生活輔助用醫電設備一般安全要求與電氣系統安全要求

台灣電子檢驗中心 生醫課

張世明

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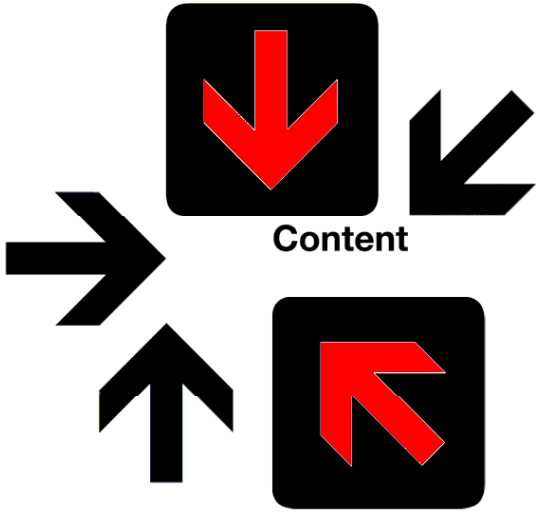
內容重點

- **IEC 60601-13rd** 概要
- 對電擊危害之要求
- 絕緣圖與絕緣距離之估算
- 結構與機械之要求
- 對溫度與火之保護
- 標示與說明書之要求

