International Standard

ISO 12487

Medical electrical equipment — Clinical performance evaluation of clinical thermometers

Appareils électromédicaux — Évaluation de la performance clinique des thermomètres médicaux

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Foreword

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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 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).

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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, *Medical equipment, software, and systems*, Subcommittee SC 62D, *Particular medical equipment, software, and systems*, 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).

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 thermometer* is at an adequate level.

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 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 *medical electrical (ME) equipment* used to measure the body temperature in *indirect measurement mode*.

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

NOTE 1 This document does not apply to *clinical thermometers* measuring the body temperature in *direct measurement mode*.

NOTE 2 For *clinical thermometers* in *direct measurement mode* determining the technical accuracy in accordance with ISO 80601-2-56:—[1)] is considered sufficient.

This document is applicable to *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), and which are treated as *predictive type thermometers* and fall under the scope of this document.

This document specifies additional disclosure requirements.

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

This document does not apply to pulmonary artery catheter for the determination of cardiac output by thermodilution.

NOTE 3 ISO 80601-2-56:—[1)] does include pulmonary artery catheter for the determination of cardiac output by thermodilution.

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 14155:2026, *Clinical investigation of medical devices for human subjects — Good clinical practice*

3 Terms and definitions

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

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

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

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

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

1) Third edition under preparation. Stage at the time of balloting: ISO/DIS 80601-2-56.

3.1
accompanying information
information supplied by the *manufacturer* (3.16) 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* (3.14), technical description, 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 20417:2026, 3.2, modified — Notes 4 and 5 to entry and the figure have been deleted.]

3.2
application site
measuring site
body location of a *patient* (3.19) that the *probe* (3.20) directly interacts with

EXAMPLE Ear canal, oral (sublingual pocket), axilla (armpit), rectum, centre of forehead, temple, inner canthus, temporal artery, bladder.

Note 1 to entry: Measurement at the *application site* is either contact or non-contact (e.g. infrared).

[SOURCE: ISO 80601-2-56:—, 201.3.220, modified —"*application site*" has been added as a preferred term, the Example was changed and Note 1 to entry was added.]

3.3
clinical accuracy
closeness of agreement between the *output temperature* (3.18) of a *clinical thermometer* (3.8) and the reference value of the temperature of the *reference site* (3.25) that the *clinical thermometer* purports to represent

[SOURCE: ISO 80601-2-56:—, 201.3.205]

3.4
clinical bias
Δ_{cb}
mean difference between *output temperatures* (3.18) of a *clinical thermometer* (3.8) and a *reference thermometer* (3.26) for the intended *reference site* (3.25)

Note 1 to entry: The *application site* (3.2) can be the same as or different from the *reference site*.

3.5
clinical investigation
clinical trial
clinical study
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a medical device

[SOURCE: ISO 14155:2026, 3.9]

3.6
clinical investigation report
clinical study report
document describing the design, conduct, statistical analysis and results of a *clinical investigation* (3.5)

[SOURCE: ISO 14155:2026, 3.11]

3.7
clinical repeatability
σ_{repeat}
pooled standard deviation (over a selected group of subjects) of changes in multiple *output temperatures* (3.18) taken from the same subject at the same *application site* (3.2) with the same *clinical thermometer* (3.8) by the same operator within a relatively short time

[SOURCE: ASTM E1965-98, 3.2.10, modified — focus changed from "ear canal temperature" to the more general "*application site*" and the parenthetical part "(over a selected group of subjects)" was included.]

3.8
clinical thermometer
medical electrical (ME) equipment (3.17) used for measuring at the *application site* (3.2) and indicating the temperature at the *reference site* (3.25)

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

[SOURCE: ISO 80601-2-56:—, 201.3.206, modified — "*measuring site*" has been replaced with "*application site*".]

3.9
clinical thermometer-under-test
DUT
clinical thermometer (3.8) undergoing *clinical investigation* (3.5)

3.10
direct measurement mode
operating mode of a *clinical thermometer* (3.8) where the *output temperature* (3.18) represents the temperature of the *application site* (3.2) with which the *probe* (3.20) is in *thermal equilibrium* (3.31)

[SOURCE: ISO 80601-2-56:—, 201.3.207, modified — "*measuring site*" has been replaced with "*application site*".]

3.11
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* (3.16) results in an unacceptable *risk* (3.27)

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

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

3.12
indicated site
indicated body site
body site to which the *output temperature* (3.18) of the *clinical thermometer* (3.8) refers

EXAMPLE 1 Ear canal, oral (sublingual pocket), axilla, rectum, core body.

Note 1 to entry: The *indicated site* may differ from the *application site* (3.2).

EXAMPLE 2 *Site conversion* (3.29) *clinical thermometers*.

Note 2 to entry: There is guidance or rationale for this definition contained in A.2.1.