the REFERENCE BODY SITE with those of a REFERENCE CLINICAL THERMOMETER (RCT) whose OUTPUT TEMPERATURES represent the same REFERENCE BODY SITE as the DUT.

The RCT PROBE might not necessarily be placed at the same MEASURING SITE as the DUT PROBE. Moreover, they both can indicate temperatures of a third site, the REFERENCE BODY SITE. For example, the DUT is a forehead skin CLINICAL THERMOMETER (the DUT MEASURING SITE is forehead skin), the RCT is an oral CLINICAL THERMOMETER (the RCT MEASURING SITE is sublingual) and they both output core temperatures (REFERENCE BODY SITE is core). The RCT CLINICAL ACCURACY in representing the REFERENCE BODY SITE temperature was previously VALIDATED. It has an acceptable value of CLINICAL BIAS that carries an acceptable diagnostic RISK. If either the DUT or the RCT uses disposable PROBE COVERS, a new PROBE COVER is used for each new measurement. This permits the test to include the PROBE COVER tolerances in the VERIFICATION of the total CLINICAL ACCURACY.

Hence, performance of a DUT in ADJUSTED MODE is assessed in two steps (see Table AA.101).

- 1) VERIFICATION of a LABORATORY ACCURACY as described in 201.101.
- 2) VALIDATION of CLINICAL ACCURACY while taking temperatures from a sufficiently large group of subjects which is described in 201.102.

Subclause 201.102.2 Human subject population requirements

There are no known data that would suggest that the CLINICAL ACCURACY of a CLINICAL THERMOMETER in an ADJUSTED MODE is affected by the gender or race of a PATIENT. However, the age of a PATIENT is a known and important factor^{[16][17]}. Thermal control in humans develops as the individual grows. Besides, with age, organs change in size, tissue texture, blood perfusion and other properties. All these can affect the adjustment algorithms. When assessing CLINICAL ACCURACY, selection of subjects for the test needs to include a sufficient number of subjects with the ages for which the DUT is intended. This document recommends that four age groups be tested (see Table 201.102).

