INSIDER’S LOOK AT THE IEC 60601 AMENDMENTS:
DETAILED GUIDANCE FROM COMMITTEE MEMBER RESPONSIBLE FOR CHANGES

October 27, 2020
Eisner Safety Consultants
Presented by Leo the “IEC 60601 Guy” Eisner
Eisner Safety Consultants is a consulting firm that supports your company through the process of on-time product approvals via safety & regulatory agencies.

**We provide consulting services for medical devices companies:**

<table>
<thead>
<tr>
<th>Service</th>
<th>Icon</th>
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</thead>
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<tr>
<td>Product Safety</td>
<td>Lightning bolt</td>
</tr>
<tr>
<td>(60601)</td>
<td></td>
</tr>
<tr>
<td>EMC</td>
<td>Radio wave</td>
</tr>
<tr>
<td>Risk Management</td>
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<td>Standards</td>
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<td>Laws/Guidances</td>
<td>DHF/TF</td>
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<td>Training</td>
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</table>

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Topics

- Background & timeline for Amendments
- IEC 60601-1 Changes
- IEC 60601-1-2 EM Disturbances Changes
- IEC 60601-1-8 Alarms Changes
- Fourth Edition on the Horizon
- Factors That May Impact Decision When to Transition to Amendments
IEC 60601-1

Scope: BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Photos from https://DepositPhotos.com
What is the Amendments Project?

Project covers most Collaterals but for IEC60601-1-3

Reasons for updates to include in ‘Short List’ = Amendments Project:
• Safety Gaps
• Known problems for regulatory bodies
• Inconsistencies within the standard
• Technical errors
• Update of key standard references
Amendments Project Timeline

- Kobe resolution Nov ’15
- Frankfurt ‘Short List’ vote Oct ’16
- Project Officially Start Dec ’16
- 1st CDs vote circulated 14 Jul ’17 & closed 6 Oct ’17
- MTs & WGs met & resolve 1st CDs OCT ’17 to - JAN ’18
- NCs commented on 1st CDs
- 2nd CDs vote prd Jan ’18 - May ’18 (60601-1, -1-8, -1-11)
- Mar/Apr ’18 Add’l 2nd CDs start vote prd (60601-1-2 & -1-10) closed Jul ’18
- Apr ’18 TC62/SC62A London teams start work on CDV
- Comments on integration of IEC 62368-1:18 Nov ’18 – Jan ’19 [impacts pushes CDV vote ≈ 7 months]
- CDV vote JUN ’19 to SEP ’19
- MTs & WGs Xian & elsewhere work on CDVs – Mar ’19
- MTs & WGs Shanghai TC62 & SCs 62A – 62D Gen Mtg work on resolving comments on CDVs & prepare FDISs – Oct ’19
- Apr – Jun ’20 FDISs vote
- Publication of ISs Jul – Sep ’20

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Amendments Project - Structure of 60601 Series & Background

General Standard Known as Base Std

IEC 60601-1
IEC 60601-2-2
IEC 60601-2-83
IEC/ISO 80601-2-78
IEC/ISO 80601-2-XX

Collaterals, Horizontal Standards, 60601-1-XX

IEC 60601-1-2
IEC 60601-1-6
IEC 60601-1-8
IEC 60601-1-11
IEC 60601-1-12

EM Disturbances
Usability
Alarm Systems
Home HC Environ
Emergency Med Srvcs Environ

IEC 62366-1
Application of usability engineering to med dvs

Clause 4.2 RMP
Clause 14 PEMS
Clause 16 Med. Elec. Sys

ISO 14971:2019
Risk Management

Software life-cycle processes

IEC TR 60601-4-2
Electromagnetic immunity: Performance of MEE & MES

Important to Amendments Proj

IEC TR 60601-4-3
Unaddressed safety aspects in 60601-1, 3rd ed. & proposals for new Rqrts

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High Level Summary of Amendments

