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Interested committees:

Title: BS EN IEC 60601-1/FRAG1 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance - General requirements (Fragment 1)

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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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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.	



62A/1628/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 60601-1/FRAG1 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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TITLE:

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

NOTE FROM TC/SC OFFICERS:

Please refer to document 62A/1627/INF for background information and context for this Committee Draft (CD) of Fragment 1 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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<https://osd.iec.ch/#/editor/archive/16d7fcf4-3016-5819-e063-1910000ac4e9/en/CD/1>

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- step-by-step explanations on [Helpscout](#).

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL
REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE -
GENERAL REQUIREMENTS (FRAGMENT 1)**

FOREWORD

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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:

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.

INTRODUCTION

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

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 1term 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, 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 \(series\) \[1\]](#);

NOTE 2 [IVD medical devices](#) with an [applied part](#) (e.g. continuous glucose monitors) in scope xxx TBD

- implantable parts of active [implantable medical devices](#) covered by the [ISO 14708 \(series\) \[2\]](#); or
- medical gas pipeline systems covered by [ISO 7396-1:2016 \[3\]](#).

NOTE 3 [ISO 7396-1:2016 \[3\]](#) applies the requirements for [alarm systems](#) to certain monitoring and [alarm signals](#) of medical gas pipeline systems.

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 62353:2014, *Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment*

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

ISO 17664 (series), *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

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

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

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

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

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3.1.49

responsibility accepted

3.1.50

responsibility rejected

3.1.51

responsibility undefined

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rise time

t_r

3.1.53

source

SRC

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3.1.55

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true positive alarm condition

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See IEV 904-01-17

3.2.2

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See IEV 904-01-01

3.2.3

environmental aspect

See IEV 904-01-02

3.2.4

environmental impact

See IEV 904-01-03

3.2.5

hazardous substance

3.2.6

life cycle

3.2.7

maintenance

See IEV 192-06-01

3.2.8

maintenance interval

3.2.9

post-production

3.2.10

recycling

See IEV 901-07-10

3.2.11

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3.2.12

refurbishment

3.2.13

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remanufacturing

3.2.15

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rework

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Class II

3.3.4

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3.3.5

detachable

3.3.6

direct cardiac application

3.3.7

duty cycle

3.3.8

fixed

3.3.9

hand-held

3.3.10

internally powered

3.3.11

mobile

3.3.12

MR conditional

3.3.13

MR safe

3.3.14

MR unsafe

3.3.15

multiple patient multiple use

3.3.16

non-continuous operation

3.3.17

permanently installed

3.3.18

portable

3.3.19

protectively earthed

3.3.20

single patient multiple use

3.3.21

single use

do not re-use

use only once

3.3.22

stationary

3.3.23

sterile

3.3.24

transit-operable

3.3.25

transportable

3.3.26

walking

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cleaning

3.4.2

disinfection

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processing

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3.5.3

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3.5.4

network/data coupling

3.5.5

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3.5.6

patient coupling point

3.5.7

patient-coupled

3.5.8

signal input/output part

SIP/SOP

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basic insulation

3.6.2

clearance

air clearance

See IEC 581-27-76

3.6.3

creepage distance

3.6.4

double insulation

3.6.5

earth leakage current

3.6.6

high voltage

HV

3.6.7

insulation coordination

3.6.8

leakage current

3.6.9

low voltage

LV

3.6.10

mains

supply mains

3.6.11

mains transient voltage

See IEC 903-04-03

3.6.12

mains voltage