ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Marec 2024

STN	**Zdravotnícke elektrické prístroje Časť 2-55: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti monitorov respiračného plynu (ISO 80601-2-55: 2018/Amd 1: 2023) Zmena A1**	**STN EN ISO 80601-2-55/A1** 85 2156

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/24

Obsahuje: EN ISO 80601-2-55:2018/A1:2023, ISO 80601-2-55:2018/Amd 1:2023

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EUROPEAN STANDARD

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December 2023

ICS 11.040.10

English Version

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors - Amendment 1 (ISO 80601-2-55:2018/Amd 1:2023)

Appareils électromédicaux - Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires - Amendement 1 (ISO 80601-2-55:2018/Amd 1:2023)

Medizinische elektrische Geräte - Teil 2 55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase - Änderung 1 (ISO 80601-2-55:2018/Amd 1:2023)

This amendment A1 modifies the European Standard EN ISO 80601-2-55:2018; it was approved by CEN on 6 June 2023.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 80601-2-55:2018/A1:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 80601-2-55:2018 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2024, and conflicting national standards shall be withdrawn at the latest by June 2024.

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Endorsement notice

The text of ISO 80601-2-55:2018/Amd 1:2023 has been approved by CEN as EN ISO 80601-2-55:2018/A1:2023 without any modification.

INTERNATIONAL STANDARD **ISO 80601-2-55**

Second edition
2018-02

AMENDMENT 1
2023-12

Medical electrical equipment —

Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

AMENDMENT 1

Appareils électromédicaux —

Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires

AMENDEMENT 1

Reference number
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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 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 or www.iec.ch/members_experts/refdocs).

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines,* in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*, and with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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ISO 80601-2-55:2018/Amd.1:2023(E)

Medical electrical equipment —

Part 2-55:
Particular requirements for the basic safety and essential performance of respiratory gas monitors

AMENDMENT 1

201.1

Replace IEC 60601-1:2005+Amd 1:2012 *with* IEC 60601-1:2005+Amd 1:2012+Amd 2:2020

201.1.1

Replace IEC 60601-1:2005+Amd 1:2012 *with* IEC 60601-1:2005+Amd 1:2012+Amd 2:2020

201.1.2

Replace IEC 60601-1:2005+Amd 1:2012 *with* IEC 60601-1:2005+Amd 1:2012+Amd 2:2020

201.1.3

Replace IEC 60601-1:2005+Amd 1:2012 *with* IEC 60601-1:2005+Amd 1:2012+Amd 2:2020

201.1.4

Replace IEC 60601-1:2005+Amd 1:2012 *with* IEC 60601-1:2005+Amd 1:2012+Amd 2:2020

201.2

Replace the following references:

IEC 60601-1:2005+Amd 1:2012 *with* IEC 60601-1:2005+Amd 1:2012+Amd 2:2020,

IEC 60601-1-2:2014 *with* IEC 60601-1-2:2014+Amd 1:2020,

IEC 60601-1-6:2010+Amd 1:2013 *with* IEC 60601-1-6:2010+Amd 1:2013+Amd 2:2020,

IEC 60601-1-8:2006+Amd 1:2012 *with* IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020, *and*

IEC 60601-1-12:2014 *with* IEC 60601-1-12:2014+Amd 1:2020