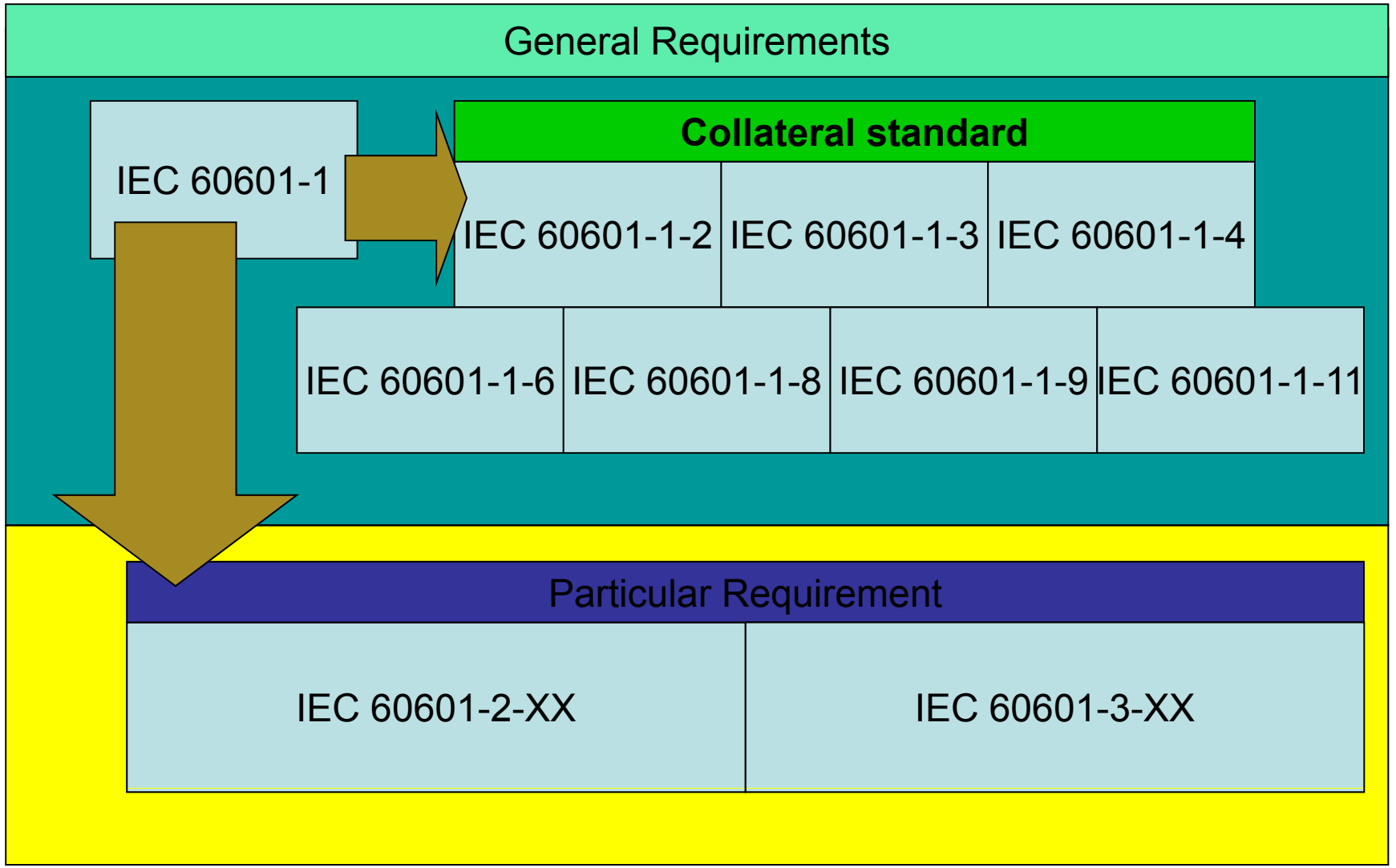


醫電設備安全標準
(IEC 60601-1)簡介

IEC60601-1 3rd 概要

- 出版日期:2005.12
- 取代IEC 60601-1 2nd+A1,+A2 (緩衝期長)
  2012.7無特別要求之產品將開始適用
- 導入風險管理流程觀念(與ISO 14971 連結)
- 醫電系統要求➔第16章
- 軟體風險管理➔第14章
- 可使用性(IEC60601-1-6)及警報系統要求(IEC60601-1-8)之引用
- 排除體外診斷設備(covered by the IEC 61010 series
- 排除主動植入式醫療器材之植入部位 (covered by ISO 14708-1
- 有關電性危害要求引用IEC 60950-1之觀念,部分條文要求甚至可以IEC 60950-1替代

IEC 60601標準系統架構



IEC 60601-1 Collateral Standards

IEC 60601-1-1	Safety Requirements for Medical Electrical Systems (06/92), Am.1 (11/95), Ed.2 (12/00).
IEC 60601-1-2	Electromagnetic Compatibility - Requirements and Tests (04/93), Ed.2 (09/01), Am.1 (09/04), Ed. 2.1 (11/04).Ed.3(03/07)
IEC 60601-1-3	Gen. Requirements for Radiation Protection in Diagnostic X-ray Equipment (07/94).
IEC 60601-1-4	Programmable Electrical Medical Systems (05/96), Am.1 (10/99), Ed.1.1 Consolidated (04/00).
IEC 60601-1-5	Image quality and dose for X-ray equipment (Project).
IEC 60601-1-6	Analysis, test and validation of human factors compatibility Ed.1 (06/04).Ed.2 (12/06)
IEC 60601-1-8	General requirements and guidelines for the application of alarms in Medical Electrical Equipment (08/03).
IEC 60601-1-9	Requirements for the reduction of environmental impacts (07/07).
IEC 60601-1-10	Process requirements for the development of therapeutic closed-loop controllers (Project).
IEC 60601-1-11	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment(04/10)

Example of IEC 60601-1 Particular Standards

IEC 60601-2-2	High Frequency Surgical Equipment Ed.5.0 (02/09).
IEC 60601-2-3	Short-Wave Therapy Equipment Ed.3 (03/08)
IEC 60601-2-4	Cardiac Defibrillators and Cardiac Defibrillator-Monitors (01/83), Ed.2 (08/02),
IEC 60601-2-5	Ultrasonic Therapy Equipment (01/84), Ed.2 (07/00)
IEC 60601-2-6	Microwave Therapy Equipment (01/84).
IEC 60601-2-10:	Nerve and Muscle Stimulators (12/87), Am.1 (09/01), Corrigendum (02/02).
IEC 60601-2-19	Baby Incubators (12/90), Am.1 (10/96).
IEC 60601-2-20	Transport Incubators Ed.2 (02/09)
IEC 60601-2-21	Infant Radiant Warmers (02/94), Am.1 (10/96)
IEC 60601-2-22	Diagnostic and Therapeutic Laser Equipment Ed. 2 (11/95), Ed. 3 (Project).
IEC 60601-2-23	Transcutaneous Partial Pressure Monitoring Equipment (09/93), Including essential performance Ed. 2 (12/99).
IEC 60601-2-38	Electrically Operated Hospital Beds (10/96), Am.1 (12/99), (Next Ed. will be IEC 60601-2-52).

醫電設備(ME Equipment)之定義

條件一	具有applied part 或 與患者有進行能量轉移 或 監測能量轉移
條件二	利用一個或多個電源進行能量供應
條件三	其用途爲對患者進行處置,診斷或監控 用於補償或減緩疾病，傷害或殘疾
條件四	包含正常使用下所必須之配件

IEC 60601-1之安全基本觀念

- **Basic safety ＋ Essential performance =Total safety situation**
- 需考量在正常使用情形、正常操作下可預見之誤用與單一失效狀況**(SFC)**
- 對生命支持設備而言，功能之可靠度亦為安全性之一部分
- 中斷處置或檢查視為對患者之危害

風險管理導入觀念

– A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.
– The term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.
– The term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.
– The policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) shall be established by the MANUFACTURER.
– Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.

