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

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:

Product Safety
(60601)

EMC

Risk
Management

Labeling
Review

Standards
Regulations
Laws/Guidances

Design

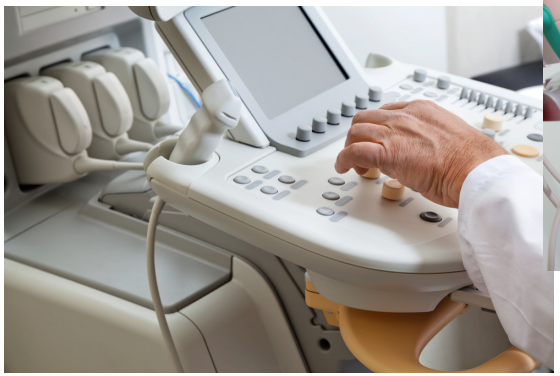
DHF/TF

Training

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

Photos from https://DepositPhotos.com

IEC 60601-1

Edition 3.2 2020-08
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ICS 11.040.01

ISBN 978-2-8322-8799-6

What is the Amendments Project?

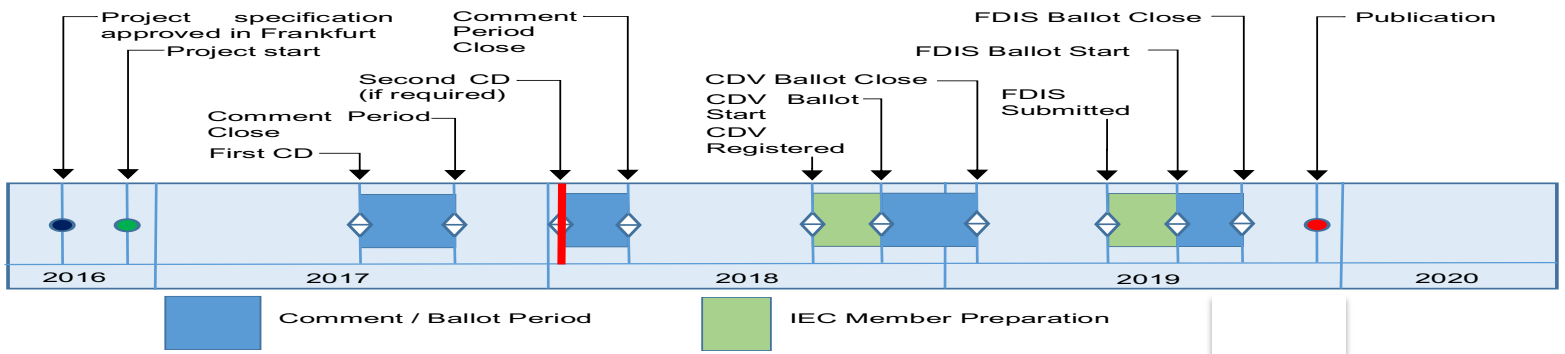
60601-1 *Electro Med*	*60601-1-2* *EM Disturbances*	*60601-1-6* *Usability*	*60601-1-8* *Alarms*
60601-1-9 *Environ … Dsgn*	*60601-1-10* *Closed loop cntrls*	*60601-1-11* *Home Use Environ*	*60601-1-12* *EMS Environ*

