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

AMENDMENT 2

Appareils électromédicaux —

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

AMENDEMENT 2





COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

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
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html

This document was prepared by 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 62 D, *Electromedical equipment*.

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-13:2011/AMD2:2018

Medical electrical equipment —

Part 2-13:

Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 2

201.1.3 Collateral standards

Replace the second paragraph with the following:

IEC 60601-1-3:2008, IEC 60601-1-9:2007+AMD1:2013 and IEC 60601-1-11:2010 do not apply.

201.2 Normative references

Delete IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*.

201.15 Construction of ME EQUIPMENT

Add the following subclause:

201.15.3.5 Rough handling test

Addition:

For an ANAESTHETIC WORKSTATION with a weight exceeding 125 kg in its NOMINAL configuration and only movable manually, the speed in c) frame-door-shock shall be reduced from 0,8 m/s to 0,4 m/s.

201.101.4.2.1 Inlet connector

Replace list item a) by the following text:

- a) female non-interchangeable screw-threaded (NIST) connector, or

209 Requirements for environmentally conscious design

Replace the existing text by:

IEC 60601-1-9 does not apply.

Bibliography

Add:

[16] IEC 60601-1-9, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral standard: Requirements for environmentally conscious design*

Renumber subsequent references.

STANDARDSISO.COM : Click to view the full PDF of ISO 80601-2-13:2011/AMD2:2018