ICS 11.040.10 SLOVENSKÁ TECHNICKÁ NORMA Marec 2020

STN	**Zdravotnícke elektrické prístroje Časť 2-13: Osobitné požiadavky na základnú bezpečnosť a na nevyhnutné prevádzkové vlastnosti anestéziologických systémov (ISO 80601-2-13: 2011/Amd 1: 2015) Zmena A1**	**STN EN ISO 80601-2-13/A1** 85 2105

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011)

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. 02/20

Obsahuje: EN ISO 80601-2-13:2012/A1:2019, ISO 80601-2-13:2011/Amd 1:2015

130231

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-13:2012/A1

November 2019

ICS 11.040.10

English Version

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation - Amendment 1 (ISO 80601-2-13:2011/Amd 1:2015)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie - Amendement 1 (ISO 80601-2-13:2011/Amd 1:2015)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Anästhesie-Arbeitsplätzen - Änderung 1 (ISO 80601-2-13:2011/Amd 1:2015)

This amendment A1 modifies the European Standard EN ISO 80601-2-13:2012; it was approved by CEN on 4 November 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

Ref. No. EN ISO 80601-2-13:2012/A1:2019 E

Contents

Page

European foreword

The text of ISO 80601-2-13:2011/Amd 1:2015 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80601-2-13:2012/A1:2019 by 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 80601-2-13:2012 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011/Amd 1:2015 has been approved by CEN as EN ISO 80601-2-13:2012/A1:2019 without any modification.

INTERNATIONAL STANDARD **ISO 80601-2-13**

First edition
2011-08-01

AMENDMENT 1
2015-03-01

Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie

AMENDEMENT 1

Reference number
ISO 80601-2-13:2011/Amd.1:2015(E)

ISO 80601-2-13:2011/Amd.1:2015(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice,* Subcommittee SC D, *Electromedical equipment*.

Introduction

The first edition of IEC 80601-2-13 was published in 2011. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012, to update the references to IEC 60601-1-6:2010 to include Amendment 1:2013, to update the references to IEC 60601-1-8:2006 to include Amendment 1:2012 and to update the references to IEC 60601-1-10 to include Amendment 1:2012. This amendment also introduces technical modifications to clarify the relationship between this standard and IEC 60601-2-49 and to further specify ACCESSORIES. It amends requirements on the following aspects, in part due to the publication of the before-mentioned amendments:

— addition of a definition on INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— marking the mass of MOBILE ME EQUIPMENT;

— movement over a threshold;

— rough handling test;

— MULTIPLE SOCKET-OUTLETS;

— specific requirements on ANAESTHETIC GAS DELIVERY SYSTEMS and ANAESTHETIC BREATHING SYSTEMS including instructions for use;

— vapour concentration during and after oxygen flush;

— inspiratory pause.

Where appropriate, this amendment also includes modifications of specific informative annexes related to the amended requirements as listed above. Finally, minor editorial updates were made.

ISO 80601-2-13:2011/Amd.1:2015(E)

Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

201.1 Scope, object and related standards

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012*.*

201.1.4 * Particular standards

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

Add the following paragraph at the end of this subclause:

If an ANAESTHETIC WORKSTATION is supplied with physiological monitoring, having more than one APPLIED PART on the PATIENT, then IEC 60601-2-49 applies. Measured parameters related to the inherent function of an ANAESTHETIC WORKSTATION (i.e. airway pressure, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, CO_2/N_2O), including derived and related parameters such as spontaneous ventilation volume or CO_2 production, are not considered to be a PHYSIOLOGICAL MONITORING UNIT as per IEC 60601-2-49.

201.2 Normative references

In the existing introductory paragraph, replace the first sentence with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application.

Add the following reference:

IEC 60601-2-49:2011, *Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*

Amend the following existing references:

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

+Amendment 1:2012

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

+Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

+Amendment 1:2012

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

