INTERNATIONAL STANDARD

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AMENDMENT 1
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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

AMENDMENT 1

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

AMENDEMENT 1

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Foreword

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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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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.

Introduction, last paragraph

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.

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.

EXAMPLE 2 TECHNICAL ALARM CONDITION caused by OUTPUT TEMPERATURE outside the RATED OUTPUT RANGE or RATED EXTENDED OUTPUT RANGE.

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).

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

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

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

ICS 11.040.55
Price based on 2 pages