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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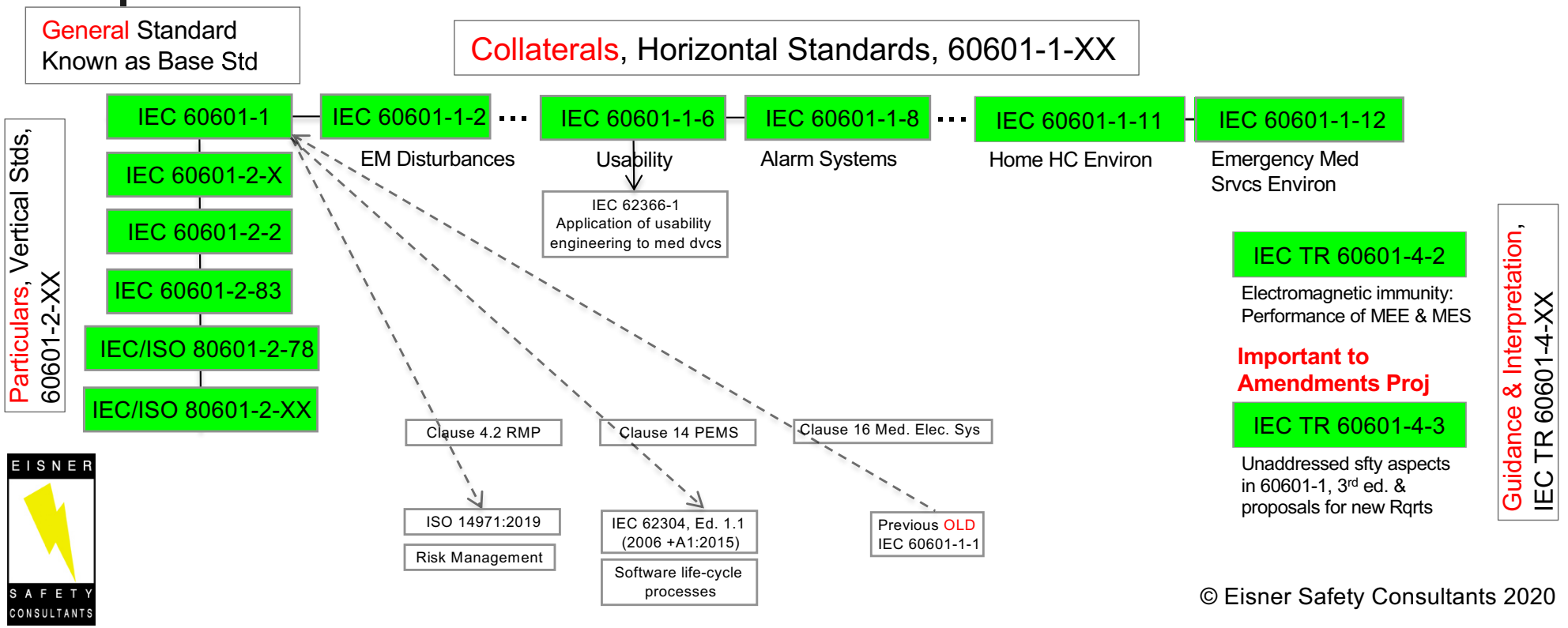
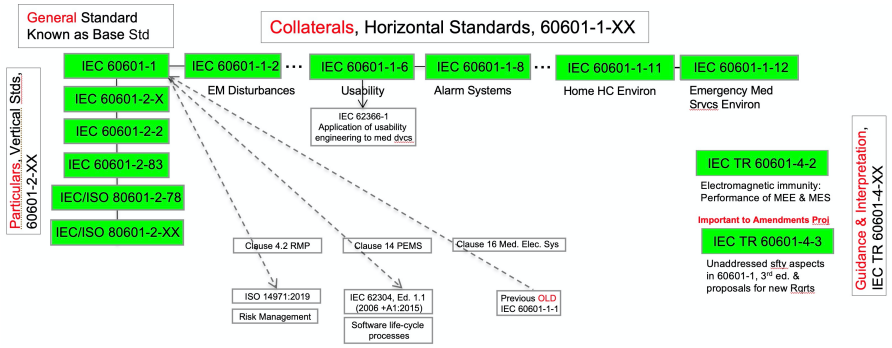
Amendments Project - Structure of 60601 Series & Background



High Level Summary of Amendments Changes



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)