General Std & Collaterals being amended:

- **Major Changes**
  - IEC 60601-1 *published 8/20/2020*
  - IEC 60601-1-2 *published 9/1/2020*
  - IEC 60601-1-8 *published 7/23/2020*
  - IEC 60601-1-10 *published 7/22/2020*

- **Editorial Changes (Terms & referenced Stds)**
  - IEC 60601-1-6 *published 7/22/2020*

- **No Technical Changes**
  - IEC 60601-1-9 *published 7/22/2020*
  - IEC 60601-1-12 *published 7/22/2020*

- **Minor Changes**
  - IEC 60601-1-11 *published 7/22/2020*

- **Still in process (Not part of Amendments Project)**
  - IEC 60601-1-3 Est'ed Sept 2021 (Changes not determined yet)
Amendments Project not incl. Particulars

- Particular Standards MTs, WGs, & JWG will need to update the Particulars
- Up to 3 years or so to update Particulars to publish
- Will this impact your transition to the Amendments?
Amendments Project - Align with Regulatory Requirements

Collaterals, Horizontal Standards, 60601-1-XX

IEC 60601-1
IEC 60601-2-XX
IEC 60601-2-83
IEC/ISO 80601-2-78
IEC/ISO 80601-2-XX

EM Disturbances
Usability
Alarm Systems
Home HC Environ
Emergency Med Srvcs Environ

Application of usability engineering to med dvc's

Clause 4.2 RMP
Clause 14 PEMS
ISO 14971:2019
Risk Management

IEC 60601-1 A1
ISO 14971, 2nd ed.
[60601-1, -1-2, -1-6, -1-10]

IEC 60601-1 A2
ISO 14971, 3rd ed.
[60601-1]

IEC 62304, Ed. 1.1
[60601-1-12]

IEC 62304, 1st ed.
IEC 62366, 1st ed.
IEC 62366-1, Ed. 1.1
[60601-1-6, -1-8, -1-10, -1-11]

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IEC 60601-1:05 + A1:12 + A2:20 (AMENDMENT 2) CHANGES
Normative References

Updated & New References – Clause 2

- IEC 60747-5-5:2007 or later Optoelectronic devices – Photocouplers

Note – red font are new referenced standards

- IEC 62133-2 Lithium systems - undated reference
- IEC 62368-1:2018 Audio/video, information and communication technology equipment
- ISO 7010:2019 Graphical Symbols - Safety Colours And Safety Signs
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- ISO 15223-1:2016 Medical devices— Symbols to be used with medical device labels, labelling and information to be supplied
Terminology & Definitions
Updates based on referenced stds – Clause 3

- 19 ISO 14971:2019 updated references:
  - Such as HARM, HAZARAD, HAZARDOUS SITUATION...
  - No significant changes to Risk Management Process (4.2)
    - Several reference updates to ISO 14971:2019
  - No changes to Essential Performance (4.3) Process
  - Draft Interpretation Sheet 62A/1403/DISH to clarify requirements for ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION.

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Terminology & Definitions
Updates based on referenced stds – Clause 3

- 4 IEC 62366-1:2015 + A1:2020 updated references:
  - USABILITY ENGINEERING FILE
  - VERIFICATION
  - PRIMARY OPERATING FUNCTION
  - USABILITY ENGINEERING FILE
  - Usability isn’t a Normative reference (Informative) - added to Bibliography

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Terminology & Definitions

Added definitions – Clause 3

- **3.148 ELECTROMAGNETIC DISTURBANCE (EM DISTURBANCE)** - any electromagnetic phenomenon that could degrade the performance of a device, equipment or system (IEC 60601-1-2:2014)


- **3.150 INFORMATION SIGNAL** - any signal that is not an ALARM SIGNAL or a reminder signal (IEC 60601-1-8:2006 & 60601-1-8:2006 + A2:2020)

