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- iii) requires additional national guidance or information

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Full document details: 25/30490346 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 80601-2-56

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*

ICS: 11.040.55

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

ISO/CEN PARALLEL PROCESSING

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Full document details: 25/30490346 DC

ISO/TC 121/SC 3

Secretariat: **ANSI**

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2026-03-11

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54 **Foreword**

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

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

66 Attention is drawn to the possibility that some of the elements of this document may be the subject of
 67 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any
 68 patent rights identified during the development of the document will be in the Introduction and/or on
 69 the ISO list of patent declarations received (see www.iso.org/patents).

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

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

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

79 This third edition cancels and replaces the second edition (ISO 80601-2-56:2017), which has been
 80 technically revised.

81 The most significant changes are the following modifications:

- 82 — harmonization with the Edition 3.2 of the general standard;
- 83 — harmonization with ISO 20417;
- 84 — deletion of the clinical performance *verification* requirements and replacement by the requirement to
- 85 conform with ISO 12487

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 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*.

There are different temperatures at each *reference site* according to the balance between the production, transfer, and loss of heat^[22] ¹.

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*.

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 conformance with a requirement or a test is mandatory for conformance with this document;

¹ Figures in square brackets refer to the Bibliography.

- 117 — “should” means that conformance with a requirement or a test is recommended but is not mandatory
118 for conformance with this document;
- 119 — “may” is used to describe a permissible way to achieve conformance with a requirement or test.

Medical electrical equipment —

Part 2-56:

Particular requirements for basic safety and essential performance of clinical thermometers for human temperature measurement

201.1 Scope, object and related standards

NOTE 1 There is guidance or rationale for this Clause contained in Clause AA.2.1.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

NOTE 2 The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 Scope

IEC 60601-1:2005+AMD1:2012, 1.1 is replaced by:

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 only applies to all electrical *clinical thermometers* that are used for measuring the temperature of *patients*.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *clinical thermometer*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *clinical thermometer*.

EXAMPLE 1 *Probes, probe cable extenders and probe covers.*

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 the temperature of a *patient* is within the scope of this document.

EXAMPLE 2 *ME equipment* using *accessories* such as a pulmonary artery catheter for the determination of cardiac output by thermodilution is in the scope of this document if it displays a temperature.

EXAMPLE 3 *ME equipment* using *accessories* such as a Foley catheter that includes a temperature *probe* is in the scope of this document.

This document does not specify requirements for screening thermographs intended to be used for the individual non-invasive human febrile temperature screening of humans under indoor environmental conditions, whose *laboratory accuracy* requirements are described 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+AMD1:2012, 7.2.13 and 8.4.1.

NOTE Additional information can be found in IEC 60601-1:2005+AMD1:2012, 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 201.3.205, 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

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

Addition (add after existing text):

This document refers to those applicable collateral standards that are listed in general standard, as well as 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-11:2015+AMD1:2020 and IEC 60601-1-12:2014+AMD1:2020 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 define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard as appropriate for the particular *ME equipment* under consideration.

A requirement of a document takes priority over the general standard and its collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 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, 206.4 in this document addresses the content of Clause 4 of the 60601-1-6 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 general standard 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 general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Clauses, 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.

Clauses, 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, 206 for IEC 60601-1-6, etc.

The term “this document” is used to make reference to the general standard, 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 general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard 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.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 applies, except as follows:

Addition:

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 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 12487:—², *Medical electrical equipment — Clinical performance evaluation of clinical thermometers*

² Under preparation. Stage at the time of publication: ISO/FDIS 12487:2025.

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

ISO 20417:—³, *Medical devices — Information to be supplied by the manufacturer*

IEC 62366-1:2015+AMD2:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62570:2025, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020 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.

201.3.201

accompanying information

information supplied by the manufacturer with or marked on a medical device or accessory for the user or responsible organization, particularly regarding safe use

Note 1 to entry: The *accompanying information* is regarded as part of the medical device or *accessory*.

Note 2 to entry: The *accompanying information* can consist of the label, *marking, instructions for use, technical description*, information shown on the packaging or graphical *user interface (GUI)*, installation manual, quick reference guide, etc and can address the installation, use, *processing, maintenance* and disposal of the *medical device* or *accessory*.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but can involve auditory, visual, or tactile materials and multiple media types (e.g. CD-ROM, DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:—, 3.2, modified — deleted note 4.]

201.3.202

alarm limit

threshold used by an *alarm system* to determine an *alarm condition*

[SOURCE: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 3.3]

³ Under preparation. Stage at the time of publication: ISO/FDIS 20417:2025.

255 **201.3.203**
 256 **blackbody**
 257 *reference temperature source* of infrared radiation characterized by precisely known temperature and
 258 having an effective emissivity close to one

259 **201.3.204**
 260 **cleaning**
 261 removal of contaminants to the extent necessary for further *processing* or for *intended use*

262 Note 1 to entry: *Cleaning* consists of the removal of adherent soil (e.g. blood, protein substances, and other debris)
 263 from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated *process* that
 264 prepares the items for safe handling or further *processing*.