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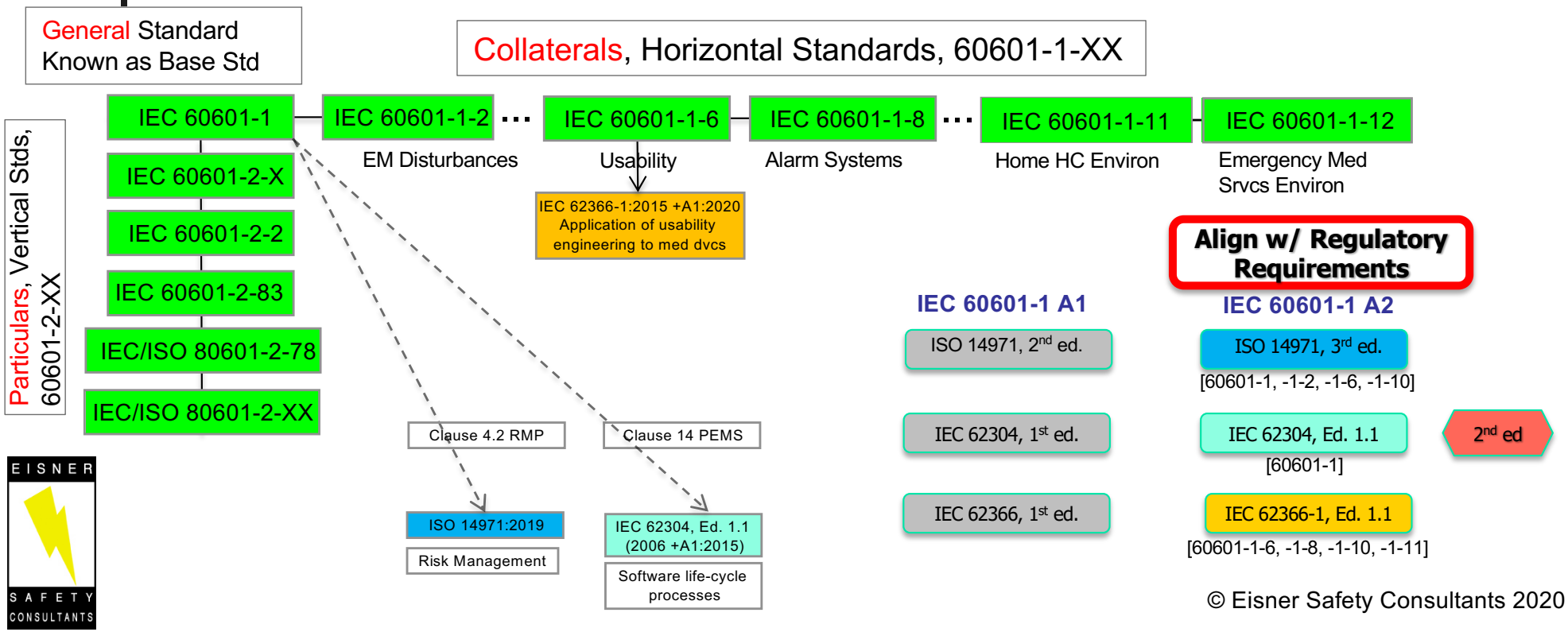
Amendments Project not incl. Particulars

- Particular Standards MTs, WGs, & JWGs 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



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

Normative References
Updated & New References – Clause 2

- IEC 60601-1-2:2014 + A1:2020 EM Disturbances
- IEC 60601-1-3:2008 + A1:2013 Diagnostic X-ray equipment
- IEC 60601-1-6:2010 + A1:2013 +A2:2020 Usability
- IEC 60601-1-8:2006 + A1:2012 + A2:2020 Alarm Systems
- IEC 60747-5-5:2007 or later Optoelectronic devices – Photocouplers
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
- IEC 60950-1:2005 + A1:2009 +A2:2013 Information technology equipment
- 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

Note – red font are new referenced standards

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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)
- 3.149 HIGH PRIORITY - indicating that immediate OPERATOR response is required (IEC 60601-1-8:2006 & 60601-1-8:2006 + A2:2020)
- 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)
- 3.153 MEDIUM PRIORITY - indicating that prompt OPERATOR response is required (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

ISO 7010-M002

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

A2 → if ACCOMPANYING 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)

ISO 7000-1641

A1 → can use advise the OPERATOR symbol to consult ACCOMPANYING 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)

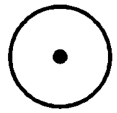
Identification, marking & documents
Clause 7

7.4.1 Power Switches

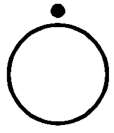
Switches controlling power to part of equipment only

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)

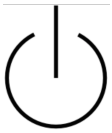
A2 →



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

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)