- **3.151 LOW PRIORITY** - indicating that OPERATOR awareness is required and future action might be needed (IEC 60601-1-8:2006 & 60601-1-8:2006 + A2:2020)


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Terminology & Definitions

New definitions – Clause 3

- **3.152 MAXIMUM EQUIPMENT PRESSURE** - the maximum gauge pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION (IEC 60601-1:2005 + A1:2012 + A2:2020)

- **3.154 SAFETY SIGN** - sign giving a general safety message, obtained by a combination of a colour and geometric shape and which, by the addition of a graphical symbol, gives a general or particular safety message (IEC 60601-1:2005 + A1:2012 + A2:2020)
Identification, marking & documents
Clause 7.2.3 – Consult ACOMPANYING DOCUMENTS

A1 → SAFETY SIGN was required by most test houses. Requirement was mandatory action then SAFETY SIGN required. (Unclear requirement needed clarification)

A2 → if ACOMPANYING DOCUMENTS (user manual) used as a RISK CONTROL measure for a RISK than use SAFETY SIGN. Refer to Annex A for important details.
ISO 7010-M002 (Table D.2, Symbol 10)

A1 → can use advise the OPERATOR symbol to consult ACOMPANYING DOCUMENTS

A2 → same as A1 OR symbol may be used advise OPERATOR of location of the IFU
ISO 7000-1641 (Table D.1, Symbol 11) Also see ISO 15223-1

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Identification, marking & documents

Clause 7

7.2.9 IP Classification

A1 → IPX0, IP0X not required to be marked

A2 → IPX0, IP0X, IP00 not required to be marked (clarification)
Identification, marking & documents
Clause 7

7.4.1 Power Switches

Switches controlling power to part of equipment only

A1 → no requirements in 7.4.1 & below symbols were incorrectly referenced in 7.4.2 Control Devices (i.e. position of control devices & different position switches) *(Needed clarification)*

A2 →

- IEC 60417-5264 (Table D.1, Symbol 16)  “on” for part of equipment
- IEC 60417-5265 (Table D.1, Symbol 17)  “off” for part of equipment
- IEC 60417-5009 (Table D.1, Symbol 29)  Stand-by (condition)

Clarification of markings for switches controlling power to parts of MEE. 3 Options: These 2 symbols, or *as before* indicated by an adjacent indicator light or other unambiguous means

Stand by switch symbol to bring MEE into “stand-by” condition may be indicated by use of symbol IEC 60417-5009

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Identification, marking & documents
Clause 7

7.5 SAFETY SIGNS

A1 → safety sign (Not a defined term)

A2 → SAFETY SIGN (Defined term – minor clarification tied to clause 3.154 definition)
Table 2 – Colors of indicator lights and their meaning for ME EQUIPMENT

<table>
<thead>
<tr>
<th>Color</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red</td>
<td>Warning – immediate response by the OPERATOR is required</td>
</tr>
<tr>
<td>Yellow</td>
<td>Caution – prompt response by the OPERATOR is required</td>
</tr>
<tr>
<td>Green</td>
<td>Ready for use</td>
</tr>
<tr>
<td>Any other color</td>
<td>Meaning other than that of red, yellow or green</td>
</tr>
</tbody>
</table>

Table 2 updated to align w/ IEC 60601-1-8 (Alarms)

Photo from: https://www.digikey.com/-/media/Images/Product%20Highlights/A/APEM%20Inc/Q%20Series%20LED%20Indicators/Q-Series-LED-Indicators-Full.jpg

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Limitation of voltage, current or energy
Clause 8.4.2c) ACCESSIBLE PARTS and APPLIED PARTS

A1
Test requirement for measuring V of all conductive ACCESSIBLE PARTS of the SIP/SOP connectors or separate power supply output connectors

A2
Added text @ end of clause (Safety Gap)
If V ≤ 60Vdc / 42.4Vpk → No test
If V ≥ 60Vdc / 42.4Vpk conduct touch current test

