Draft for Public Comment

Form 36

DPC: 24 / 30506273 DC

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Project No. 2024/03562

Responsible committee: CH/62/1 Common aspects of medical equipment, software, and systems

Interested committees:

Title:	BS EN IEC 60601-1/FRAG11 Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Electromagnetic exposure hazards (Fragment 11)

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard
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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/Figure/ Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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62A/1629/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: **IEC 60601-1/FRAG11 ED4**	
DATE OF CIRCULATION: **2024-12-06**	CLOSING DATE FOR COMMENTS: **2025-02-28**
SUPERSEDES DOCUMENTS: **62A/1582/RR**	

IEC SC 62A : COMMON ASPECTS OF MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Colleen Elliott
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 3C,SC 22E,TC 61,TC 62,SC 62B,SC 62C,SC 62D,TC 65,TC 66,TC 76,TC 77,TC 85,TC 96,TC 106,TC 108,TC 111,TC 124,SyC Smart Cities	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Electromagnetic Compatibility,Safety	

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Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing “In Some Countries” clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Electromagnetic exposure hazards (Fragment 11)

NOTE FROM TC/SC OFFICERS:

Please refer to document 62A/1627/INF for background information and context for this Committee Draft (CD) of Fragment 11 of IEC 60601-1 Ed 4.0.

Please note the terms used in this fragment of IEC 60601-1 Ed. 4.0 are defined in IEC 60050-880 ED1; see 1/2634/CDV, which will be available to National Committees of all applicable TCs on 2024-12-13. Comments on the terms should be submitted in response to 1/2634/CDV and not in response to this IEC 60601-1 fragment.

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Link to Committee Draft (CD) online document:

https://osd.iec.ch/#/editor/archive/16d880f4-31b7-d519-e063-1910000ad21b/en/CD/1

How to access

This link will lead you to the Online Standards Development (OSD) platform for national mirror committee's comments. It replaces the project content, which is usually circulated as a PDF.

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As an alternative solution, OSD NC Commenters who wish to continue using the IEC comment form can use the regular template together with a PDF of the draft document downloadable from the OSD platform. However, please note that line numbers are no longer available, and it is not possible to add tables and graphics or use track changes.

For Voters

Once all your national comments have been resolved, it is no longer necessary to upload the comment form to the IEC Voting System anymore. Instead, please use the following radio buttons in the IEC Voting System to indicate whether or not your National Committee has submitted comments in the OSD:

Comment:	☐ **No Comment at this stage**	☐ **Comments in OSD**

Reference materials

We recommend that OSD NC Managers and OSD NC Commenters review the available materials to better understand the member commenting on the OSD platform. This includes:

- latest videos and presentations on the OSD webpage, and
- step-by-step explanations on Helpscout.

Contact

Should you require any assistance, please contact the OSD project team at osd_support@iec.ch.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - ELECTROMAGNETIC EXPOSURE HAZARDS (FRAGMENT 11)

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.

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IEC was prepared by subcommittee : , of IEC technical committee : . It is .

*In the case of a **new edition replacing a previous edition** , complete the following text. In the case of a first edition, delete it, as it does not apply.*

This edition cancels and replaces the edition published in , Amendment 1: and Amendment 2: . This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

The text of this is based on the following documents:

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Draft	Report on voting

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs . The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications .

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

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INTRODUCTION

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MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - ELECTROMAGNETIC EXPOSURE HAZARDS (FRAGMENT 11)

1 Scope

The Scope clause is a mandatory element of the text. For rules on the drafting of the Scope, refer to the ISO/IEC Directives, Part 2:2018, Clause 14.

This document applies to medical electrical equipment and medical electrical systems, hereafter referred to as MEE and MES.

This document specifies the general requirements for the basic safety and essential performance of MEE and MES, intended for use by the specific users and in the specific environments of use as specified in the instructions for use (IFU).

This document applies to software integrated into an MEE (SiMD). This document applies to software as a medical device (SaMD) in an MES when the SaMD contributes to basic safety or essential performance.

This document can be applied to sub-assemblies of MEE or MES.

EXAMPLE Power supply unit or x-ray tube assembly.