IEC 60601-1風險管理符合評估原則

All requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:

– *established a RISK MANAGEMENT PROCESS*;

– *established acceptable levels of RISK; and*

– *demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK*).

等效安全

- **Cl.4.5**

  Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard.

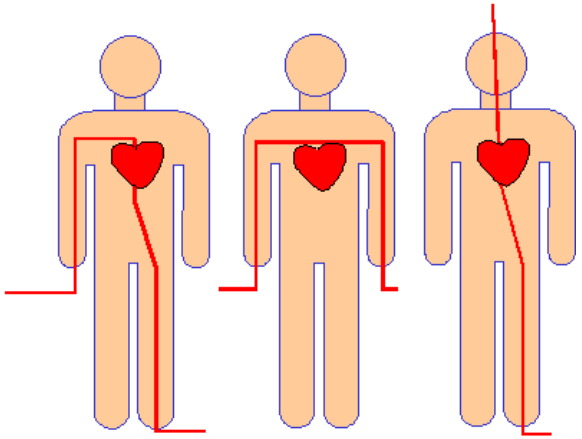
爲何IEC 60601-1之要求比一般電氣產品之安全標準嚴格?

- 患者或操作者無法察覺危險之存在
- 患者可能因生病，無意識，麻醉等原因而無法正常反應
- 患者皮膚因穿透處理造成低阻抗
- 依賴儀器之穩定性來支持人體功能
- 同時連接一個以上之儀器至患者
- 電氣電路可能透過接皮膚或侵入體腔與人體接觸

Annex A of IEC 60601-1

電器類醫療器材可能產生之危險

- 電殛
- 機械危險
- 熱能
- 火
- 電磁相容性
- 化學性危險 (dangerous liquids, 笑氣，氧氣)
- 高能量輸出(雷射，X-Ray, ….)
- 生物性危險
- 軟體失效
- 人因介面
- 標示/說明



電氣類產品相關之安全標準

- IEC60601 系列 (Safety and essential performance requirements)
- IEC 61010 系列
- IEC 10993 系列 Bio-compability
- ISO 13485 Quality system
- ISO 14971 Risk management

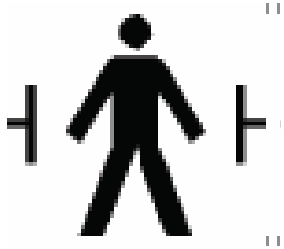
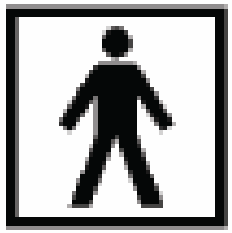
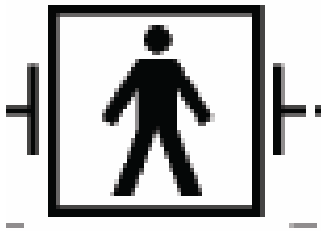
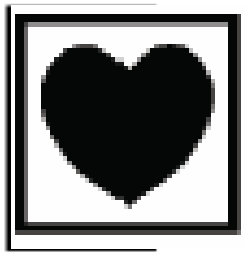
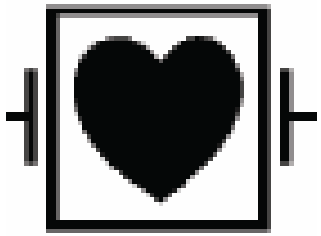
典型的醫電設備安全測試項目

- 接地阻抗測試
- 洩漏電流測試
- 絕緣耐電壓測試
- 工作溫度測試
- 防水測試
- 耐燃測試
- 電磁相容測試
- 生物相容性測試

醫療器材之分類

分類項目	分類方法
對電殛保護型式	Class I, II, internal power
Applied part	Type B, BF, CF
防塵防水等級 IP	IPX(0-6)X(0-8)
使用於含麻醉氣體環境	AP,  APG 

可接觸部位保護等級符號標示

Symbols	Description	Symbols	Description
	Type B		Type B Defib Protection
	Type BF		Type BF Defib Protection
	Type CF		Type CF Defib Protection

