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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
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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