FINAL
DRAFT

AMENDMENT

IEC 60601-1-12:2014 FDAM 1

ISO/TC **121**/SC **3**

Secretariat: ANSI

Voting begins on:
2020-04-24

Voting terminates on:
2020-06-19

Medical Electrical Equipment —

Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment

AMENDMENT 1

Appareils électromédicaux —

Partie 1-12: Exigences générales pour la sécurité de base et les performances essentielles — Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins d'urgence

AMENDEMENT 1

This draft is submitted to a parallel vote in ISO and in IEC.

Reference number
IEC 60601-1-12:2014/FDAM 1:2020(E)

FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee 3: Respiratory devices and related equipment used for patient care of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

The text of this amendment is based on the following documents of IEC:

FDIS	Report on voting
62A/XXX/FDIS	62A/XXX/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the amendment has been approved by XXX P members out of YYY having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION TO AMENDMENT 1

The first edition of IEC 60601-1-12 was published in 2014. Since the publication of IEC 60601-1-12:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the second edition of IEC 60601-1-12, which is presently targeted for publication sometime after 2024.

As directed in item 1 of Kobe Resolution 1, the IEC/SC 62A Chairman Advisory Group (CAG) considered the 27 issues collected by the SC/62A Secretariat for IEC 60601-1-12:2014 and determined that none met the selection criteria stated in Kobe Resolution 1.

However, an amendment is needed to update the references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. In London in 2018, SC 62A approved the development of an administrative amendment to IEC 60601-1-12:2014.

Because this is an amendment to IEC 60601-1-12:2014, the style in force at the time of publication of IEC 60601-1-12 has been applied to this amendment. The specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

1.3.1 IEC 60601-1

Delete, in the existing first paragraph, the words "hereafter referred to as the general standard".

Add, in the first two dashes of the existing second paragraph, the words ", including any amendments".

2 Normative references

Replace the existing references to IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11 and ISO 7010 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013
IEC 60601-1-6:2010/AMD2:2020

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*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD1:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

ISO 7010:2019, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

3 Terms and definitions

Replace the existing first paragraph with:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-6:2006, IEC 60601-1-6:2006/AMD1:2013 and IEC 60601-1-6:2006/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020, and the following definitions apply.

Index of defined terms used in this collateral standard

Replace the following existing terms: