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
National foreword

This British Standard is the UK implementation of EN 60601‑1‑11:2015+A1:2021. It is identical to IEC 60601‑1‑11:2015, incorporating amendment 1:2020. It supersedes BS EN 60601‑1‑11:2015, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by [ amendment 1].

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient’s own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law.

Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.
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)
European foreword


The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2016-01-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

This document supersedes EN 60601-1-11:2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-1-11:2015 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335-1:2010 NOTE Harmonized as EN 60335-1:2012 (modified).
IEC 60364 NOTE Harmonized in HD 384 / HD 60364 series (partly modified).
IEC 60601-1-9 NOTE Harmonized as EN 60601-1-9.
IEC 60721-3-7:1995 NOTE Harmonized as EN 60721-3-7:1995 (not modified).
Foreword to amendment A1


The following dates are fixed:

• latest date by which the document has to be implemented at national (dop) 2022-01-16
• latest date by which the national standards conflicting with the (dow) 2024-07-16
document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users’ national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice


In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 62368-1:2018 NOTE Harmonized as EN IEC 62368-1:2020 (not modified)
8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT ........................................ 24
8.3.2 * Ingress of water or particulate matter into ME SYSTEMS ........................................... 24
8.4 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM ................................................................. 24
8.5 Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE ...................... 25
8.5.1 * Indication of state ...................................................................................................... 25
8.5.2 Accessibility of small INTERNAL ELECTRICAL POWER SOURCES ............................. 26
8.5.3 * Additional requirements for separation of parts .......................................................... 26
9 Accuracy of controls and instruments and protection against hazardous outputs ............... 26
10 Construction of ME EQUIPMENT ...................................................................................... 27
10.1 * Additional requirements for mechanical strength .......................................................... 27
10.1.1 General requirements for mechanical strength ............................................................ 27
10.1.2 * Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT .............................................................................................................. 28
10.1.3 * Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT .................................................................................................................. 29
10.2 Additional requirements for actuating parts of controls of ME EQUIPMENT ....................... 30
11 Protection against strangulation or asphyxiation ................................................................. 31
12 Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS ................................................................................................................. 31
13 Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS .......... 31
13.1 * Additional requirement for generation of ALARM SIGNALS ........................................... 31
13.2 * Additional requirement for ALARM SIGNAL volume ..................................................... 31
Annex A (informative) General guidance and rationale .......................................................... 32
A.1 General guidance .............................................................................................................. 32
A.2 Rationale for particular clauses and subclauses ................................................................ 33
Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS ................................................................................................................. 53
B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts ........................................ 53
B.2 Accompanying documents, general .................................................................................. 53
B.3 ACCOMPANYING DOCUMENTS, instructions for use .................................................. 53
B.4 ACCOMPANYING DOCUMENTS, technical description .................................................... 55
Annex C (informative) Symbols on marking ............................................................................. 56
Bibliography .............................................................................................................................. 58
Index of defined terms used in this collateral standard .............................................................. 60

Figure 1 – Small finger probe Ø 5,6 .......................................................................................... 18
Figure A.1 – Saturation water vapour pressure as function of temperature ................................. 37
Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE ............................... 27
Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE ..................................... 28
Table A.1 – Saturation water vapour pressure as function of temperature ..................................... 38
Table A.2 – Summary by use of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT ENCLOSURE ingress of water and particulate matter requirements ...................................... 47
Table A.3 – Qualitative assessment of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT subjected to shock and vibration ................................................................. 49
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts ................ 53
Table B.2 – ACCOMPANYING DOCUMENTS, general ............................................................... 53
Table B.3 – ACCOMPANYING DOCUMENTS, instructions for use ................................................. 54
Table B.4 – ACCOMPANYING DOCUMENTS, technical description ............................................... 55
Table C.1 – General symbols (1 of 2) .............................................................................................. 56
FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

6) All users should ensure that they have the latest edition of this publication.

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-1-11 has been prepared by a joint working group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

This second edition constitutes a collateral standard to IEC 60601-1 (third edition, including Amendment 1): Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, hereafter referred to as the general standard.
This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

– correction of test method for relative humidity control at temperatures above 35 °C;
– redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
– harmonizing with the changes to the amendments to the general standard and other collateral standards.

The text of this collateral standard is based on the following documents:

<table>
<thead>
<tr>
<th>FDIS</th>
<th>Report on voting</th>
</tr>
</thead>
<tbody>
<tr>
<td>62A/959/FDIS</td>
<td>62A/978/RVD</td>
</tr>
</tbody>
</table>

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 17 P-members out of 17 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

– requirements and definitions: roman type;
– test specifications: italic type;
– informative material appearing outside of tables, such as notes, examples and references: in smaller type.
Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this collateral standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.3.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, published under the general title: Medical electrical equipment, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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 Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC 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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.
INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the HOME HEALTHCARE ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

The potential lack of training of the LAY OPERATOR and possibly of those supervising the use of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM and their level of education need to be addressed in the development of the ACCOMPANYING DOCUMENTS and in the relevant marking on the equipment itself so that this material can be understood. This collateral standard gives special guidance on how this should be addressed in the instructions for use.

This collateral standard was developed with contributions from clinicians, engineers and regulators. The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for the development of particular standards.

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.
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

1 Scope, object and related standards

1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.1, and specified by the MANUFACTURER in the instructions for use. This International Standard applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

The HOME HEALTHCARE ENVIRONMENT includes:

– the dwelling place in which a PATIENT lives;
– other places where PATIENTS are present both indoors and outdoors, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, covered by IEC 60601-1-12 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-12 or this collateral standard. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the HOME HEALTHCARE ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEMS intended for both the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

NOTE HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can frequently be used in locations with unreliable electrical sources and poor electrical grounding.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone[^1], including any amendments[^2];
– "this collateral standard" designates IEC 60601-1-11 alone[^3], including any amendments[^4];
– "this standard" designates the combination of the general standard and this collateral standard.