醫電設備抗電殛危害之保護
Protection against electrical HAZARDS from ME EQUIPMENT

防止電殛之基本原則

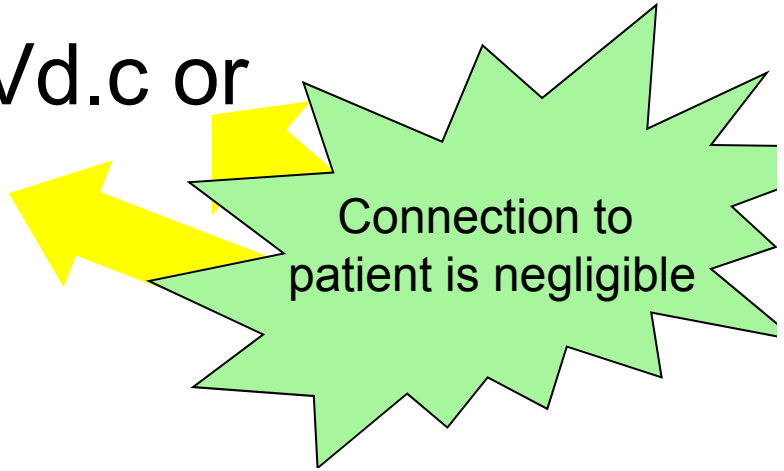
- 在Normal Condition及Single Fault Condition狀況下,Accessible part及Applied part 仍符合8.4節之要求

Cl.8.4 之要求

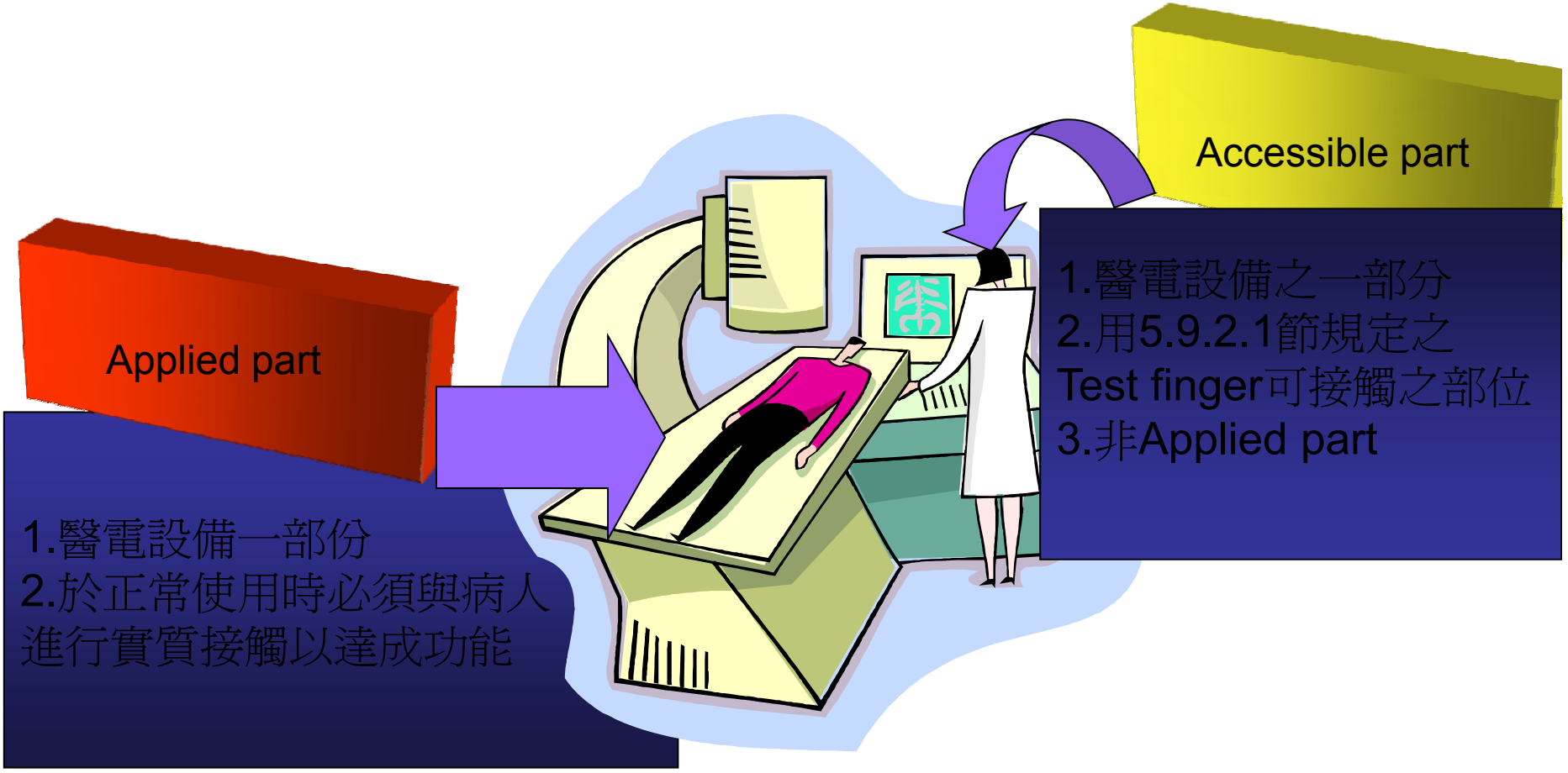
-Leakage current (I_p I_{aux} I_t) ≤ limit of 8.7.3

