IEC 60601-1-11

Edition 2.0 2020-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux –
Partie 1-11: 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 à domicile

IEC 60601-1-11:2015-01/AMD1:2020-07(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.020.10; 11.040.01

ISBN 978-2-8322-8623-4

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/1395/FDIS	62A/1410/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 15 P members out of 15 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- withdrawn,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 second edition of IEC 60601-1-11 was published in 2015. Since the publication of IEC 60601-1-11:2015, 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 third edition of IEC 60601-1-11, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, four items were presented to the National Committees present. All four items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-11.

The "short list" of issues was documented in the design specification for Amendment 1. As IEC 60601-1-11 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 6. JWG 6 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-11:2015, the style in force at the time of publication of IEC 60601-1-11 has been applied to this amendment. The style 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

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 60601-1-12, IEC 62366-1, ISO 7010 and ISO 15223-1 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/AMD2:2020

IEC 60601-1-12:2014, *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 intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-1:2015/AMD1:2020

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

ISO 15223-1:2016, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

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 and IEC 60601-1:2005:AMD1:2012 + IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 + IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 + IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-12:2014 and
IEC 60601-1-12:2014/AMD1:2020, IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, and the following definitions apply.

4.2.2 * Environmental conditions of transport and storage between uses

Replace, in the existing fourth paragraph, the reference "ISO 15223-1:2012" *with* "ISO 15223-1:2016" *in three places*.

4.2.3.1 Continuous operating conditions

Replace, in the existing fourth paragraph, the reference "ISO 15223-1:2012" *with* "ISO 15223-1:2016" *in three places.*

7.2 * Additional requirements for marking of IP classification

Replace the existing first paragraph with:

In addition to the requirements of 7.2.9 of the general standard, the ME EQUIPMENT or its parts and, when appropriate, a carrying case shall be marked with the appropriate IP classification as tested in 8.3.1.

If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then:

a) the ENCLOSURE of the ME EQUIPMENT shall be marked with its degree of protection and SAFETY SIGN ISO 7010-W001 (see IEC 60601-1:2005, Table D.2, SAFETY SIGN 2), as well as with
   – 'keep dry', or
   – the symbol ISO 15223-1:2016, 5.3.4 (ISO 7000-0626 (2014-06)) (see Table C.1, symbol 1); and
b) the carrying case shall be marked with its degree of protection.

If the ENCLOSURE of the ME EQUIPMENT is classified IPXX, IP00, IPX0 or IP0X, then it need not be marked as such. However, the other marking requirements in a) still apply.

Add, at the end of the existing example, the following new sentence:

The ENCLOSURE, when installed in the carrying case, would comply with the IP22 test requirement in 8.3.1.

7.4.1 Additional requirements for warning and safety notices

In the existing first paragraph, replace "safety sign" *with* "SAFETY SIGN".

8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT

Add, after the existing first paragraph, the following new paragraph:

If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the ME EQUIPMENT shall be tested while inside the carrying case.

8.5 Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE

Add, after 8.5.2, the following new subclause:

8.5.3 * Additional requirements for separation of parts

For ME EQUIPMENT or ME SYSTEM with an INTERNAL ELECTRICAL POWER SOURCE, if simultaneous connection of the ME EQUIPMENT to the PATIENT and the SUPPLY MAINS is possible, then APPLIED PARTS and parts that are likely to come into contact with the PATIENT shall have two MOPP from the SUPPLY MAINS.

However, parts which the PATIENT intentionally handles as the intended OPERATOR according to 7.9.2.1 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 + IEC 60601-1:2005/AMD2:2020 (e.g. touch keys, ENCLOSURE) while the ME EQUIPMENT is not being used for its intended medical function may be insulated with two MOOP from SUPPLY MAINS.

A.1 General guidance

Replace, in the existing last paragraph, the reference "IEC 60601-1:2005/AMD1:2012" *with* "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 + IEC 60601-1:2005/AMD2:2020".

A.2 Rationale for particular clauses and subclauses

Subclause 7.1 – USABILITY of the ACCOMPANYING DOCUMENTS

Replace, in the existing first paragraph, the reference "IEC 60601-1-6:2010 and IEC 60601-1-6/AMD1:2013" *with* "IEC 60601-1-6:2010 and IEC 60601-1-6/AMD1:2013 + IEC 60601-1-6:2010/AMD2:2020".

Replace the existing next-to-last paragraph with:

Most often, some combination of these methods is used to develop a USE SPECIFICATION for the most effective ACCOMPANYING DOCUMENTS possible. The MANUFACTURER VERIFIES that the final ACCOMPANYING DOCUMENTS fulfil the USE SPECIFICATION typically by testing with representative LAY OPERATORS.

