



BSI Standards Publication

Medical electrical equipment

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

This is a preview of BS EN ISO 80601-2-55:2018+A1:2023. [Click here to purchase the full version from the ANSI s](#)

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-55:2018+A1:2023. It is identical to ISO 80601-2-55:2018, incorporating amendment 1:2023. It supersedes BS EN ISO 80601-2-55:2018, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/121/1, Breathing attachments and anaesthetic machines.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments/corrigenda issued since publication

Date	Text affected
31 December 2023	Implementation of ISO amendment 1:2023 with CEN endorsement A1:2023. National foreword updated.

EUROPÄISCHE NORM

December 2023

ICS 11.040.10

Supersedes EN ISO 80601-2-55:2011

English Version

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

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

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

This European Standard was approved by CEN on 18 January 2018.

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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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 80601-2-55:2018) 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 August 2018, and conflicting national standards shall be withdrawn at the latest by August 2021.

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 80601-2-55:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

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Table 1 — Correlation between normative references and dated EN and ISO standards

Normative references as listed in 201.2	Equivalent dated International Standard	
	EN	ISO
ISO 7000:2014	-	ISO 7000:2014
ISO 7010:2011	EN ISO 7010:2012	ISO 7010:2011
ISO 14937:2009	EN ISO 14937:2009	ISO 14937:2009
ISO 15223-1:2016, corrected version 2017	EN ISO 15223-1:2016	ISO 15223-1:2016, corrected version 2017
ISO 17664:2004	EN ISO 17664:2004	ISO 17664:2004
ISO 80601-2-13:2011 + Amd 1:2015 and Amd 2:— ^a	EN ISO 80601-2-13:2012 ^a + Amd 1: — and Amd 2:— ^a	ISO 80601-2-13:2011 + Amd 1:2015 and Amd 2:— ^a
ISO 80369-1: 2010 ^b	EN ISO 80369-1:2010 ^b	ISO 80369-1:2010 ^b
ISO 80369-2 ^a	EN ISO 80369-2:— ^a	ISO 80369-2 ^a
ISO 80369-3	EN ISO 80369-3:2016	ISO 80369-3:2016
IEC 80369-5	EN ISO 80369-5:2016	IEC 80369-5:2016
ISO 80369-6	EN ISO 80369-6:2016	ISO 80369-6:2016
ISO 80369-7	EN ISO 80369-7:2017	ISO 80369-7:2017
ISO 80369-20	EN ISO 80369-20:2015	ISO 80369-20:2015
IEC 60601-1:2005 + Amd 1:2012	EN 60601-1:2006 + Cor:2010 and + Amd 1:2013	IEC 60601-1:2005 + Amd 1:2012
IEC 60601-1-2:2014	EN 60601-1-2:2015	IEC 60601-1-2:2014
IEC 60601-1-6:2010 + Amd 1:2013	EN 60601-1-6:2010 + Amd 1:2015	IEC 60601-1-6:2010 + Amd 1:2013
IEC 60601-1-8:2006 + Amd 1:2012	EN 60601-1-8:2007 + Cor:2010 and Amd 1:2013	IEC 60601-1-8:2006 + Amd 1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-1-12:2014	EN 60601-1-12:2015	IEC 60601-1-12:2014
IEC 60068-2-27:2008	EN 60068-2-27:2009	IEC 60068-2-27:2008
IEC 60068-2-64:2008	EN 60068-2-64:2008	IEC 60068-2-64:2008
IEC 60529:1989 + Amd 1:1999 and Amd 2:2013	EN 60529:1991 + Amd 1:2000 and Amd 2:2013	IEC 60529:2001
^a To be published.		
^b Under revision.		

Endorsement notice

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

European foreword to amendment A1

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.