265 [SOURCE: ISO 17664-2:2021, 3.1, modified — replaced “and/or” with “or”.]

266 **201.3.205**
 267 **clinical accuracy**
 268 closeness of agreement between the *output temperature* of a *clinical thermometer* and the reference value
 269 of the temperature of the *reference site* that the *clinical thermometer* purports to represent

270 **201.3.206**
 271 **clinical thermometer**
 272 *ME equipment* used for measuring at the *measuring site* and indicating the temperature at the *reference*
 273 *site*

274 Note 1 to entry: The *measuring site* can be the same as the *reference site*.

275 Note 2 to entry: There is guidance or rationale for this definition contained in AA.2.2.

276 **201.3.207**
 277 **direct measurement mode**
 278 *operating mode* of a *clinical thermometer* where the *output temperature* represents the temperature of
 279 the *measuring site* with which the *probe* is in thermal equilibrium

280 Note 1 to entry: There is guidance or rationale for this definition contained in AA.2.3.

281 **201.3.208**
 282 **disinfection**
 283 *process* to reduce the number of viable microorganisms to a level previously specified as being
 284 appropriate for a defined purpose

285 [SOURCE: ISO 17664-1:2021, 3.3]

286 **201.3.209**
 287 **essential principles**
 288 **essential principles of safety and performance**
 289 fundamental high-level requirements that when complied with ensure a medical device is safe and
 290 performs as intended

291 [SOURCE: ISO 16142-1:2016, 3.3]

292 **201.3.210**
 293 **extended output range**
 294 *output temperature* range having one or both limits that are outside of the *rated output range*

201.3.211

fluid bath

reference temperature source containing fluid at a uniform temperature

EXAMPLE Water, oil and air.

201.3.212

home healthcare environment

dwelling place in which a *patient* lives or other places where *patients* are present, excluding the *professional healthcare environment* and the *EMS environment*

EXAMPLE Other places include in a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Nursing homes are considered *home healthcare environments*.

Note 2 to entry: In some countries, nursing homes are considered *professional healthcare facilities*.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1, modified —replaced “professional healthcare facility environments where operators with medical training are continually available when patients are present” with “the professional healthcare environment and the EMS environment”, deleted notes 1 and 3, modified note 2 as new note 1, added note 2 and added to the example “Other places include”.]

201.3.213

immunity

ability of *ME equipment* or an *ME system* to perform without degradation in the presence of an electromagnetic disturbance

[SOURCE: IEC 60601-1-2:2014+AMD1:2020, 3.8]

201.3.214

indirect measurement mode

operating mode of a *clinical thermometer* where the *output temperature* represents the temperature of a *measuring site* with which the *probe* is not in thermal equilibrium

Note 1 to entry: Infrared *clinical thermometers* are not typically in thermal equilibrium with the *measuring site* and are therefore typically in *indirect measurement mode*.

Note 2 to entry: There is guidance or rationale for this definition contained in AA.2.4.

201.3.215

information supplied by the manufacturer

information related to the identification and use of a medical device or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the medical device or *accessory*

Note 1 to entry: *e-documentation* is included in the *information supplied by the manufacturer*.

Note 2 to entry: Shipping documents (e.g. packing list and customs documents) and promotional material are excluded from *information supplied by the manufacturer*. However, some *authorities having jurisdiction* can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the medical device or *accessory* and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use.

[SOURCE: ISO 20417:—, 3.15, modified — deleted note 4.]

201.3.216

instructions for use

IFU

package insert

portion of the *accompanying information* that is

- directed to the user;

- essential for the safe and effective use of a medical device or *accessory*

Note 1 to entry: A user can be either a *lay* user or professional user with relevant specialized training.

Note 2 to entry: Instructions for the professional *processing* between uses of a medical device or *accessory* can be included in the *instructions for use*.

Note 3 to entry: The *instructions for use*, or portions thereof, can be located on the display of a medical device or *accessory*.

Note 4 to entry: Medical devices or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:—, 3.16, modified — deleted note 5.]

201.3.217

laboratory accuracy

closeness of agreement between the *output temperature* of a *clinical thermometer* and a *reference thermometer*

Note 1 to entry: *Laboratory accuracy* is sometimes referred to as maximum permissible error.

201.3.218

lay, adj

lay person, adj

not having formal education in a relevant field of healthcare or medical discipline and, if appropriate, not

having relevant specialized training on the use of the specific medical device

EXAMPLE *Lay operator, lay responsible organization.*

[SOURCE: ISO 20417:—, 3.19]

201.3.219

marking

information, in text or graphical format, durably affixed, printed, etched or by equivalent means to a product

Note 1 to entry: The word *marked* is used to designate the corresponding act.

Note 2 to entry: *Marking* is different from 'direct *marking*' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct *marking*' is a type of *marking*.

[SOURCE: ISO 20417:—, 3.22, modified — deleted note 3.]

201.3.220

measuring site

body location of a *patient* that the *probe* directly interacts with

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