Identification, marking & documents
Clause 7.8.1 Colours of Indicator Lights

A1 → A2

Table 2 – Colors of indicator lights and their meaning for ME EQUIPMENT

Color	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other color	Meaning other than that of red, yellow or green

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

Table 2 – Colours and meanings of indicator lights and alarm indicator lights for ME EQUIPMENT

Name	On when	Indicator light [a]	Alarm indicator light	Accompanied by sound	Operator requirement
Warning [b]	HAZARDOUS SITUATION is to be avoided	Red, not flashing	–	– [c]	Avoidance of a HAZARDOUS SITUATION which could cause death or serious injury
Caution [b]	HAZARDOUS SITUATION is to be avoided	Yellow, not flashing	–	–	Avoidance of a HAZARDOUS SITUATION which could cause minor or moderate injury or equipment damage
Ready for use	ME EQUIPMENT is ready for use	Green	–	–	–
HIGH PRIORITY ALARM CONDITION	Interruption of current workflow is needed	–	Red, flashing [d]	Typically [d]	Immediate action to prevent injury
MEDIUM PRIORITY ALARM CONDITION	Re-planning of current workflow is needed	–	Yellow, flashing [d]	Typically [d]	Prompt action to prevent injury
LOW PRIORITY ALARM CONDITION	Planning of future workflow is needed	–	Yellow or cyan, not flashing [d]	Optional [d]	Awareness for future action
Other	Situations other than that of red, yellow or green	Any colour other than red, yellow, cyan or green	–	–	–

Alarms

[a] These indicator lights are INFORMATION SIGNALS and IEC 60601-1-8 requires that they be perceived as different than visual ALARM SIGNALS.

[b] Such warnings and cautions are frequently accompanied by a SAFETY SIGN.

[c] Sound may be utilized, but IEC 60601-1-8 requires that it be perceived as different than auditory ALARM SIGNALS.

[d] As specified in IEC 60601-1-8.

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

SIP/SOP's

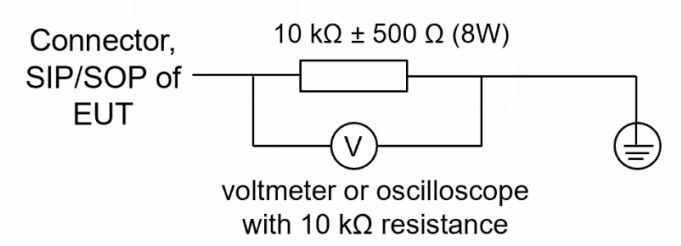
Pwr supply output connectors

A2

Added text @ end of clause (Safety Gap)

If V ≤ 60Vdc / 42.4Vpk → No test

If V ≥ 60Vdc / 42.4Vpk conduct touch current test



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Images from https://www.bhphotovideo.com/c/product/1373926-REG/iogear_gud3c03_compact_usb_c_docking_station.html
https://www.meanwell.com/webapp/product/search.aspx?prod=GST60A

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)