-$V_{E\text{-}A}$ ≤ 42.4V $_{peak}$ a.c. or 60Vd.c or

-energy≤240VA,60s or 20J



Accessible part /Applied part



電壓，電流或能量之限制

可接觸部位	要求	舉例
患者連接部位	患者洩漏電流不可超過限制值	**ECG leads**
非患者連接之可接觸部位	**Touch current≤ 100uA(NC) 500uA(SFC)**	機殼/面板
其他可接觸部位	**≤ 42.4Vpeak a.c.或 60V d.c.**	**USB**連接埠
	能量**≤ 240VA**	
	儲存能量**≤ 20J (**電壓小於**2V)**	

Applied Part之分類規定

用途	Applied Part 類別	範例
可直接用於心臟方面之應用	CF	心臟節律器電極
傳遞電能或電生理訊號(from or to patient)	BF or CF	心電圖機電極
其他	B,BF or CF	噴霧器咬嘴

隔離之要求

- 爲了確保符合8.4節之要求,醫電設備必須設計成具有雙重保護方式之結構:

  隔離與保護之方法分爲兩種:

- **MEANS OF PATIENT PROTECTION (MOPP)**
- **MEANS OF OPERATOR PROTECTION (MOOP)**

Class I之電殛保護模式

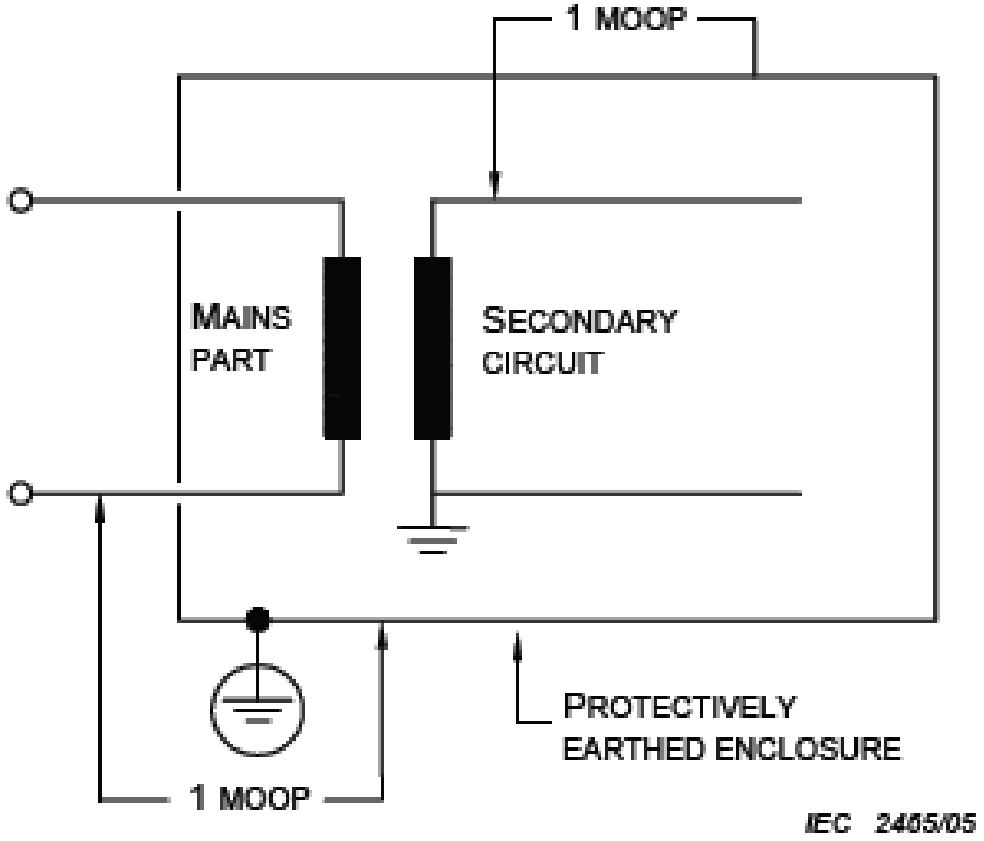


Figure J.1 – Insulation example 1

Class II之電殛保護模式

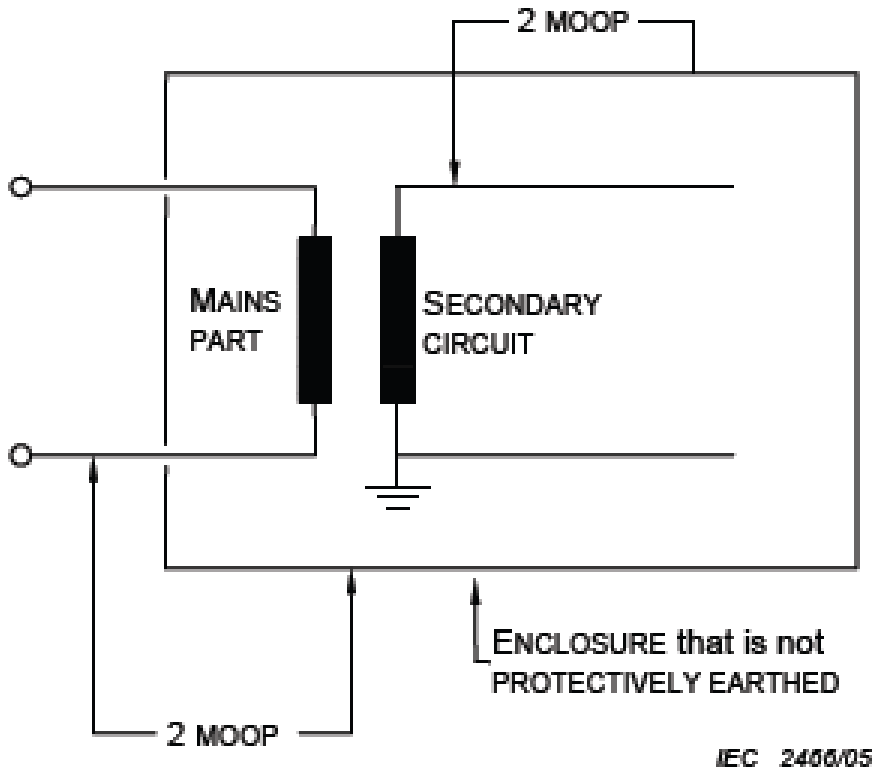


Figure J.2 – Insulation example 2

患者接觸部位與其他電路之隔離

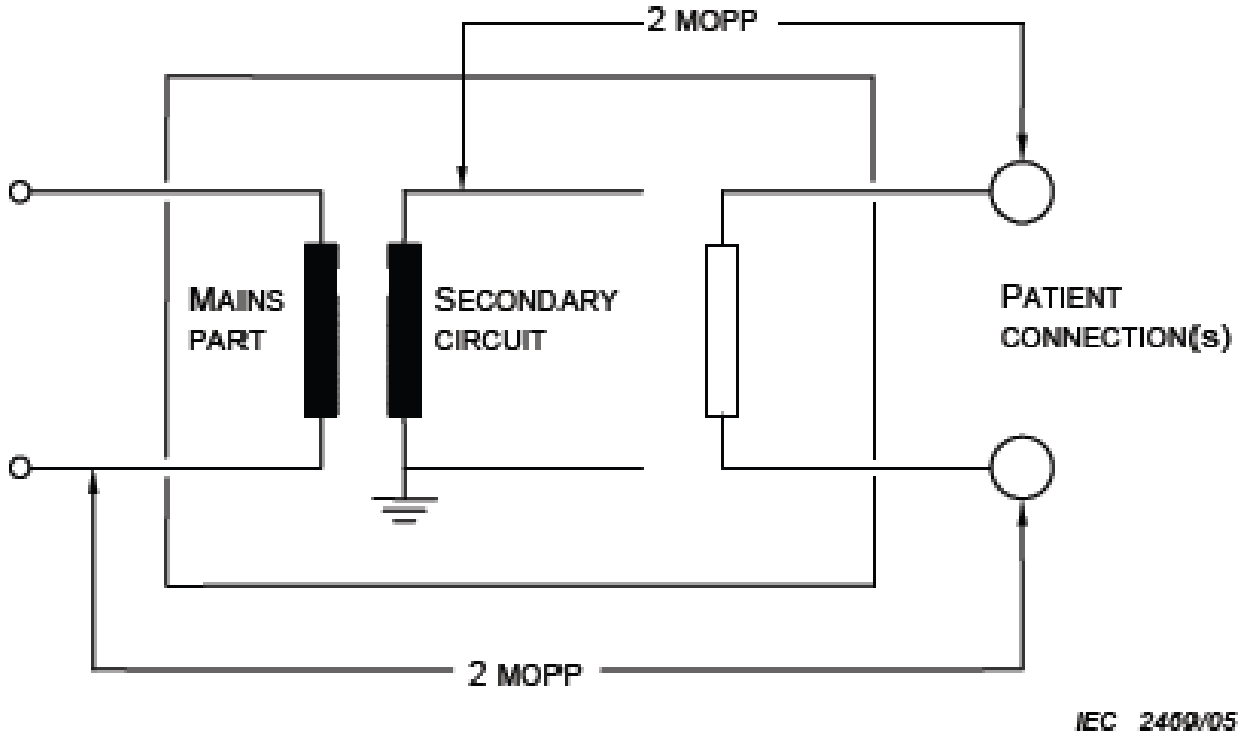
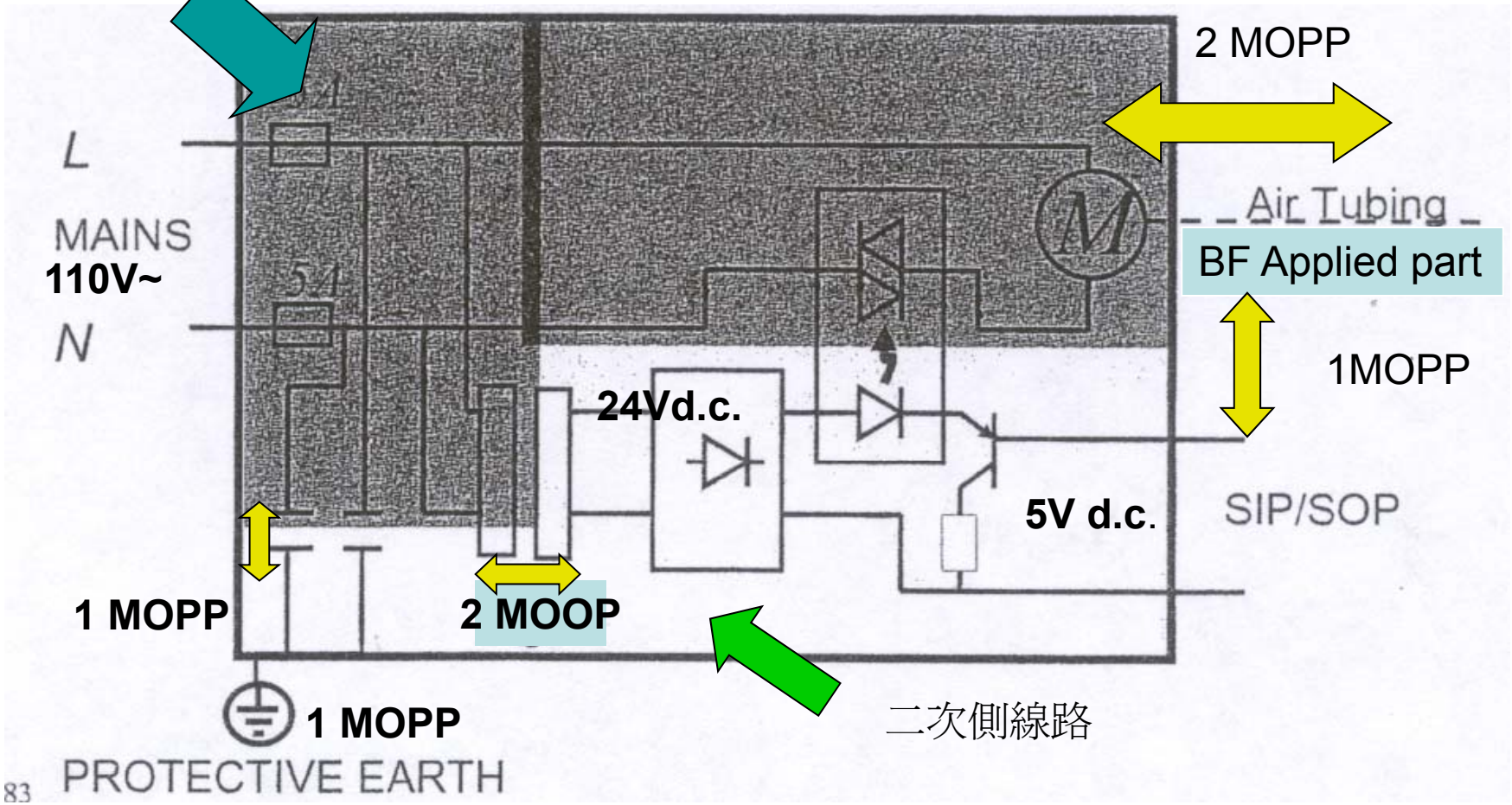