Hazards related to the intended physiological effect of MEE or MES are not covered by the specific requirements of this document except in xxx (formerly 7.2.13) and xxx (formerly 8.4.1).

NOTE 1 See also xxx (formerly 4.2).

The IEC 60601 series does not apply to: – in vitro diagnostic medical device that does not fall within the definition of MEE, which is covered by the IEC 61010 series; – implantable parts of active implantable medical devices covered by the ISO 14708 series; or – medical gas pipeline systems covered by ISO 7396-1.

NOTE 2 ISO 7396-1 applies the requirements for alarm systems to certain monitoring and alarm signals.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60038:2009/AMD1:2021, *Amendment 1 - IEC standard voltages*

IEC 61140:2016, *Protection against electric shock - Common aspects for installation and equipment*

IEC/IEEE 62209-1528:2020, *Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-worn wireless communication devices - Human models, instrumentation and procedures (Frequency range of 4 MHz to 10 GHz)*

IEC 62311:2019, *Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz to 300 GHz)*

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IEC 62479:2010, *Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

EN 50360:2017, *Product standard to demonstrate the compliance of wireless communication devices, with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 300 MHz to 6 GHz: devices used next to the ear*

EN 50499:2019, *Procedure for the assessment of the exposure of workers to electromagnetic fields*

EN 50566:2017, *Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body*

C95.3:2021, *IEEE Recommended Practice for Measurements and Computations of Electric, Magnetic, and Electromagnetic Fields with Respect to Human Exposure to Such Fields, 0 Hz to 300 GHz*

Directive 2013/35/EU, *Directive 2013/35/EU of the European Parliament the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)*

Safety Code 6

3 Terms and definitions

The Terms and definitions clause is a mandatory element of the text.

For rules on the drafting of the Terms and definitions, refer to the ISO/IEC Directives, Part 2:2018, Clause 16 *.*

To insert a new terminological entry, go to the *Structure* tab and click on *Insert Term entry* .

For the purposes of this document, the *following terms and definitions / terms and definitions given in , as well as the following [delete what doesn't apply]* apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1 Alarm systems

3.1.1
acknowledged

3.1.2
advisory signal

advisory

3.1.3
alarm condition

3.1.4
alarm condition delay

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3.1.5
alarm de-escalation

3.1.6
alarm escalation

3.1.7
alarm fatigue

3.1.8
alarm flood

3.1.9
alarm limit

3.1.10
alarm off

3.1.11
alarm paused

3.1.12
alarm preset

3.1.13
alarm reset

3.1.14
alarm settings

3.1.15
alarm signal

3.1.16
alarm signal generation delay

3.1.17
alarm system

3.1.18
alert

3.1.19
audio off

3.1.20
audio paused

3.1.21
auditory icon

3.1.22
auditory pointer

3.1.23
burst

3.1.24
clinically actionable

3.1.25
clinically nonactionable

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3.1.26
communicator

COM

annunciator

3.1.27
default alarm preset

3.1.28
distributed alarm system

DAS

3.1.29
distributed alarm system with user confirmation

CDAS

3.1.30
distributed information system about alarm conditions

DIS

3.1.31
fall time

t_f

3.1.32
false negative alarm condition

3.1.33
false positive alarm condition

3.1.34
high priority

3.1.35
information signal

3.1.36
integrator

INT

alarm manager

3.1.37
intelligent alarm system

3.1.38
interburst interval

t_b

3.1.39
latching alarm signal

3.1.40
low priority

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3.1.41
medium priority

3.1.42
non-latching alarm signal

3.1.43
nuisance alarm signal

3.1.44
physiological alarm condition

3.1.45
pulse

3.1.46
pulse frequency

f_o

3.1.47
redirection

3.1.48
reminder signal

3.1.49
responsibility accepted

3.1.50
responsibility rejected

3.1.51
responsibility undefined

3.1.52
rise time

t_r

3.1.53
source

SRC

3.1.54
technical alarm condition

3.1.55
true negative alarm condition

3.1.56
true positive alarm condition

3.2 Circular economy

3.2.1
end of life
See IEV 904-01-17.

3.2.2
environment
See IEV 904-01-01.

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