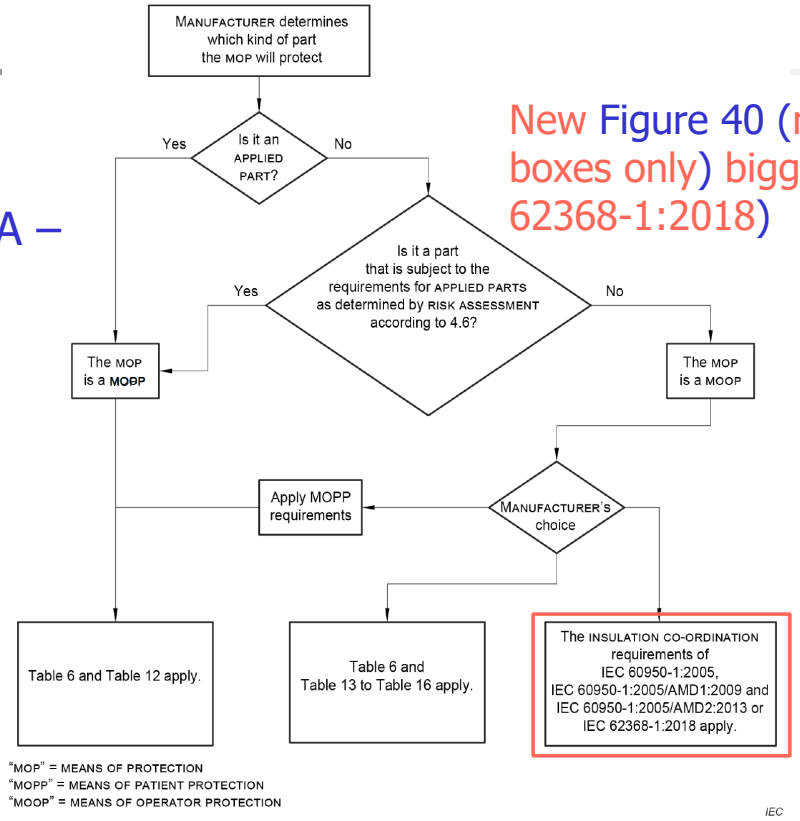

Figure 40 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

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)

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Separation of parts

Clause 8.5.1.2 MEANS OF PATIENT PROTECTION (MOPP)

A1

DI in IEC60950-1 = 1MOPP

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

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 = $1MOPP_{AIR\ CLEARANCE}$

- WORKING V > 707 Vdc / 500 Vrms,

DI in 60950-1 or 2MOOP@60601-1 ≠ $1MOPP_{AIR\ CLEARANCE}$

IEC62368-1:2018

- WORKING V ≤ 354 Vdc / 250 Vrms,

DI in 62368-1 or 2MOOP@60601-1 = $1MOPP_{AIR\ CLEARANCE}$

- WORKING V > 354 Vdc / 250 Vrms,

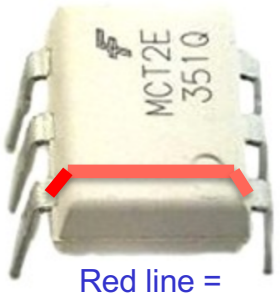
DI in 62368-1 or 2MOOP@60601-1 ≠ $1MOPP_{AIR\ CLEARANCE}$

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.

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

A1

No existing requirement but labs expected



Red line = Measured outside distance

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

Separation of parts
Clause 8.5.1.3 MEANS OF OPERATOR PROTECTION (MOOP)

A1

- Opto-couplers – No requirement
- IEC 60950-1 non dated reference
- No IEC 62368-1

A2

Added requirement – Same as 8.5.1.2

Added IEC 60950-1:05, A1:09, A2:13

8.5.1.3 added IEC 62368-1 as option allow for MOOP for requirements of:

1) Solid insulation forming a MOOP or

2) CREEPAGE DISTANCES & AIR CLEARANCES forming a MOOP or

3) PROCTECTIVE EARTH CONNECTIONS forming a MOOP

Separation of parts
Clause 8.5.4 WORKING VOLTAGE

A1

Not specified

A2

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.

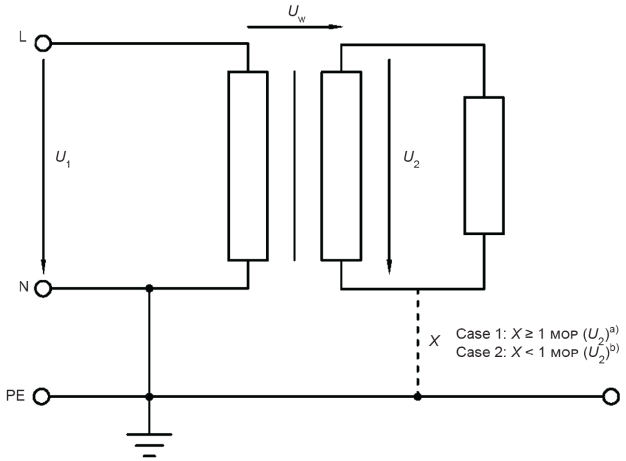


Figure 41 – WORKING VOLTAGE measurement

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 17

RATED current (I) of ME EQUIPMENT A	NOMINAL cross-sectional area mm^2 Cu
$I \leq 6$	0.75
$6 < I \leq 10$	1
$10 < I \leq 16$	1.5
$16 < I \leq 25$	2.5
$25 < I \leq 32$	4
$32 < I \leq 40$	6
$40 < I \leq 63$	10

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

A1

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

A2

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 T1or 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.

