SLOVENSKI STANDARD
SIST EN ISO 80601-2-56:2017/oprA1:2018

01-april-2018

Medicinska električna oprema - 2-56. del: Posebne zahteve za osnovno varnost in bistvene lastnosti kliničnih termometrov za merjenje telesne temperature - Dopolnilo A1 (ISO 80601-2-56:2017/DAM 1:2018)

Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement - Amendment 1 (ISO 80601-2-56:2017/DAM 1:2018)

Medizinische elektrische Geräte - Teil 2-56: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Thermometern zum Messen der Körpertemperatur (ISO 80601-2-56:2017/DAM 1:2018)

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 (ISO 80601-2-56:2017/DAM 1:2018)

Ta slovenski standard je istoveten z: **EN ISO 80601-2-56:2017/prA1**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment
17.200.20	Instrumenti za merjenje temperature	Temperature-measuring instruments

SIST EN ISO 80601-2-56:2017/oprA1:2018 **en**

DRAFT AMENDMENT

ISO 80601-2-56:2017 DAM 1

ISO/TC **121**/SC **3**

Secretariat: **ANSI**

Voting begins on:
2018-03-07

Voting terminates on:
2018-05-30

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

ICS: 11.040.55

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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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 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).

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).

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 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.

The committee responsible for this document is 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 Amendment 1 modifies the second edition (ISO 80601-2-56:2017), which has been technically revised.

The most significant changes are the following modifications:

— clarify that ME EQUIPMENT that measures and displays a body temperature is inside the scope of this document;

— reduce the required RATED OUTPUT RANGE; and

— correct formatting errors.

Introduction

The second edition of ISO 80601-2-56 was published in 2017. Since its publication, the ISO Subcommittee (SC) 3 Secretariat has received reports of issues with the standard.

This limited scope amendment is designed to resolve these issues.

The attention of users of this document are drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

In the INTRODUCTION replace 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 express an external constraint.

In the last paragraph of the INTRODUCTION replace 'Member Bodies and National Committees' with 'users of this document'.

Medical electrical equipment —

Part 2-56:
Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

AMENDMENT 1

201.1.1 Scope

Amendment (replace the third paragraph):

ME EQUIPMENT that measures 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.

Amendment (correct misspelling of OUTPUT TEMPERATURE in definition 201.3.215):

Amendment (replace existing example of definition 201.3.222 with the following):

EXAMPLE BLACKBODY, FLUID BATH.

201.12.1.101 Additional requirements for accuracy of controls and instruments

Replacement (replace the entire subclause):

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.

Amendment (in the title correct the formatting by expressing USABILITY in small caps):

201.12.2 USABILITY

Amendment (in the title correct the formatting by expressing the defined terms in small caps):

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general, of a CLINICAL THERMOMETER

Annex BB

Amendment (in the title correct the formatting by expressing the defined term REFERENCE TEMPERATURE SOURCE in small caps):

