

【 Medical 】 IEC, EN, ANSI/AAMI ES60601-1 (Ed. 3.2) Status



IEC 60601-1:2005+A1:2012+A2:2020 (ED. 3.2)



EN 60601-1:2006+A1:2013+A12:2014+A2:2021

(OJ MDR mandatory Date: expect 2024-05-27,
refer COMMISSION IMPLEMENTING DECISION M/575)

BS EN 60601-1:2006+A1:2013+A12:2014+A2:2021



ANSI AAMI ES 60601-1:2005+A2:2021 (2022/2/1)

(FDA mandatory Date: 2023-12-17)

CAN/CSA-C22.2 No. 60601-1:14/A2:22 (2022/3)

【Medical】 IEC, EN 60601-1 (Ed. 3.2) Major requirement



- Update requirement for ball pressure test (**Impact**)
 - 1). ED. 3.1 test temperature only refer " Normal & Overload condition"
 - 2). ED. 3.2 add an evaluation "Single fault condition"
- MOOP accept IEC 62368 (ED. 3.1: only 60950) (**Relax**)
Insulation comply IEC 60950 or IEC 62368 can be used as a MOOP
- RISK MANAGEMENT standard update to ISO 14971:2019
- Usability standard update to IEC 60601-1-6: 2020 & IEC 62366-1:2020
- Allowable maximum temperatures for Accessible part add Table 34 (**Relax**)
=> **likely to be touched** & **intended to be touched**

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

ME EQUIPMENT and its parts		Maximum temperature °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "t"	$t < 1\text{ s}$	74	80	86
	$1\text{ s} \leq t < 10\text{ s}$	56	66	71
	$10\text{ s} \leq t < 1\text{ min}$	51	56	60
	$1\text{ min} \leq t$	48	48	48

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 $t < 1\text{ s}$	80	90	104	150

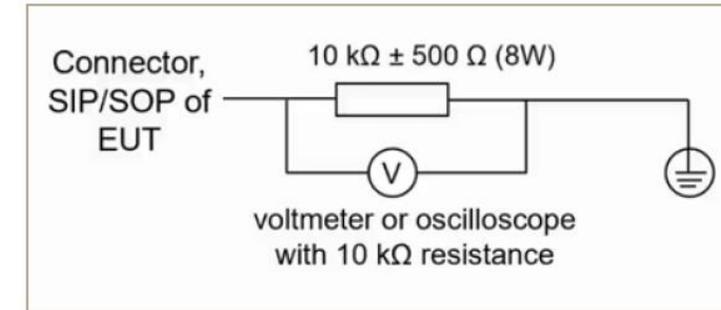
【Medical】 IEC, EN 60601-1 (Ed. 3.2) Major requirement

- 8.4.2 c) ACCESSIBLE PARTS and APPLIED PARTS: (Not impact)

1). Output voltage \leq 60Vdc or 42.4Vpk -> Pass

2). Output voltage $>$ 60Vdc or 42.4Vpk

-> leakage current test with $10\text{ k}\Omega \pm 500\ \Omega$ resistor (NEW)



- 8.6.4 Impedance and Current-carrying Capability (Not Impact)

1). ED. 3.1 testing with 3m length power cord only

2). ED. 3.2 Testing shall be carried out using a DETACHABLE POWER SUPPLY CORD as provided or specified (length and cross-sectional area) by the MANUFACTURER.



- National Differences

Group/Country	Reference	Last Modified
 Canada	CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14	2022-08-06
 Canada	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14	2022-08-12
 United States of America	National standard AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012, ES60601-1:2005/AMD2:2021	2022-07-01