Images from [https://www.bhphotovideo.com/c/product/1373926-REG/iogear_gud3c03_compact_usb_c_docking_station.html](https://www.bhphotovideo.com/c/product/1373926-REG/iogear_gud3c03_compact_usb_c_docking_station.html)

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Separation of parts
Clause 8.5.1.1 MEANS OF PROTECTION (MOP) - General

A1
Moved Figure A.12 (from Annex A – Informative) to new Figure 40 (Normative)

A2
New Figure 40 (modified - updated bottom 3 boxes only) biggest update is to include IEC 62368-1:2018

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IEC 62368-1 Background

- IEC 60950-1 is disappearing because of EU LVD, US & Canada will be replaced by IEC 62368-1, 3rd ed. ‘state of the art’ standard
- Impacted Amendments Project
  - shifted project 7 months
  - Ad Hoc Team met 2018 – 2019 formulate requirements & propose to NCs to integrate into A2 of 60601
- Ad Hoc Team found that IEC 62368-1 ≠ IEC 60950-1 not generically accepted as an option as requirements from IEC 62368-1 < MOOP@60601-1 or MOOP@60950-1 (A1 2MOOP@60950-1 RI accepted for 1MOPP@60601-1)
- Impact to significant parts of Clause 8 of 60601-1 – Electrical Hazards including Annex A Guidance & Rationale (Significant Update related to IEC 62368-1)
Separation of parts
Clause 8.5.1.2 MEANS OF PATIENT PROTECTION (MOPP)

Q to consider:
Can we accept ITE power or 60601 power. Does 2MOOP=1MOPP Isolation? NOT ALWAYS

**A1**

DI in IEC60950-1 = 1MOPP

**A2**

Clarification note for both IEC 60950-1 & 62368-1

IEC60950-1:05, A1:09, A2:13 or IEC60601-1 Tables 13-15

- WORKING V ≤ 707 Vdc / 500 Vrms,
  DI in 60950-1 or 2MOOP@60601-1 = 1MOPPAIR CLEARANCE

- WORKING V > 707 Vdc / 500 Vrms,
  DI in 60950-1 or 2MOOP@60601-1 ≠ 1MOPPAIR CLEARANCE

IEC62368-1:2018

- WORKING V ≤ 354 Vdc / 250 Vrms,
  DI in 62368-1 or 2MOOP@60601-1 = 1MOPPAIR CLEARANCE

- WORKING V > 354 Vdc / 250 Vrms,
  DI in 62368-1 or 2MOOP@60601-1 ≠ 1MOPPAIR CLEARANCE

**ALERT:** If relying on an IEC 62368-1 or even a 60950-1 device (i.e. Pwr supply) to provide MOPP verify in your design the WORKING V, CREEPAGE & AIR-CLEARANCE to determine 60601-1 A2 insulation requirements.

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Separation of parts
Clause 8.5.1.2 MEANS OF PATIENT PROTECTION (MOPP)

A1
No existing requirement but labs expected

A2
Added requirement
Opto-couples complying w/
IEC 60747-5-5:2007 or later are considered equivalent to 8.8.2 (distance thru solid insulation) & 8.9.3 (spaces filled by insulating compound)

All of the following apply:
– AIR CLEARANCE at the outside of the opto-coupler;
– CREEPAGE DISTANCE at the outside of the opto-coupler; and
– dielectric strength across the opto-coupler.