8.8.3 Dielectric Strength

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

A1

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

PEAK WORKING VOLTAGE (*U*) V peak	PEAK WORKING VOLTAGE (*U*) V d.c.	A.C. test voltages in V r.m.s.							
		MEANS OF OPERATOR PROTECTION				MEANS OF PATIENT PROTECTION			
		Protection from MAINS PART		Protection from SECONDARY CIRCUITS		Protection from MAINS PART		Protection from SECONDARY CIRCUITS	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOPP	Two MOPP	One MOPP	Two MOPP
U < 42.4	*U* < *60*	1,000	2,000	No test	No test	1,500	3,000	500	1,000
42.4 < *U* ≤ 71	60 < *U* ≤ 71	1,000	2,000	See Table 7	See Table 7	1,500	3,000	750	1,500
71 < *U* ≤ 184	71 < *U* ≤ 184	1,000	2,000	See Table 7	See Table 7	1,500	3,000	1,000	2,000
184 < *U* ≤ 212	184 < *U* ≤ 212	1,500	3,000	See Table 7	See Table 7	1,500	3,000	1,000	2,000
212 < *U* ≤ 354	212 < *U* ≤ 354	1,500	3,000	See Table 7	See Table 7	1,500	4,000	1,500	3,000
354 < *U* ≤ 848	354 < *U* ≤ 848	See Table 7	3,000	See Table 7	See Table 7	√2*U* + 1,000	2 x (√2*U* + 1,500)	√2*U* + 1,000	2 x (√2*U* + 1,500)
848 < *U* ≤ 1,414	848 < *U* ≤ 1,414	See Table 7	3,000	See Table 7	See Table 7	√2*U* + 1,000	2 x (√2*U* + 1,500)	√2*U* + 1,000	2 x (√2*U* + 1,500)
1,414 < *U* ≤ 10,000	1,414 < *U* ≤ 10,000	See Table 7	See Table 7	See Table 7	See Table 7	*U*/√2 + 2,000	√2*U* + 5,000	*U*/√2 + 2,000	√2*U* + 5,000
10,000 < *U* ≤ 14,140	10,000 < *U* ≤ 14,140	1.06 x *U*/√2	1.06 x *U*/√2	1.06 x *U*/√2	1.06 x *U*/√2	*U*/√2 + 2,000	√2*U* + 5,000	*U*/√2 + 2,000	√2*U* + 5,000
U > 14,140	*U* > 14,140	If necessary, to be prescribed by particular standards							

NOTE 1 For a barrier according to:

- Figure J.6, use the column MEANS OF PATIENT PROTECTION – Protection from SECONDARY CIRCUITS – Two MOPP.
- 8.5.2.1 and Figure J.7, use the column MEANS OF PATIENT PROTECTION – Protection from MAINS PART – One MOPP.

NOTE 2 See the rationale for 8.8.3.

A2

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

PEAK WORKING VOLTAGE (*U*) V peak	PEAK WORKING VOLTAGE (*U*) V d.c.	A.C. test voltages in V r.m.s.							
		MEANS OF OPERATOR PROTECTION				MEANS OF PATIENT PROTECTION			
		Protection from MAINS PART		Protection from SECONDARY CIRCUITS		Protection from MAINS PART		Protection from SECONDARY CIRCUITS	
		One MOPP	Two MOPP	One MOPP	Two MOPP	One MOPP	Two MOPP	One MOPP	Two MOPP
U < 42,4	*U* < *60*	1 000	2 000	No test	No test	1 500	3 000	500	1 000
42,4 < *U* ≤ 71	60 < *U* ≤ 71	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
71 < *U* ≤ 184	71 < *U* ≤ 184	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
184 < *U* ≤ 212	184 < *U* ≤ 212	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
212 < *U* ≤ 354	212 < *U* ≤ 354	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
354 < *U* ≤ 848	354 < *U* ≤ 848	See Table 7	3 000	See Table 7	See Table 7	√2*U* + 1 000	2 x (√2*U* + 1 500)	√2*U* + 1 000	2 x (√2*U* + 1 500)
848 < *U* ≤ 1 414	848 < *U* ≤ 1 414	See Table 7	3 000	See Table 7	See Table 7	√2*U* + 1 000	2 x (√2*U* + 1 500)	√2*U* + 1 000	2 x (√2*U* + 1 500)
1 414 < *U* ≤ 10 000	1 414 < *U* ≤ 10 000	See Table 7	See Table 7	See Table 7	See Table 7	*U*/√2 + 2 000	√2*U* + 5 000	*U*/√2 + 2 000	√2*U* + 5 000
10 000 < *U* ≤ 14 140	10 000 < *U* ≤ 14 140	1,06 x *U*	1,06 x *U*	1,06 x *U*	1,06 x *U*	*U*/√2 + 2 000	√2*U* + 5 000	*U*/√2 + 2 000	√2*U* + 5 000
U > 14 140	*U* > 14 140	If necessary, to be prescribed by particular standards							

