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Title: Draft BS EN ISO 12487. Respiratory equipment # Clinical investigation of clinical thermometers

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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.

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Submission of Comments

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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	Commend (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.	



62D/2051/CD

COMMITTEE DRAFT (CD)

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62D/1922/NP, 62D/1951A/RVN

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT:

United States of America

SECRETARY:

Ms Ladan Bulookbashi

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:

☐

Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☐ SAFETY

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Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

Respiratory equipment -- Clinical investigation of clinical thermometers

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ISO TC 121/SC 3 **N 2994**

Date: 2023-06-09

ISO CD 12487:2023(E)

ISO TC 121/SC 3/JWG 8

Secretariat: ANSI

Medical electrical equipment — Clinical investigation of clinical thermometers

Appareils électromédicaux — Investigation clinique des thermomètres cliniques

CD stage

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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).

The main changes compared to the previous edition are as follows:

- addition of Clause 7 acceptance criteria,
- editorial changes.

A list of all parts in the ISO 80601 series can be found on the ISO website.

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

- 107 Determining body temperature is an important *procedure* that is clinically used to assess the status of
108 *patients* as well as blood pressure, SpO₂ and pulse rate. This document is intended to provide the
109 necessary requirements for the *clinical investigation* to ensure that the *essential performance* of these
110 *clinical thermometers* is at an adequate level.
- 111 This document has been drafted in accordance with the ISO/IEC Directives, Part 2.
- 112 In this document, the following print types are used.
- 113 — Requirements and definitions: roman type.
- 114 — Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
115 Normative text of tables is also in a smaller type.
- 116 — *Terms defined in clause 3 of the general standard, in this document or as noted: italic type.*
- 117 In referring to the structure of this document, the term
- 118 — “clause” means one of the numbered divisions within the table of contents, inclusive of all
119 subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.), and
- 120 — “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of
121 Clause 7).
- 122 References to clauses within this document are preceded by the term “Clause” followed by the clause
123 number. References to subclauses within this document are by number only.
- 124 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
125 of the conditions is true.
- 126 The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives,
127 Part 2. For the purposes of this document, the auxiliary verb:
- 128 — “shall” indicates a requirement;
- 129 — “should” indicates a recommendation;
- 130 — “may” indicates a permission;
- 131 — “can” is used to describe a possibility or capability.

Medical electrical equipment — Clinical investigation 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*.

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

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 14155:2020, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 80601-2-56:—, 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:

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

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

3.1 clinical bias

Δ_{cb}

mean difference between *output temperatures* of a *clinical thermometer* and a *reference clinical thermometer* for the intended *reference body site*

¹ xxx