Image from https://components101.com/articles/what-is-optocoupler-and-how-it-works
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### Separation of parts

**Clause 8.5.1.3 MEANS OF OPERATOR PROTECTION (MOOP)**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A1</strong></td>
<td><strong>A2</strong></td>
</tr>
<tr>
<td>Opto-couplers – No requirement</td>
<td>Added requirement – Same as 8.5.1.2</td>
</tr>
<tr>
<td>IEC 60950-1 non dated reference</td>
<td>Added IEC 60950-1:05, A1:09, A2:13</td>
</tr>
<tr>
<td>No IEC 62368-1</td>
<td>8.5.1.3 added IEC 62368-1 as option allow for MOOP for requirements of:</td>
</tr>
<tr>
<td></td>
<td>1) Solid insulation forming a MOOP or</td>
</tr>
<tr>
<td></td>
<td>2) CREEPAGE DISTANCES &amp; AIR CLEARANCES forming a MOOP or</td>
</tr>
<tr>
<td></td>
<td>3) PROTECTIVE EARTH CONNECTIONS forming a MOOP</td>
</tr>
</tbody>
</table>

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Separation of parts
Clause 8.5.4 WORKING VOLTAGE

NEW requirement

WORKING VOLTAGE measurement, all ckts shall be connected to earth except floating parts providing ≥ 1MOP to Earth (See case 1 & 2 of Fig 41)

In which case highest measured V on either side of insulation barrier is the WORKING V (Uw) [of the mains barrier of both sides].

Case 1: X ≥ 1MOP floating ckt is isolated from earth by ≥ 1MOP. Uw of mains barrier is highest V of 1 side of barrier (higher of U1 or U2)

Case 2: X < 1 MOP floating ckt is not isolated by at least 1 MOP from earth so measurement of Uw of mains barrier both sides have to be earthed to obtain repeatable worst case results.
Separation of parts
Clause 8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

A1
No clear requirement for:
Testing of 1 APPLIED PART with multiple electrodes (PATIENT CONNECTIONS) that are physically close together, inside the body and surrounded by fluid.

A2
8.5.5.1 Defibrillation protection (Clarification)
differential-mode test not be performed on an APPLIED PART with multiple PATIENT CONNECTIONS if, based on the INTENDED USE, the PATIENT CONNECTIONS are intended to be completely w/in body & in close proximity to ea. other where it can be assumed that they will all be at same V potential when PATIENT is defibrillated.

8.5.5.2 Energy reduction test (Clarification)
If INTENDED USE of 1 APPLIED PART w/ multiple PATIENT CONNECTIONS that are all w/in close proximity to ea. other & completely w/in the body, these PATIENT CONNECTIONS are treated as a single PATIENT CONNECTION.
8.6.4 Impedance and current carrying capability

**DETACHABLE POWER SUPPLY CORD**

**A1**

neither supplied nor specified [by mfr], testing shall be carried out using a 3 m long cord [by test house] of appropriate cross sectional area based on 8.11.3.3 & Table 17

<table>
<thead>
<tr>
<th>RATED current (I) of ME EQUIPMENT A</th>
<th>NOMINAL cross-sectional area mm² Cu</th>
</tr>
</thead>
<tbody>
<tr>
<td>I ≤ 6</td>
<td>0.75</td>
</tr>
<tr>
<td>6 &lt; I ≤ 10</td>
<td>1</td>
</tr>
<tr>
<td>10 &lt; I ≤ 16</td>
<td>1.5</td>
</tr>
<tr>
<td>16 &lt; I ≤ 25</td>
<td>2.5</td>
</tr>
<tr>
<td>25 &lt; I ≤ 32</td>
<td>4</td>
</tr>
<tr>
<td>32 &lt; I ≤ 40</td>
<td>6</td>
</tr>
<tr>
<td>40 &lt; I ≤ 63</td>
<td>10</td>
</tr>
</tbody>
</table>

**A2**

Changed test requirement

Testing shall be carried out using a DETACHABLE POWER SUPPLY CORD as provided or specified (length and cross-sectional area) by mfr.