NOTE 1 For a barrier according to:

- Figure J.6, use the column MEANS OF PATIENT PROTECTION – Protection from SECONDARY CIRCUITS – Two MOPP.
- 8.5.2.1 and Figure J.7, use the column MEANS OF PATIENT PROTECTION – Protection from MAINS PART – One MOPP.

NOTE 2 See the rationale for 8.8.3.

NOTE 3 Insulation meeting the requirements for the test voltage for reinforced insulation for a nominal mains system voltage up to and including 250 V r.m.s according to IEC 62368-1:2018, Table 27 meets the requirements for 1 MOPP according to this table for a peak WORKING VOLTAGE up to 1 293 V. At higher WORKING VOLTAGES the insulation does not necessarily provide 1 MOPP.

Insulation meeting the requirements for the test voltage for reinforced insulation for a nominal mains system voltage above 250 V r.m.s. up to and including 600 V r.m.s. according to IEC 62368-1:2018, Table 27 meets the requirements for 1 MOPP according to this table for a peak WORKING VOLTAGE up to 2 172 V. At higher WORKING VOLTAGES the insulation does not necessarily provide 1 MOPP.

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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)

Image from: https://www.hammfg.com/electronics/small-case/plastic/1598r

Clause 11.3 Constructional requirements of fire ENCLSOURES 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

A1

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

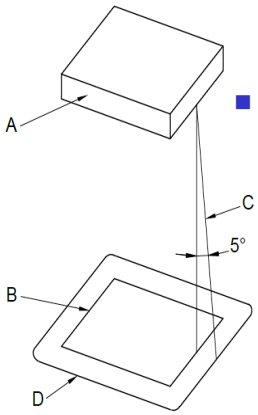

Fig 39

A2

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

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)
- 12.2 revised to IEC 60601-1-6:2010 + A1:2013 +A2:2020 (ties to IEC 62366-1:2015 +A1:2020)
- 12.3 revised to IEC 60601-1-8:2006 + A1:2012 + A2:2020

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11.1.1 Maximum temperature during NORMAL USE
13.1.2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature

A1

Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched

ME EQUIPMENT and its parts		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Molded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "*t*"	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

A2

ACCESSIBLE PARTS Intended to be touched to "operate" [NORMAL USE]

Table 23 – Allowable maximum temperatures for ACCESSIBLE PARTS that are likely to be touched

ACCESSIBLE PARTS		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ACCESSIBLE PARTS that are likely to be touched for a time "*t*"	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

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

New Table

Table 34 – Allowable maximum temperatures for ACCESSIBLE PARTS that are likely to be touched, but not intended to be touched to operate the ME EQUIPMENT

ME EQUIPMENT and its parts	Maximum temperature °C			
	Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber	Wood
External surfaces of ACCESSIBLE PARTS that are likely to be touched for a time *t* < 1 s	80	90	104	150

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 rqrts

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

IEC 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/ rgrd 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

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IEC 60601-1-11, A1 HOME HEALTHCARE ENVIRONMENT CHANGES

IEC 60601-1-11:15 + A1:20 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.

IEC 60601-1-11:15 + A1:20 Changes

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

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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;

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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.,

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