

【醫療類】 IEC, EN, ANSI/AAMI ES60601-1 (Ed. 3.2) 現況



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 已公佈強制日為 2023-12-17)

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

【醫療類】IEC, EN, ANSI/AAMI ES60601-1 (Ed. 3.2)主要要求

- 球壓測試的溫度判定方式變嚴
 - ED. 3.1 球壓測試溫度僅參考“正常+過載”條件
 - ED. 3.2 球壓測試溫度參考“正常+過載+增加單一故障”條件
- MOOP新增接受IEC 62368 (ED. 3.1: only 60950)
- 風險評估標準更新為最新版ISO 14971:2019
- Usability標準更新為 IEC 60601-1-6: 2020 & IEC 62366-1:2020
- Accessible part 的溫度要求修正為兩種判定方式
 - => likely to be touched & intended to be touched



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

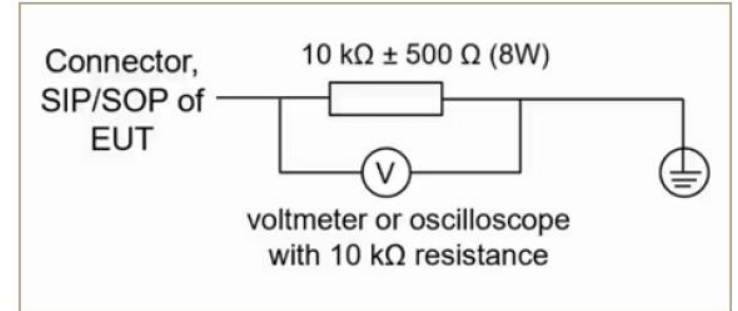
ME EQUIPMENT and its parts		Maximum temperature °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "t"	t < 1 s	74	80	86
	1 s ≤ t < 10 s	56	66	71
	10 s ≤ t < 1 min	51	56	60
	1 min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

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

【醫療類】IEC, EN, ANSI/AAMI ES60601-1 (Ed. 3.2)主要要求




- 8.4.2 c) ACCESSIBLE PARTS and APPLIED PARTS: 輸出須加量 $10\text{ k}\Omega \pm 500\ \Omega$ 漏電流
電壓 $\leq 60\text{Vdc}$ or 42.4Vpk -> 不須量測漏電流
電壓 $> 60\text{Vdc}$ or 42.4Vpk -> 須加量漏電流* $10\text{ k}\Omega \pm 500\ \Omega$



- 8.6.4 Impedance and Current-carrying Capability
ED. 3.1 測試限定3m 電源線
ED. 3.2 可由製造商自行定義規格(線徑/長度), 控管於COA



● 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