Provides an option for mfr to provide power cords for testing or specifying in ACCOMPANYING DOCUMENTS (not clear if IFU or Technical Description how written)
8.7.4.2 Measuring supply circuits -- INTERNALLY POWERED MEE

Deleted from 2nd to 3rd ed. Leakage Current Tests diagrams for INTERNALLY POWERED MEE

Added clarification text:
8.7.4.2 a) MEE specified for connection to a SUPPLY MAINS or INTERNALLY POWERED MEE that has a means of connection to a SUPPLY MAINS...
8.7.4.2 b) INTERNALLY POWERED MEE Fig’s 14 – 20 don’t use iso xfrmrs T1 or Switches S1 or S5. However, INTERNALLY POWERED MEE that has a means of connection to a SUPPLY MAINS shall be tested according to a) for that connection.

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### 8.8.3 Dielectric Strength

#### Table 6 - Test voltages for solid insulation forming a MEANS OF PROTECTION

<table>
<thead>
<tr>
<th>Peak working voltage (U) V peak</th>
<th>A.C. test voltages in V r.m.s.</th>
<th>Protection from mains part</th>
<th>Protection from secondary circuits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One MOOP</td>
<td>Two MOOP</td>
<td>One MOOP</td>
</tr>
<tr>
<td>U = 42.4</td>
<td>1,000</td>
<td>2,000</td>
<td>No test</td>
</tr>
<tr>
<td>U ≤ 71</td>
<td>See Table 7</td>
<td>See Table 7</td>
<td>See Table 7</td>
</tr>
<tr>
<td>71 ≤ U ≤ 154</td>
<td>1,000</td>
<td>2,000</td>
<td>See Table 7</td>
</tr>
<tr>
<td>154 ≤ U ≤ 312</td>
<td>1,500</td>
<td>3,000</td>
<td>1,000</td>
</tr>
<tr>
<td>312 ≤ U ≤ 564</td>
<td>1,500</td>
<td>2,000</td>
<td>See Table 7</td>
</tr>
<tr>
<td>564 ≤ U ≤ 1,141</td>
<td>1,500</td>
<td>2,000</td>
<td>See Table 7</td>
</tr>
<tr>
<td>1,141 ≤ U ≤ 2,300</td>
<td>1,500</td>
<td>2,000</td>
<td>See Table 7</td>
</tr>
<tr>
<td>U ≤ 60</td>
<td>1,000</td>
<td>2,000</td>
<td>No test</td>
</tr>
<tr>
<td>U ≤ 1,140</td>
<td>1,000</td>
<td>2,000</td>
<td>See Table 7</td>
</tr>
</tbody>
</table>

#### A2

**Note:** For a barrier according to:
- Figure 6.6, use the column MEANS OF PATIENT PROTECTION – Protection from secondary circuits – Two MOOP.
- Figure 7.2.1 and Figure 7.7. use the column MEANS OF PATIENT PROTECTION – Protection from mains part – One MOOP.

**Note 2:** See the rationale for 8.8.3.
8.9.1.16 Conductive surface coatings

New requirement

- Test houses have been requiring but never in standard
- Flaking or peeling doesn’t result in reduction of any AIR CLEARANCES or CREEPAGE DISTANCES
- Check by either exam of construction & data or appropriate coating test standard (i.e. UL 746C, ISO 2409, ISO 4624 – Informative noted standards)
Clause 11.3 Constructional requirements of fire ENCLOSED of ME EQUIPMENT

A1

11.3a)
- Insulated wire w/in fire encl. ≥ FV-1
- Connectors, PCBs, insulating mtl’s ≥ FV-2

A2

Updated & Clarified 11.3a)
- Insulated wire & connectors w/in fire encl. ≥ V-2 or be insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide
- PCBs & insulating mtl’s ≥ V-2

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Clause 11.3 Constructional requirements of fire ENCLSOURES of ME EQUIPMENT

11.3b)1) Bottom openings → busy confusing paragraph

1) The bottom shall have no openings or, to the extent specified in Figure 39, shall be constructed with baffles as specified in Figure 38, or be made of metal, perforated as specified in Table 25, or be a metal screen with a mesh not exceeding 2 mm × 2 mm center to center and a wire diameter of at least 0.45 mm.

