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AMENDMENT 1
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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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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

201.7.9.2.9

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

201.7.9.2.9.101

Replace the first sentence with the following:

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

201.7.9.2.13

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

201.7.9.2.14

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

201.7.9.2.15

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

201.7.9.3

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