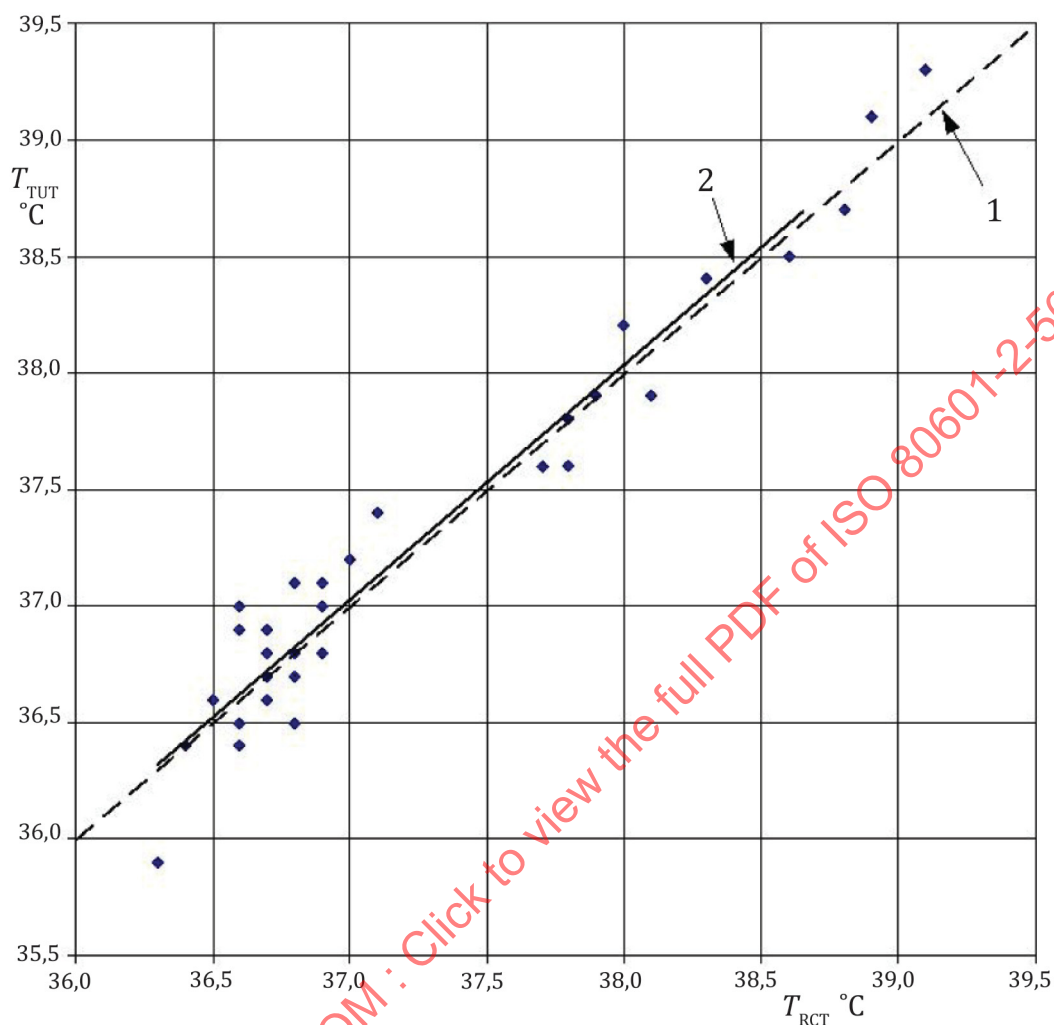
If a CLINICAL THERMOMETER is intended for a subject of any age, all four groups are required to be tested separately. Generally, it is preferable that ages of subjects are distributed within a group as uniformly as possible. The total number of valid subjects in any group is required to be no less than 35 and the total number of the tested subjects is required to be at least 105. However, if a particular DUT is not intended for all ages, the total number of tested subjects is still required to be at least 105. For example, if a basal CLINICAL THERMOMETER is intended for ovulating females, it would be tested only with Group C. The total number of subjects in that group is still required to be at least 105. However, there is no need to test too young or too old female subjects. For that particular type of CLINICAL THERMOMETER, the subjects should be females between 15 years and 50 years of age and there is no need to test older or younger subjects.

For VALIDATION of an ADJUSTED MODE continuous CLINICAL THERMOMETER, no separation of age groups is required. However, the ages of the subjects should be uniformly distributed within the tested population. The total number of tested subjects is still required to be at least 105.

Subclause 201.102.3 CLINICAL BIAS calculation

To evaluate a CLINICAL BIAS, a sufficiently large number of temperature pairs should be taken by two thermometers, the CLINICAL THERMOMETER under test (DUT) and the REFERENCE CLINICAL THERMOMETER (RCT), from multiple subjects with at least one pair of OUTPUT TEMPERATURES per subject. See Figure AA.103.

Since three consecutive temperatures are taken from the MEASURING SITE by the DUT, only the first one is used in computation of the CLINICAL BIAS, because in clinical practice, typically only one temperature measurement is performed.