11.3b)2) Sides shall have no openings within area that is included within inclined line C in Fig 39

Updated to clarify 11.3b)1)
- Same wording reformatted to dashed text
- Added options & new note to 11.3b)2)
  - Similar to b)1) but added options (2 items)
  - made of perforated metal (spec’ed Tbl 25)
  - metal screen w/ a mesh ≤ 2 × 2 mm centre to centre & dia ≥ 0,45 mm

- Other dsgn solutions for openings (e.g. baffles) could be acceptable, like solutions provided in other stds. See 1st para of 11.3 w.r.t RISK MANAGEMENT

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12.2 USABILITY OF ME EQUIPMENT

12.3 ALARM SYSTEMS

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**A1**

- Collaterals standards are referenced in cl 1.3 applicable collateral standards become normative at date of publication
- 12.2 refers to IEC 60601-1-6 UNDATED
- 12.3 refers to IEC 60601-1-8 UNDATED

**A2**

- Revised text for collaterals
- Applicable collateral standards shall apply together with this standard (1.3)
- Add’l collateral standards of IEC 60601 series, which issued subsequent to pub...of...std, shall apply together with...std when applicable. (2)

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11.1.1 Maximum temperature during NORMAL USE

13.1.2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature

ACCESSIBLE PARTS Intended to be touched to “operate” [NORMAL USE]

<table>
<thead>
<tr>
<th>External surfaces of ENCLOSURE that are likely to be touched for a time &gt; 1s</th>
<th>Metal and liquids</th>
<th>Glass, porcelain, vitreous material</th>
<th>Moulded material, plastic, rubber, wood</th>
</tr>
</thead>
<tbody>
<tr>
<td>48</td>
<td>50</td>
<td>55</td>
<td>60</td>
</tr>
</tbody>
</table>

ACCESSIBLE PARTS likely to be touched but not intended to be touched to “operate” [ABNORMAL USE]

<table>
<thead>
<tr>
<th>External surfaces of ACCESSIBLE PARTS that are likely to be touched for a time 1s ≤ T &lt; 1 min</th>
<th>Metal and liquids</th>
<th>Glass, porcelain, vitreous material</th>
<th>Moulded material, plastic, rubber, wood</th>
</tr>
</thead>
<tbody>
<tr>
<td>48</td>
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<td>60</td>
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15.4.3.4 Lithium batteries

A1
- IEC 62133 secondary lithium batteries

A2
Still can use IEC 62133
Added alternative option for newer standard
- IEC 62133-2 (undated) Lithium systems
- If regulator or a vendor/customer requires newer std what’s the impact
- **Implications:**
  - testing for a new CB certificate (assuming you’ve done IEC 62133).
  - test cost
  - test samples
  - potential project delays
  - redesign batteries / pack meet new reqts
Not an Exhaustive List of Changes

- Many other changes
- Highlighting some of more important ones to be aware of
- Be alert to other changes when do your gap assessment for your product
- We hope to have IEC 60601-1 gap assessment published and for sale in next couple months
IEC 60601-1-2, A1 EM DISTURBANCES CHANGES
IC 60601-1-2, A1 Changes

4th ed.
- Conducted emissions (CISPR 11)
  - Any 1 V (Table 1 – Power input V’s & frequencies during tests)
- Annex F – Risk Management w/ regard to EM DISTURBANCES

4th ed. + A1
- Updated test configurations (CISPR 11) – Min & Max rated V
  - No impact on single V dvcs.
  - Caution: Found to affect RF emission levels
- New tests (Tbl 11, cl 8.11) – Immunity to proximity magnetic fields (Test method IEC 61000-4-39)
  - 134.2 kHz @ 65A/m & 13.56Mhz @ 7.5A/m from AIM 7351731
  - 30kHz @ 8A/m test is only intended for MEE & MES for use in HOME HEALTHCARE ENVIRONMENT
- Rewritten Annex F – RISK MGMT with regard to EM DISTURBANCES

