INTERNATIONAL STANDARD

ISO 80601-2-13

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AMENDMENT 1
2015-03-01

Medical electrical equipment —

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

AMENDMENT 1

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie

AMENDEMENT 1

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Foreword

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is 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 D, *Electromedical equipment*.

Introduction

The first edition of IEC 80601-2-13 was published in 2011. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012, to update the references to IEC 60601-1-6:2010 to include Amendment 1:2013, to update the references to IEC 60601-1-8:2006 to include Amendment 1:2012 and to update the references to IEC 60601-1-10 to include Amendment 1:2012. This amendment also introduces technical modifications to clarify the relationship between this standard and IEC 60601-2-49 and to further specify ACCESSORIES. It amends requirements on the following aspects, in part due to the publication of the before-mentioned amendments:

— addition of a definition on INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— marking the mass of MOBILE ME EQUIPMENT;

— movement over a threshold;

— rough handling test;

— MULTIPLE SOCKET-OUTLETS;

— specific requirements on ANAESTHETIC GAS DELIVERY SYSTEMS and ANAESTHETIC BREATHING SYSTEMS including instructions for use;

— vapour concentration during and after oxygen flush;

— inspiratory pause.

Where appropriate, this amendment also includes modifications of specific informative annexes related to the amended requirements as listed above. Finally, minor editorial updates were made.

Medical electrical equipment —

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

AMENDMENT 1

201.1 Scope, object and related standards

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.1.4 * Particular standards

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

Add the following paragraph at the end of this subclause:

If an ANAESTHETIC WORKSTATION is supplied with physiological monitoring, having more than one APPLIED PART on the PATIENT, then IEC 60601-2-49 applies. Measured parameters related to the inherent function of an ANAESTHETIC WORKSTATION (i.e. airway pressure, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, CO_2/N_2O), including derived and related parameters such as spontaneous ventilation volume or CO_2 production, are not considered to be a PHYSIOLOGICAL MONITORING UNIT as per IEC 60601-2-49.

201.2 Normative references

In the existing introductory paragraph, replace the first sentence with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application.

Add the following reference:

IEC 60601-2-49:2011, *Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*

Amend the following existing references:

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

+Amendment 1:2012

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

+Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

+Amendment 1:2012