INTERNATIONAL STANDARD

ISO 80601-2-56

Second edition 2017-03-01 **AMENDMENT 1** 2018-11

Medical electrical equipment —

Part 2-56:

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

(stamendment.1i)

Appareils électromédicaux —

https://standards.iteh.Partie 2-56d Exigences particulières relatives à la sécurité
7eff512a fondamentale et aux performances essentielles des thermomètres
médicaux pour mesurer la température de corps

AMENDEMENT 1



ISO 80601-2-56:2017/AMD1:2018 https://standards.iteh.ai/catalog/standards/sist/eae17f10-76e8-4c92-b9ee-7eff512a755e/iso-80601-2-56-2017-amd1-2018



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This document was prepared jointly 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 D, Electromedical equipment.

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ISO 80601-2-56:2017/AMD1:2018 https://standards.iteh.ai/catalog/standards/sist/eae17f10-76e8-4c92-b9ee-7eff512a755e/iso-80601-2-56-2017-amd1-2018

Medical electrical equipment —

Part 2-56:

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

AMENDMENT 1

Introduction, penultimate paragraph

Replace the third bullet in the verbal forms with the following:

- "may" is used to describe a permission (e.g. a permissible way to achieve compliance with a requirement or test);
- "can" is used to describe a possibility or capability; and
- "must" is used to express an external constraint. (Standards.iteh.ai)

Introduction, last paragraph https://standards.iteh.ai/catalog/standards/sist/eae17f10-76e8-4c92-b9ee-

Replace "Member Bodies and National Committees" with "users of this document".

201.1.1 Scope, third paragraph

Replace the paragraph with:

ME EQUIPMENT that measures and displays a BODY TEMPERATURE is inside the scope of this document.

EXAMPLE 1 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 BODY TEMPERATURE.

EXAMPLE 2 ME EQUIPMENT using ACCESSORIES such as a Foley catheter that includes a temperature PROBE is in the scope of this document.

201.3.215

Replace "temperture" with "temperature".

201.3.222

Replace the Example with the following:

EXAMPLE BLACKBODY, FLUID BATH.

ISO 80601-2-56:2017/Amd.1:2018(E)

201.12.1.101

Replace the entire subclause with the following:

When the CLINICAL THERMOMETER is not capable of indicating a temperature within the LABORATORY ACCURACY, it shall provide a TECHNICAL ALARM CONDITION or it shall not provide an OUTPUT TEMPERATURE.

EXAMPLE 1 Technical alarm condition caused by low voltage of the internal electrical power source.

 $\begin{tabular}{ll} EXAMPLE~2 & Technical~alarm~condition~caused~by~output~temperature~outside~the~rated~output~range~or~rated~extended~output~range. \end{tabular}$

The output temperature of clinical thermometers shall cover the minimum rated output range from 34.0 °C to 42.0 °C.

NOTE In some applications, a wider RATED OUTPUT RANGE can be utilized.

For some intended uses, a narrower rated output range may be utilized.

EXAMPLE 3 Ovulation CLINICAL THERMOMETER.

Compliance is checked by inspection and functional testing.

201.12.2

Replace the title "Usability" with "Usability" (to correct formatting).

(standards.iteh.ai)

201.C.4.101, Table 201.C.102

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https://standards.iteh.ai/catalog/standards/sist/eae17f10-76e8-4c92-b9ee-

Replace the title with the following (to correct formatting) 5-2017-amd1-2018

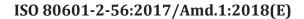
Table 201.C.102 — Accompanying documents, general, of a clinical thermometer

Annex BB, title

Replace the title with the following (to correct formatting):

REFERENCE TEMPERATURE SOURCE

ISO 80601-2-56:2017/AMD1:2018 https://standards.iteh.ai/catalog/standards/sist/eae17f10-76e8-4c92-b9ee-7eff512a755e/iso-80601-2-56-2017-amd1-2018



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