Irish Standard
I.S. EN ISO 80601-2-13:2022

Version 2.00

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2022)

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

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I.S. EN ISO 80601-2-13:2022 V2.00 was published under the authority of the NSAI and came into effect on: 2022-06-16

ICS number(s): 11.040.10

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National Foreword

I.S. EN ISO 80601-2-13:2022 V2.00 is the version of the NSAI adopted European document EN ISO 80601-2-13:2022, *Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2022),* including any Corrections, Amendments etc. to EN ISO 80601-2-13:2022.

This normative document by CEN/CENELEC the elaboration of which includes a public enquiry, followed by a Formal Vote of CEN/CENELEC national members and final ratification. This European Standard is published as an identical national standard and every conflicting national standard will be withdrawn. The content of a European Standard does not conflict with the content of any other EN (and HD for CENELEC).

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with this document does not of its self confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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I.S. EN ISO 80601-2-13:2022 V2.00

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 80601-2-13

June 2022

ICS 11.040.10

Supersedes EN ISO 80601-2-13:2012

English Version

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2022)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie (ISO 80601-2-13:2022)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2022)

This European Standard was approved by CEN on 25 May 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a 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 European Standard 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

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European foreword

This document (EN ISO 80601-2-13:2022) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by June 2025.

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.

This document supersedes EN ISO 80601-2-13:2012.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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 80601-2-13:2022 has been approved by CEN as EN ISO 80601-2-13:2022 without any modification.

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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.

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).

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) or the IEC list of patent declarations received (see patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared jointly by Technical Committee 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 62D *Electromedical equipment*, in collaboration 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).

This second edition cancels and replaces the first edition (ISO 80601-2-13:2011), which has been technically revised. It also incorporates the Amendments ISO 80601-2-13:2011/Amd 1:2015 and ISO 80601-2-13:2011/Amd 2:2018.

The main changes are as follows:

— update of normative references;

— update of terms and definitions;

— consideration of *anaesthetic workstations* using Oxygen 93;

— addition of requirements for *expected service life*;

— amendment of the requirements on test equipment;

— amendment of the requirements on warning and safety notices, on the instructions for use and on the technical description as well as design documentation;

— addition of marking requirements regarding the suitability of *anaesthetic workstations* and its components for use in a magnetic resonance environment;

— amendment of the requirements on compatibility with substances used with the *anaesthetic workstation* and its components;

— amendment of the requirements on *internal electrical power source*;

— amendment of the requirements on the exhaled volume *monitoring equipment*;

— amendment of the requirements on detachable, flow-direction-sensitive parts and accessories;

— amendment of the requirements on *multiple socket-outlets*;

— amendment of the requirements and recommendations for signal input/signal output part;

— amendment of the requirements on the flow-rate adjustment control;

— amendment of the requirements on the *maximum limited pressure protection device*;

— amendment of the requirements on the reservoir bag port connection port connector;

— amendment of the requirements on the inspiratory and expiratory pressure/flow rate characteristics

— amendment of the requirements on *breathing tubes* and *breathing tube* sets;

— amendment of the requirements on circle absorber assemblies;

— addition of requirements on ventilation modes;

— amendment of the requirements on *anaesthetic gas scavenging systems* by differentiation between active and non-active systems;

— amendment of the requirements on *anaesthetic ventilators* in case of interruption of the electrical or pneumatic *power supply*.

A list of all parts in the ISO 80601 and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

In this document, the following print types are used:

— Requirements and definitions: roman type.

— Terms defined in Clause 3 of the general standard, in this particular standard and test specifications: italic type.

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term

— “clause” means one of the eight numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all subclauses of Clause 201.7).

References to clauses within this document are preceded by the term “Clause” followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformity with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e. g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This document considers both an *anaesthetic workstation* supplied complete and its individual components in combination with its *accessories*. It has been structured to allow *responsible organizations* to configure an *anaesthetic workstation* from individual components in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this document identifies particular requirements pertinent to specific *anaesthetic workstation* components, including associated *monitoring equipment*, *alarm system(s)* and *protection device(s),* and defines the interfaces.

Thus this document also defines requirements for individual components that can be used to form *an anaesthetic workstation*.

The following table identifies the individual components of an *anaesthetic workstation* and provides an overview of the structure of this document.

Table 201.101 — Configuration of an *anaesthetic workstation* and corresponding organization of this document

<table>
<tr><td colspan="3">anaesthetic workstation</td></tr>
<tr><td>General requirements
Clauses 201.1 – 201.17, 201.106, 201.107, 202-212</td><td rowspan="3">including associated monitoring equipment, alarm systems and protection devices</td><td rowspan="3">These are mandatory components;
see also Table AA.1</td></tr>
<tr><td>anaesthetic gas delivery system
Clause 201.101</td></tr>
<tr><td>anaesthetic breathing system
Clause 201.102</td></tr>
<tr><td>anaesthetic gas scavenging system (AGSS)
Clause 201.103</td><td rowspan="3">including associated monitoring equipment, alarm systems and protection devices</td><td rowspan="3">These are optional components;
see also Table AA.1</td></tr>
<tr><td>anaesthetic vapour delivery system
Clause 201.104</td></tr>
<tr><td>anaesthetic ventilator
Clause 201.105</td></tr>
</table>

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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 * Scope

Replacement:

This document is applicable to the *basic safety* and *essential performance* of an *anaesthetic workstation* for administering inhalational anaesthesia whilst continuously attended by a professional *operator*.

This document specifies particular requirements for a complete *anaesthetic workstation* and the following *anaesthetic workstation* components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant *anaesthetic workstation* components, to form an *anaesthetic workstation* to a given specification:

— *anaesthetic gas delivery system;*

— *anaesthetic breathing system;*

— *anaesthetic gas scavenging system (AGSS);*

— *anaesthetic vapour delivery system;*

— *anaesthetic ventilator;*

— *monitoring equipment;*

— *alarm system;*

— *protection device.*

NOTE 1 *Monitoring equipment, alarm systems* and *protection devices* are summarized in Table AA.1.

An *anaesthetic workstation* supplied complete and its individual components are considered as *ME equipment* or *ME systems* with regard to the general standard.

NOTE 2 The applicability of this document is indicated in Table AA.2.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *anaesthetic workstation* where the characteristics of those *accessories* can affect the *basic safety* and *essential performance* of the *anaesthetic workstation.*

If a clause or subclause is specifically intended to be applicable to *anaesthetic workstation* components or its *accessories* only, the title and content of that clause or subclause will say so. If that is not the case,