

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

© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: 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.

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).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and <https://patents.iec.ch>. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

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 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).

A list of all parts in the ISO/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.

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-55:2018/AMD1:2023

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

201.3

Replace the introductory sentence with the following sentence:

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005+Amd 1:2012+Amd 2:2020, IEC 60601-1-2, IEC 60601-1-6:2010+Amd 1:2013+Amd 2:2020, IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020, IEC 60601-1-11, IEC 60601-1-12 and ISO 80601-2-13:2011+Amd 1:2015 and the following apply.

201.4

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

201.4.3

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

201.5

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

201.6

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

201.7

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

201.7.2.3

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

201.7.4.3

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

201.7.9.2

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

201.7.9.2.2

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

201.7.9.2.2.101

Replace the first paragraph with:

The instructions for use of a DIVERTING RGM that is equipped with a gas exhaust connection shall include a warning regarding the RISK of PATIENT cross-infection if the sampled gas is returned to the breathing system, unless the MANUFACTURER can demonstrate that the RISK of PATIENT cross-infection is reduced to an acceptable level in the returned gas. Additional requirements are found in 201.105.2.

Note the means of risk control can be part of a host device.

Change the check compliance sentence to:

Check conformance by inspection of the MANUFACTURER'S instructions for use or RISK MANAGEMENT FILE.

201.7.9.2.5

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

201.7.9.2.8

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

201.79.2.9

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

201.79.2.9.101

Replace the first sentence with the following:

The instructions for use shall include the following, if applicable:

201.79.2.13

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

201.79.2.14

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

201.79.2.15

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

201.79.3

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

201.8

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

201.9

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

201.10

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

201.11

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

201.11.6.6

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

201.11.6.7

Replace IEC 60601-1:2005+Amd 1:2012 with IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 and IEC 60601-1-11:2015 with IEC 60601-1-11:2015+Amd 1:2020

201.12

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

201.12.1

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

201.12.1.101.2

Replace the first paragraph with:

For each respiratory gas that an RGM is intended to monitor, the MEASUREMENT ACCURACY shall meet the accuracy requirements specified in Table 201.102 or the levels specified by the MANUFACTURER, if better, for not less than 6 h when used in accordance with the instructions for use with mixtures of gases as indicated in Table 201.103. If applicable the DRIFT shall be disclosed in the instructions for use.

Table 201.103

Replace Table 201.103 with the following table:

Nitrogen	Nitrous oxide ^a	Halothane ^a	Enflurane ^a	Isoflurane ^a	Sevo-flurane ^a	Des-flurane ^a	Oxygen	Carbon dioxide
Balance	30							
Balance	65 ^{c, d}							
Balance		0,5						
Balance		1,0 ^c						
Balance		4,0 ^{b, d}						
Balance			0,5					
Balance			1,0 ^c					
Balance			5,0 ^{b, d}					
Balance				0,5				
Balance				1,0 ^c				
Balance				5,0 ^{b, d}				
Balance					0,5			
Balance					1,0 ^c			
Balance					5,0 ^{b, d}			
Balance						5		
Balance						10 ^c		
Balance						15 ^{b, d}		
Balance								2,5
Balance								5,0 ^{c, d}
Balance								10,0
Balance							15,0	
Balance							21,0	
Balance							40,0	
Balance							60,0 ^{c, d}	
Balance							100,0	

^a Included if the RGM is intended for use with this halogenated agent.
^b Or full-scale reading, if lower than the specified value.
^c This mixture is to be used for DRIFT of MEASUREMENT ACCURACY test (if applicable).
^d This mixture is to be used as the end concentration for TOTAL SYSTEM RESPONSE TIME testing (if applicable). For TOTAL SYSTEM RESPONSE TIME testing, a lower accuracy of the test gas mixture is acceptable.

NOTE For all TOTAL RESPONSE TIME tests, the initial concentration is intended to be 0 % of that gas except for oxygen which is intended to be 21 %. For gas SENSOR systems with automatic agent identification features (e.g. for halothane, enflurane, isoflurane, sevoflurane and desflurane), increasing the initial concentration up to 10 % of the end value for verification is allowed.

