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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**

*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](http://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 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](http://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](http://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<sup>[1]</sup>;

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<sup>[2]</sup>. 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<sup>[3]</sup>. 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).

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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.