Subclause 8.3.1 – Ingress of water or particulate matter into ME EQUIPMENT

Add, after the existing last paragraph, the following new paragraphs:

Care should be taken to ensure that liquid does not accumulate or that it drains away such that it does not:

– interfere with BASIC SAFETY or ESSENTIAL PERFORMANCE;
– deposit on insulation parts where it could lead to tracking along the creepage distances; or
– reach live parts, including INTERNAL ELECTRICAL POWER SOURCES, or windings not designed to operate when wet.

There are particular standards that exempt certain types of ME EQUIPMENT from these requirements.

Add, after the existing rationale for 8.5.1, the following new text:

Subclause 8.5.3 – Additional requirements for separation of parts

ME EQUIPMENT that is BODY-WORN and used in the HOME HEALTHCARE ENVIRONMENT clearly requires two MOPP.

If ME EQUIPMENT is:

– INTERNALLY POWERED during its INTENDED USE (e.g. a BODY-WORN ME EQUIPMENT); and
– constructed such that it can only be connected to an external power source (e.g. a battery charger) while disconnected from the PATIENT;

then, during charging:

– the PATIENT is only in contact with ACCESSIBLE PARTS but not with APPLIED PARTS.

The PATIENTS, now in their role as LAY OPERATORS, can just as well handle a cell phone or a notebook, as they can connect that specifically designed ME EQUIPMENT to the charger. So, the separation of ACCESSIBLE PARTS (other than APPLIED PARTS) from external power sources needs only MOOP instead of MOPP in this specific case.

A SUPPLY MAINS connected charger is permitted by the general standard to be IEC 60950-1 [8] or IEC 62368-1 [27] compliant as long as simultaneous connection of the ME EQUIPMENT or ME SYSTEM to the charger and to the PATIENT is not possible. In this case, only MOOP is required.

If simultaneous connection of the ME EQUIPMENT to the PATIENT and the ME EQUIPMENT to a SUPPLY MAINS-connected charger is possible, then clearly two MOPP are required and the charger might need to comply with the MOPP requirements of IEC 60601-1 to achieve two MOPP.

Table C.1 – General symbols

Replace, in the existing reference column, the reference "ISO 15223-1:2012" *with* "ISO 15223-1:2016" *in six places.*

Replace, for symbol no. 1, the reference "2004-01" *with* "2014-06".

Bibliography

Add, at the end of the existing Bibliography, the following new reference:

[27] IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

Index of defined terms used in this collateral standard

Replace the following existing terms:

DISTRIBUTED ALARM SYSTEM ..... IEC 60601-1-8:2006/AMD2:2020, 3.17
HAZARD ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005/AMD2:2020, 3.40
HIGH PRIORITY ..... IEC 60601-1:2005/AMD2:2020, 3.149
INFORMATION SIGNAL ..... IEC 60601-1:2005/AMD2:2020, 3.150
INTENDED USE ..... IEC 60601-1:2005/AMD2:2020, 3.44
LOW PRIORITY ..... IEC 60601-1:2005/AMD2:2020, 3.151
MANUFACTURER ..... IEC 60601-1:2005/AMD2:2020, 3.55
MEDIUM PRIORITY ..... IEC 60601-1:2005/AMD2:2020, 3.153
OPERATOR PROFILE ..... IEC 60601-1-6:2010/AMD2:2020, 3.2
PROCEDURE ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.88
PROCESS (PROCESSING) ..... IEC 60601-1:2005/AMD2:2020, 3.89
RISK ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.102
RISK ANALYSIS ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.103
RISK CONTROL ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.105
RISK MANAGEMENT ..... IEC 60601-1:2005/AMD2:2020, 3.107
RISK MANAGEMENT FILE ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.108

USABILITY ..... IEC 60601-1:2005/AMD2:2020, 3.136

USABILITY ENGINEERING ..... IEC 60601-1:2005/AMD2:2020, 3.137

USABILITY ENGINEERING FILE ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.147

VERIFICATION ..... IEC 60601-1:2005/AMD1:2012/AMD2:2020, 3.138

Add, after the existing term "RISK MANAGEMENT FILE"*, the following new term:*

SAFETY SIGN ..... IEC 60601-1:2005/AMD2:2020, 3.154

Replace the existing entry for USABILITY SPECIFICATION *with:*

USE SPECIFICATION ..... IEC 62366-1:2015/AMD1:2020, 3.23

Delete the existing term "VALIDATION" *and its reference.*