Key

1 line of equality

2 linear regression line

T_{DUT} is the OUTPUT TEMPERATURE of the DUT

T_{RCT} is the OUTPUT TEMPERATURE of the RCT

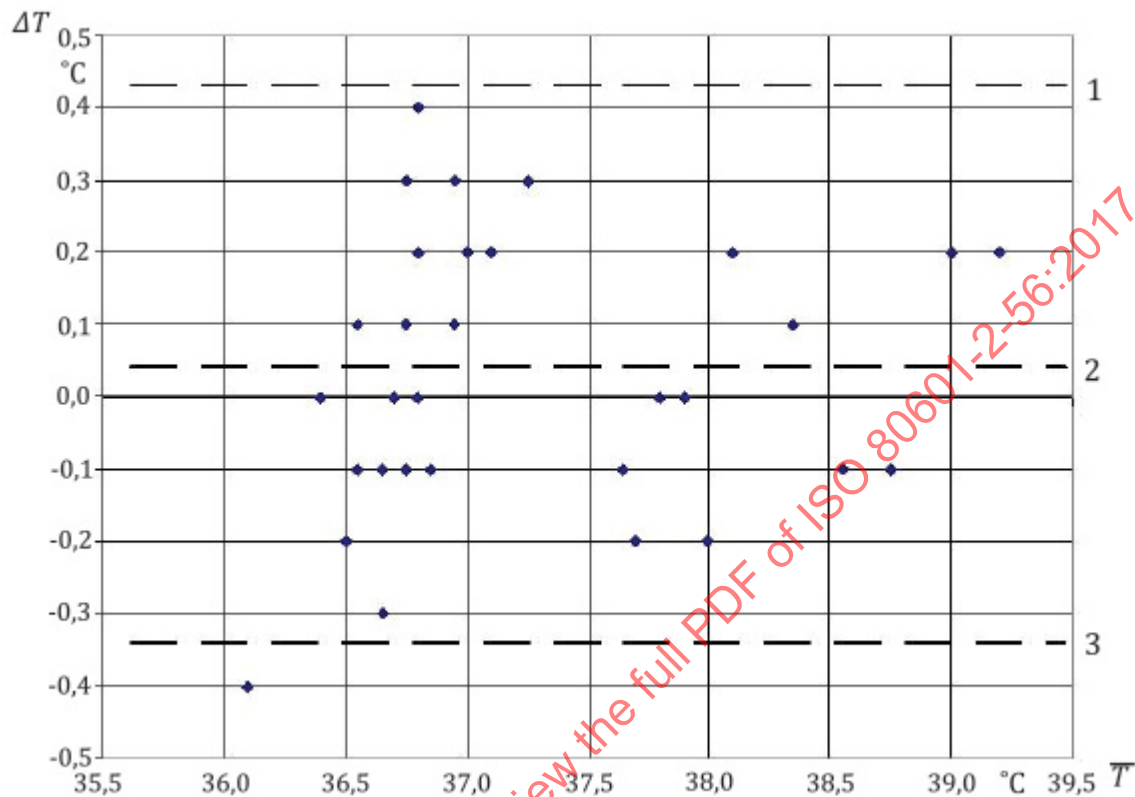
Figure AA.103 — Example of a comparison plot for DUT and RCT

Subclause 201.102.4 LIMITS OF AGREEMENT calculation

Dispersion of OUTPUT TEMPERATURES around the CLINICAL BIAS can be estimated by the standard deviation σ_d of the temperature differences between the CLINICAL THERMOMETER under test (DUT) and the RCT as measured from multiple subjects. For a graphical illustration and analysis, it is convenient to plot the differences, ΔT , against the average values of OUTPUT TEMPERATURES from the DUT and the RCT, i.e. $(T_{DUT} + T_{RCT})/2$, as shown in Figure AA.104.

If the differences are normally distributed, it can be expected that about 95 % of them will fall in the range of $\bar{d} \pm 2 \times \sigma_d$. This range is called the “95 % limits of the agreement”. This document defines

LIMITS OF AGREEMENT as $2 \times \sigma_d$. It characterizes the range within which most differences between the OUTPUT TEMPERATURES by the DUT and the RCT lie.



Key

- 1 $\bar{d} + 2 \times \sigma_d$
- 2 $\bar{d}$ is the mean difference between OUTPUT TEMPERATURES from the DUT and the RCT
- 3 $\bar{d} - 2 \times \sigma_d$
- ΔT is the temperature differences between the CLINICAL THERMOMETER under test (DUT) and the RCT
- $\bar{T}$ is the average of OUTPUT TEMPERATURES from the DUT and the RCT

Figure AA.104 — Example of a Bland-Altman Plot^[18] of the temperature difference (DUT minus RCT) versus the average OUTPUT TEMPERATURES of two thermometers

