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Interested committees:

Title: BS EN IEC 60601-1/FRAG3 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance - User interface hazards (Fragment 3)

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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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

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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/1631/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
IEC 60601-1/FRAG3 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 - User interface hazards (Fragment 3)

NOTE FROM TC/SC OFFICERS:

Please refer to document 62A/1627/INF for background information and context for this Committee Draft (CD) of Fragment 3 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/16d87879-108b-e174-e063-1910000adffc/en/CD/1>

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- latest videos and presentations on the [OSD webpage](#), and
- 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 -
USER INTERFACE HAZARDS (FRAGMENT 3)**

FOREWORD

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*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 - USER INTERFACE HAZARDS (FRAGMENT 3)

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 60127-1:2023, *Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60417:2024 DB:2024, *Graphical symbols for use on equipment - 12-month subscription to regularly updated online database comprising all graphical symbols published in IEC 60417*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

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

ISO 7000:2019, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 80000-1:2022, *Quantities and units - Part 1: General*

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

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nuisance alarm signal

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physiological alarm condition

3.1.45

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3.1.50

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responsibility undefined

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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

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

refurbisher

3.2.12

refurbishment

3.2.13

remanufacturer

3.2.14

remanufacturing

3.2.15

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rework

3.2.17

shelf-life

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3.3.2

Class I

3.3.3

Class II

3.3.4

continuous operation

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

3.4 Cleaning, disinfection and sterilization**3.4.1**

cleaning

3.4.2

disinfection

3.4.3

processing

3.4.4

sterilization

3.5 Connections

3.5.1

EMC port

3.5.2

fluid port

3.5.3

functional connection

3.5.4

network/data coupling

3.5.5

patient connection

3.5.6

patient coupling point

3.5.7

patient-coupled

3.5.8

signal input/output part

SIP/SOP

3.6 Electrical hazards

3.6.1

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

See IEC 195-05-26

3.6.7

insulation coordination

3.6.8

leakage current

3.6.9

low voltage

LV

See IEC 195-05-25

3.6.10

mains

supply mains

3.6.11**mains transient voltage**

See IEV 903-04-03

3.6.12

mains voltage

3.6.13

maximum mains voltage

3.6.14

patient auxiliary current

3.6.15

patient leakage current

3.6.16

peak working voltage

3.6.17

public mains

3.6.18

reinforced insulation

3.6.19

supplementary insulation

3.6.20

touch current

3.6.21

working voltage

3.7 Electromagnetic compatibility (EMC)**3.7.1****effective radiated power****ERP**

power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

Note 1 to entry: Note 1 to entry: The term *effective radiated power* appears without qualification only when the reference antenna is a half-wave dipole.

[SOURCE: IEV 60050-161:2021, 161-04-16, modified — replaced note.]

3.7.2**electromagnetic compatibility****EMC**

See IEV 161-01-07

3.7.3**electromagnetic disturbance****EM disturbance**

See IEV 161-01-05

3.7.4**electromagnetic emission**

See IEV 161-01-08

3.7.5**electromagnetic environment****EM environment**

See IEV 161-01-01

3.7.6**electromagnetic interference****EMI**

See IEV 161-01-06

3.7.7**electrostatic discharge****ESD**

See IEV 161-01-22

3.7.8**immunity**

<to a disturbance> See IEV 161-01-20

3.7.9**immunity test level**

See IEV 161-04-41

3.7.10**radio frequency****RF**

frequency in the portion of the electromagnetic spectrum between 9 kHz and 3 000 GHz that is useful for radio transmission

Note 1 to entry: Note 1 to entry: This portion of the electromagnetic spectrum is between audio-frequencies and infrared.

3.8 Environment**3.8.1**

basic care area

3.8.2**cold condition**

condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature

[SOURCE: IEC 60601-1:2005, 3.16]

3.8.3

critical care area

3.8.4

emergency medical services environment

EMS environment

3.8.5

home healthcare environment

3.8.6

intermediate care area

3.8.7

magnetic resonance environment

MR environment

3.8.8

oxygen rich environment

3.8.9

patient care area

3.8.10

patient environment

3.8.11

professional healthcare environment

3.8.12

protected area

3.8.13

restricted area

3.8.14

special environment

3.8.15

thermal stability

3.8.16

use environment

3.8.17

wet procedure area

3.9 Equipment and its parts and accessories

3.9.1

access cover

3.9.2

accessible part

3.9.3

accessible surface

3.9.4

accessory

3.9.5

appliance coupler

3.9.6

appliance inlet

3.9.7

applied part

3.9.8

connector

3.9.9

control panel

3.9.10

defibrillation-proof applied part

3.9.11**enclosure**

See IEV 151-13-08

3.9.12

F-type applied part

F-type isolated (floating) applied part

3.9.13

flow-direction-sensitive

3.9.14

gas pathway

3.9.15

high-pressure inlet

3.9.16

implantable medical device

3.9.17

in vitro diagnostic medical device

IVD medical device

3.9.18

information technology equipment

ITE

See IEV 161-05-04

3.9.19

internal electrical power source

3.9.20

mains connector

3.9.21

mains part

3.9.22

mains plug

3.9.23

mains socket-outlet

MSO

multiple socket-outlet

3.9.24

medical device

3.9.25

medical device family

3.9.26

medical electrical equipment

MEE

ME equipment

3.9.27

medical electrical system

MES

ME system

3.9.28

monitoring equipment

3.9.29

packaging

3.9.30

potential equalization conductor

3.9.31

power supply cord

3.9.32

programmable electrical medical system

PEMS

3.9.33

programmable electronic subsystem

PESS

3.9.34

protective earth conductor

3.9.35

protective earth connection

3.9.36

protective earth terminal

3.9.37

secondary circuit

3.9.38

sterile barrier system

3.9.39

terminal device

3.9.40

thermostat

3.9.41

type B applied part

3.9.42

type BF applied part

3.9.43

type CF applied part

3.10 General (Generic)**3.10.1**

anomaly

3.10.2

architecture

3.10.3

biocompatibility

3.10.4

essential principles of safety and performance

essential principles

3.10.5

health

3.10.6

legacy

3.10.7

mechanical instability

3.10.8

nominal

3.10.9

phantom

3.10.10

product

3.10.11

rated

3.10.12

stability

3.10.13

state of the art

3.10.14

system

3.10.15

tool

3.10.16

type test

3.11 Information supplied by the manufacturer**3.11.1**

accompanying information

accompanying documentation

accompanying documents

3.11.2

catalogue number

commercial product code

commercial product name

3.11.3

electronic documentation

e-documentation

3.11.4

information for safety

3.11.5

information supplied by the manufacturer

3.11.6

instructions for use

IFU

package insert

3.11.7

label

3.11.8

lot

batch

3.11.9

lot number

lot code

batch number

batch code

3.11.10

marking

marked

3.11.11

model number

3.11.12

pictogram

3.11.13

safety sign

3.11.14

serial number

3.11.15

symbol

3.11.16

technical description

3.11.17

UDI carrier

3.11.18

unique device identification