201.12.1.101.4.1

Add the following sentence after the first paragraph of item d):

This requirement is only applicable for calibration/zeroing that is automatically done by the RGM without operator interaction.

Add the following sentence at the end of the paragraph of item e):

This requirement is only applicable for calibration/zeroing that is automatically done by the RGM without operator interaction.

201.13

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

201.14

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

201.15

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

201.15.3.5

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

201.15.3.5.101.1

Replace IEC 60601-1-12:2014 with IEC 60601-1-12:2014+Amd 1:2020 and IEC 60601-1-11:2015 with IEC 60601-1-11:2015+Amd 1:2020

201.15.3.5.101.2

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

201.16

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

201.17

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

202

Replace IEC 60601-1-2:2014 with IEC 60601-1-2:2014+Amd 1:2020

206

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

208

Replace IEC 60601-1-8:2006+Amd 1:2012 with IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020

208.6.6.2

Replace IEC 60601-1-8:2006+Amd 1:2012 with IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020

208.6.8.5

Replace IEC 60601-1-8:2006+Amd 1:2012 with IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020

211

Replace IEC 60601-1-11:2015 with IEC 60601-1-11:2015+Amd 1:2020

212

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

Annex D

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

Annex AA

201.11.8.101.2

Replace IEC 60601-1-8:2006+Amd 1:2012 with IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020

Annex DD

Amend the references to the following terms

accessory	IEC 60601-1:2005+A1:2012+A2:2020, 3.3
accompanying document	IEC 60601-1:2005+A1:2012+A2:2020, 3.4
alarm condition	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.1
alarm limit	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.3
alarm paused	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.5
alarm preset	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.6
alarm settings	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.8
alarm signal	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.9

alarm system	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.11
applied part	IEC 60601-1:2005+A1:2012+A2:2020, 3.8
audio paused	IEC 60601-1-8:2006+A1:2012+2:2020, 3.13
basic safety	IEC 60601-1:2005+A1:2012+A2:2020, 3.10
clearly legible	IEC 60601-1:2005+A1:2012+A2:2020, 3.15
component with high-integrity characteristics	IEC 60601-1:2005+A1:2012+A2:2020, 3.17
continuous operation	IEC 60601-1:2005+A1:2012+A2:2020, 3.18
distributed alarm system	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.17
enclosure	IEC 60601-1:2005+A1:2012+A2:2020, 3.26
essential performance	IEC 60601-1:2005+A1:2012+A2:2020, 3.27
expected service life	IEC 60601-1:2005+A1:2012+A2:2020, 3.28
functional connection	IEC 60601-1:2005+A1:2012+A2:2020, 3.33
hand-held	IEC 60601-1:2005+A1:2012+A2:2020, 3.37
harm	IEC 60601-1:2005+A1:2012+A2:2020, 3.38
hazard	IEC 60601-1:2005+A1:2012+A2:2020, 3.39
hazardous situation	IEC 60601-1:2005+A1:2012+A2:2020, 3.40
high priority	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.22
home healthcare environment	IEC 60601-1-11:2015+Amd 1:2020, 3.2
informational signal	IEC 60601-1-8:2006+A1:2012+A2:2020, 3.23
intended use	IEC 60601-1:2005+A1:2012+A2:2020, 3.44
internal electrical power source	IEC 60601-1:2005+A1:2012+A2:2020, 3.45
IT-network	IEC 60601-1:2005+A1:2012+A2:2020, 3.145
Low priority	IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020, 3.27
manufacturer	IEC 60601-1:2005+A1:2012+A2:2020, 3.55
medical electrical equipment (ME equipment)	IEC 60601-1:2005+A1:2012+A2:2020, 3.63
medical electrical system (ME system)	IEC 60601-1:2005+A1:2012+A2:2020, 3.64
medium priority	IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020, 3.28
model or type reference	IEC 60601-1:2005+A1:2012+A2:2020, 3.66
normal condition	IEC 60601-1:2005+A1:2012+A2:2020, 3.70
normal use	IEC 60601-1:2005+A1:2012+A2:2020, 3.71
operator	IEC 60601-1:2005+A1:2012+A2:2020, 3.73