Draft for Public Comment

Form 36

DPC: 24 / 30506277 DC

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

Interested committees:

Title: BS EN IEC 60601-1/FRAG2 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance - Physical environment hazard (Fragment 2)

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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.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

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 Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.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

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62A/1630/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER: **IEC 60601-1/FRAG2 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 - Physical environment hazard (Fragment 2)

NOTE FROM TC/SC OFFICERS:

Please refer to document 62A/1627/INF for background information and context for this Committee Draft (CD) of Fragment 2 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/16d8714f-1523-7b71-e063-1910000ab321/en/CD/1

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

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

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Document Sharing Hub

CONTENTS

FOREWORD ... 3
Introduction ... 5
1 Scope ... 6
2 Normative references ... 6
3 Terms and definitions ... 6
3.1 Alarm systems ... 7
3.2 Circular economy ... 10
3.3 Classifications ... 11
3.4 Cleaning, disinfection and sterilization ... 12
3.5 Connections ... 12
3.6 Electrical hazards ... 13
3.7 Electromagnetic compatibility (EMC) ... 14
3.8 Environment ... 15
3.9 Equipment and its parts and accessories ... 16
3.10 General (Generic) ... 18
3.11 Information supplied by the manufacturer ... 19
3.12 Mechanical hazards ... 20
3.13 Organizations, people and roles ... 21
3.14 Physiologic closed-loop control ... 22
3.15 Processes ... 24
3.16 Protection against hazards ... 25
3.17 Quality ... 26
3.18 Risk management ... 26
3.19 Security ... 28
3.20 Software ... 28
3.21 Usability ... 29
4 Clauses under development with WG38 ... 31
5 Environmental conditions for MEE ... 34
5.1 General ... 34
5.2 Environmental operating conditions ... 34
5.2.1 Continuous operating conditions ... 34
5.2.2 Transient operating conditions ... 37
5.3 Environmental conditions of transport and storage between uses ... 38
5.4 Environmental conditions of transport and storage prior to first use ... 39
6 Overflow, spillage, ingress of water or particulate matter, and outdoor crosion ... 40
6.1 General ... 40
6.2 Overflow in MEE ... 40
6.3 Spillage on MEE and MES ... 41
6.4 Ingress of water or particulate matter into MEE ... 41
6.5 Ingress of water or particulate matter into MES ... 43
6.6 Effect of corrosive pollutants ... 43
Annex A (normative) Guidance and rationale for terminology and definitions ... 44
A.1 Subclause 3. 44

Documents
Document Sharing Hub
Full document details: 24/30506277 DC

Annex B (normative) Rationale for particular clauses and subclauses 45
B.1 Subclause 5.1 – Environmental conditions for MEE 45
B.1.1 Explanation / rationale for the subclause 45
B.2 Subclause 5.2.1 –Continuous operating conditions 47
B.2.1 Explanation / rationale for the subclause 47
B.3 Subclause 5.2.2 – Environmental shock 49
B.3.1 Explanation / rationale for the subclause 49
B.4 Subclause 5.2.3 – Transient operating conditions 50
B.4.1 Explanation / rationale for the subclause 50
B.5 Subclause 5.3 – Environmental conditions of transport and storage between uses 51
B.5.1 Explanation / rationale for the subclause 51
B.6 Subclause 5.3 –Environmental conditions of transport and storage prior to first use 51
B.6.1 Explanation / rationale for the subclause 51
B.7 Subclause 6.2 – Overflow in MEE 52
B.7.1 Explanation / rationale for the subclause 52
B.8 Subclause 6.3 – Spillage on MEE and MES 52
B.8.1 Explanation / rationale for the subclause 52
B.9 Subclause 6.4 – Ingress of water or particulate matter into MEE 52
B.9.1 Explanation / rationale for the subclause 52
B.10 Subclause 6.5 – Ingress of water or particulate matter into MES 52
B.10.1 Explanation / rationale for the subclause 52
B.11 Subclause 6.6 – Effect of corrosive pollutants 52
B.11.1 Explanation / rationale for the subclause 52
Bibliography 53

Table 1 – Environmental Operating Ranges 34
Table 2 – 42
Table B.1 – 46

Documents
Document Sharing Hub
Full document details: 24/30506277 DC

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - PHYSICAL ENVIRONMENT HAZARD (FRAGMENT 2)

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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

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- 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 - PHYSICAL ENVIRONMENT HAZARD (FRAGMENT 2)

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 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 (Placeholder) (formerly 7.2.13) and (Placeholder) (formerly 8.4.1).

NOTE 1 See also (Placeholder) (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

There are no normative references in this document.

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/

Documents
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Full document details: 24/30506277 DC

- 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

Documents
Document Sharing Hub

Full document details: 24/30506277 DC

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

Documents
Document Sharing Hub

Full document details: 24/30506277 DC

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

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

Documents
Document Sharing Hub

Full document details: 24/30506277 DC

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
repair

Documents
Document Sharing Hub
Full document details: 24/30506277 DC

3.2.16
rework

3.2.17
shelf-life

3.3 Classifications

3.3.1
body-worn

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

Documents
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Full document details: 24/30506277 DC

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

Documents
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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 IEV 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 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

Documents
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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.

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