SLOVENSKI STANDARD
oSIST prEN ISO 12487:2025

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Medicinska električna oprema - Klinično vrednotenje učinkovitosti kliničnih termometrov (ISO/DIS 12487:2024)

Medical electrical equipment - Clinical performance evaluation of clinical thermometers (ISO/DIS 12487:2024)

Medizinische elektrische Geräte - Prüfung der klinischen Leistung von medizinischen Thermometern (ISO/DIS 12487:2024)

Équipement respiratoire - Investigation clinique des thermomètres cliniques (ISO/DIS 12487:2024)

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Medical electrical equipment — Clinical performance evaluation of clinical thermometers

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

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

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 document 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 and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

For an explanation of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 12487 together with the third edition of ISO 80601-2-56, cancels and replaces the second edition of ISO 80601-2-56 published in 2017 and its Amendment 1 (2019).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Determining body temperature is an important *procedure* that is clinically used to assess the status of *patients* as well as blood pressure, SpO_2 and pulse rate. This document is intended to provide the necessary requirements for the *clinical investigation* to ensure that the *essential performance* of these *clinical thermometers* is at an adequate level.

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.

— *Terms defined in clause 3 of this document or as noted: 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.

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 particular 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.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" is used to describe a possibility or capability; and

— "must" is used to indicate an external constraint.

Medical electrical equipment — Clinical performance evaluation of clinical thermometers

1 Scope

This document specifies the requirements and methods for the *clinical investigation* of *ME equipment* used to measure the body temperature in *indirect measurement mode*.

This document covers both intermittently and continuously measuring *clinical thermometers*.

This document is not intended for *clinical thermometers* measuring the body temperature in *direct measurement mode*.

NOTE 1 For *clinical thermometers* in *direct measurement mode* determining the technical accuracy in accordance with IEC 80601-2-56 is considered sufficient.

NOTE 2 For *clinical thermometers* with claimed measurement time shorter than 60 seconds (for methods such as oral or rectal measurement), or shorter than 5 minutes (for methods such as axillary measurement) are treated as *predictive type thermometers* and fall under the scope of this document.

This document specifies additional disclosure requirements.

This document is not applicable to the *clinical investigation* of a screening thermographs for human febrile temperature screening whose *laboratory accuracy* requirements are described in IEC 80601-2-59.

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.

ISO 80601-2-56:—[1], *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

ISO 14155:—[2], *Clinical investigation of medical devices for human subjects — Good clinical practice*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance +Amendment 1:2012 +Amendment 2:2020*

JCGM 100:2008, *Evaluation of measurement data — Guide to the expression of uncertainty in measurement* (GUM 1995 with minor corrections)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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1 Under preparation. Stage at the time of publication: ISO/DIS 80601-2-56:2024.

2 Under preparation. Stage at the time of publication: ISO/DIS 14155:2024.

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

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

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

3.1
accompanying information
information accompanying or *marked* on a medical device or accessory for the user or those accountable for the installation, use, processing, maintenance, decommissioning and disposal of the medical device or accessory, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be 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*, installation manual, quick reference guide, etc.

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

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

3.2
clinical accuracy
closeness of agreement between the *output temperature* of a *clinical thermometer* and the reference value of the temperature of the reference site that the *clinical thermometer* purports to represent

[SOURCE: ISO 80601-2-56:—, 201.3.202]

3.3
clinical bias
Δ_{cb}
mean difference between *output temperatures* of a *clinical thermometer* and a *reference thermometer* for the intended *reference body site*

Note 1 to entry: The *measuring site* can be the same as or different from the *reference body site*.

3.4
clinical investigation
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a medical device

Note 1 to entry: For the purpose of this document, “clinical trial” or “clinical study” are synonymous with “clinical investigation”.

[SOURCE: ISO 14155:—, 3.9]

3.5
clinical investigation report
document describing the design, conduct, statistical analysis and results of a *clinical investigation*

[SOURCE: ISO 14155:—, 3.11]

3.6
clinical repeatability
σ_{repeat}
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

[SOURCE: ASTM 1965-98, 3.2.10, modified — focus changed from "ear canal temperature" to the more general "*measuring site*" and the parenthetical part "(over a selected group of subjects)" was included.]

3.7
clinical thermometer
ME equipment used for measuring at the *measuring site* and indicating the temperature at the reference site

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

[SOURCE: ISO 80601-2-56:—, 201.3.203]

3.8
clinical thermometer-under-test
DUT
clinical thermometer undergoing *clinical investigation*

3.9
direct measurement mode
operating mode of a *clinical thermometer* where the *output temperature* represents the temperature of the *measuring site* with which the *probe* is in *thermal equilibrium*

[SOURCE: ISO 80601-2-56:—, 201.3.204]

3.10
essential performance
performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the *manufacturer* results in an unacceptable *risk*

Note 1 to entry: *Essential performance* is most easily understood by considering whether its absence or degradation would result in an unacceptable *risk*.

[SOURCE: ISO 60601-1:2005+AMD1:2012+AMD2:2020, 3.27]

3.11
indicated body site
body site of a subject to which the *output temperature* relates

Note 1 to entry: There is guidance or rationale for this definition contained in Clause AA.2.

3.12
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*.