Table AA.103 exemplifies results of a CLINICAL ACCURACY test, with the total number of PATIENTS in the group $n = 36$, both febrile and afebrile. Three sequential OUTPUT TEMPERATURES from each PATIENT are measured and indicated by a DUT as T_1 , T_2 and T_3 . Note that only one DUT temperature, T_1 , was taken from febrile PATIENTS (subject numbers 3 and 5). The bias and standard deviation were calculated from the temperature differences ($T_1 - T_{\text{RCT}}$) as $+0,07^{\circ}\text{C}$ and $0,37^{\circ}\text{C}$, respectively. The bias is acceptable. Although the LIMITS OF AGREEMENT ($0,44^{\circ}\text{C}$) are on the high side, they could be considered by some to be clinically acceptable. The CLINICAL REPEATABILITY of all subjects, other than febrile subjects less than 5 years old, as computed using Formula (5), is $\sigma_r = 0,23^{\circ}\text{C}$. This number appears to be reasonable. As a result of the test, the DUT could be considered a clinically useful thermometer.

Table AA.103 — Example of CLINICAL ACCURACY VALIDATION test results

PATIENT	T_1 °C	T_2 °C	T_3 °C	T_{RCT} °C	$T_1 - T_{RCT}$ °C	σ_j °C
1	36,5	36,7	36,2	36,4	0,1	0,25
2	37,1	37,0	36,8	36,9	0,2	0,15
3	39,9			39,3	-0,4	
4	35,8	35,9	36,2	35,8	0,0	0,21
5	38,2			38,0	0,2	
6	37,4	37,1	36,9	37,1	0,3	0,25
...	...	...	...	...	...	...
34	36,7	36,5	36,4	36,5	0,2	0,15
35	36,6	36,9	36,7	36,8	-0,2	0,15
36	36,1	36,3	36,3	36,0	0,1	0,12
Bias, $\bar{d}$					0,07	
Standard deviation					0,22	
LIMITS OF AGREEMENT, L_A					0,44	
CLINICAL REPEATABILITY, σ_r						0,23

Subclause 201.102.5 CLINICAL REPEATABILITY calculation

CLINICAL REPEATABILITY (sometimes called the perceived accuracy) is a measure of the consistency of repeated measurements with identical operating conditions when temperatures are taken within short time intervals from the same MEASURING SITE of the same subject by the same OPERATOR with the same intermittent CLINICAL THERMOMETER. This characteristic is applicable only to intermittent CLINICAL THERMOMETERS. To determine the CLINICAL REPEATABILITY, three OUTPUT TEMPERATURES ($T_{1,j}$, $T_{2,j}$, and $T_{3,j}$) are taken from each subject by the CLINICAL THERMOMETER under test (DUT). No RCT is required as the DUT OUTPUT TEMPERATURES are compared with themselves. Reasonable time delays between the measurements are necessary to minimize effects of cooling the MEASURING SITE by the PROBE and thermal drifts in the PROBE. The ACCOMPANYING DOCUMENT recommends the minimum time between measurements (the highest possible rate of taking temperatures) at the MEASURING SITE. The CLINICAL REPEATABILITY does not show the CLINICAL ACCURACY of the DUT, only the consistency of the OUTPUT TEMPERATURES.

CLINICAL REPEATABILITY is a pooled standard deviation of triplicate measurements over the population of subjects, other than febrile subjects less than 5 years old.

Subclause 201.103 PROBES, PROBE CABLE EXTENDERS and PROBE COVERS

PROBES, PROBE CABLE EXTENDERS and PROBE COVERS are as important in establishing the safety and accuracy of the complete CLINICAL THERMOMETER as is the indicating unit and any software algorithms. This subclause establishes that the MANUFACTURER of the PROBE, PROBE CABLE EXTENDER or PROBE COVER (including a MANUFACTURER of a REPROCESSED PROBE, PROBE CABLE EXTENDER or PROBE COVER) is responsible not only for the separately testable properties (such as biocompatibility) of the PROBE, PROBE CABLE EXTENDER or PROBE COVER itself, but also for the affected combined properties (such as accuracy, electromagnetic compatibility, and electrical safety) of the CLINICAL THERMOMETERS that the MANUFACTURER specifies that the PROBE, PROBE CABLE EXTENDER or PROBE COVER can be used with. As an example of a possible effect of REPROCESSING on biocompatibility, glutaraldehyde sterilization of silicone rubber materials can result in impregnation of the material with solvent which, if not sufficiently