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IEC 60601-1-8, A2 ALARMS CHANGES
IEC 60601-1-8:06 + A1:12 + A2:20

Changes

Clause 3 (Terms & definitions)
- Changes to Distributed Alarm System (DAS), False Negative Alarm Condition, Low, Medium, & High Priority, Information Signal, Interburst Interval, Acknowledged
- New defined terms - Alarm Fatigue, Alarm Flood, Alert, Auditory Icon, Auditory Pointer, Clinically Actionable or Nonactionable, Communicator, DAS With Operator Confirmation, Distributed Information System About Alarm Conditions, Nuisance Alarm Signal,…

Clause 6 (Alarm System Rqrts)
- Auditory Alarm Signals (6.3.3.1) – Annex G – new audio sound files (optional). Old sound files still allowed.
- Note: Alarms comm. considering making Annex G mandatory next rev of std
- Volume & Characteristics of Auditory Alarm Signals & Information Signals (6.3.3.2) - Test set-up & config’s chng due to previously incorrectly referenced fig & table of ISO 3744
- DISTRIBUTED ALARM SYSTEMS and DISTRIBUTED INFORMATION SYSTEMS (DIS) ABOUT ALARM CONDITIONS (6.11.1) – Section revised to include DIS
IEC 60601-1-11, A1 HOME HEALTHCARE ENVIRONMENT CHANGES
8.3.1 (Annex A General guidance and rationale) – Clarification

- Infers: Ingress of liquid – parts rated for operating wet – but states:
  - Liquid doesn’t accumulate or it drains away such that it doesn’t:
    - interfere with BASIC SAFETY or ESSENTIAL PERFORMANCE;
    - deposit on insulation parts where it could lead to tracking along the creepage distances; or
    - reach live parts, including INTERNAL POWER SOURCES, or windings not designed to operate when wet.
8.5.3 Additional requirements for separation of parts (new)

- MEE or MES w/ INTERNAL POWER SOURCE, if simultaneous connection of MEE to PT & SUPPLY MAINS is possible, then APPLIED PARTS & parts likely to come into contact w/ PT shall have 2 MOPP from SUPPLY MAINS.

- Parts which PT intentionally handles as the intended OPERATOR (i.e. not the PT) while MEE not being used for its intended medical function may be insulated w/ 2 MOOP from SUPPLY MAINS.

Image from https://images.app.goo.gl/nZS6ogAnRwcEwDJe8
FOURTH EDITION ON THE HORIZON
60601-1, 4th Ed Architecture & Series

- Earliest start of development project 2024 but likely delayed
- Some ideas looking at
  - One requirement, “shall” statement per identifiable element (i.e. bullet, sub-cl., etc.)
  - Write clearer less interlaced & complex requirements
  - Use clear testable requirements
  - Integrate some Collaterals into IEC 60601-1
  - Possible db standard - i.e. integrate General Standard with Collaterals and any applicable Particular Standards for specific product type so have requirements for that product
FACTORS THAT MAY IMPACT DECISION WHEN TO TRANSITION TO AMENDMENTS
Factors That May Impact Decision When to Transition to Amendments

- Particular standards;
- When will national standards adopt the Amendments;
- Transition dates of national certifiers such as UL, CSA, BSI, etc.;
- National regulators transition periods/timelines;
- Manufacturer regulatory approvals;
- Manufacturer design time lines;
- Existing safety certifications;
- New product being ready for market or legacy product lines;
- Business, regulatory, & quality system strategy & impact;
Factors That May Impact Decision When to Transition to Amendments

- When will you start a full gap assessment?
  - What are the consequence of all the changes can impact your:
    - Design
    - Resubmission of regulatory approvals,
    - Resubmission of safety test house approvals,
    - Etc.,
Contact Us

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