Figure J.5 – Insulation example 5

建立電殛保護之方法

保護方法(MOP)	評估方法
1.Solid insulation	耐電壓測試(CL.8.8)
2.具有足夠空氣距離(Air clearance)與爬行距離(Creepage)之空間	距離量測(Cl.8.9)
3.保護性接地	接地阻抗與電流承載測試 結構評估

Circuit Block, Isolation Components



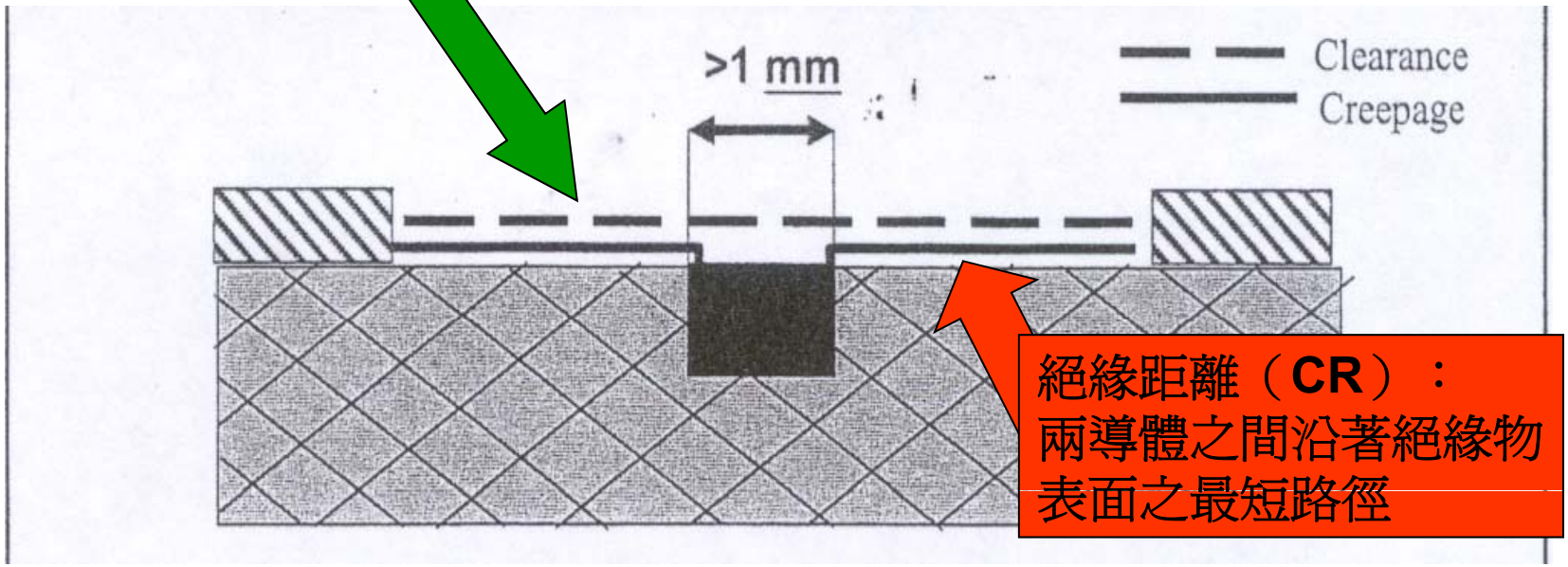
絕緣距離與空氣距離之量測

絕緣距離與空氣距離評估基本原則

保護部位	絕緣距離及空氣距離要求
提供患者保護(MOPP)	需符合IEC 60601 3rd 表12之要求.
提供操作人員保護(MOOP)	– 符合符合IEC 60601-1 3rd 表13至表16之要求; or – 符合IEC 60950-1 for INSULATION CO-ORDINATION.之要求

絕緣距離與空氣距離之定義

空氣距離(CL):
兩導體之間之最短路徑



絕緣距離（**CR**）：
兩導體之間沿著絕緣物表面之最短路徑

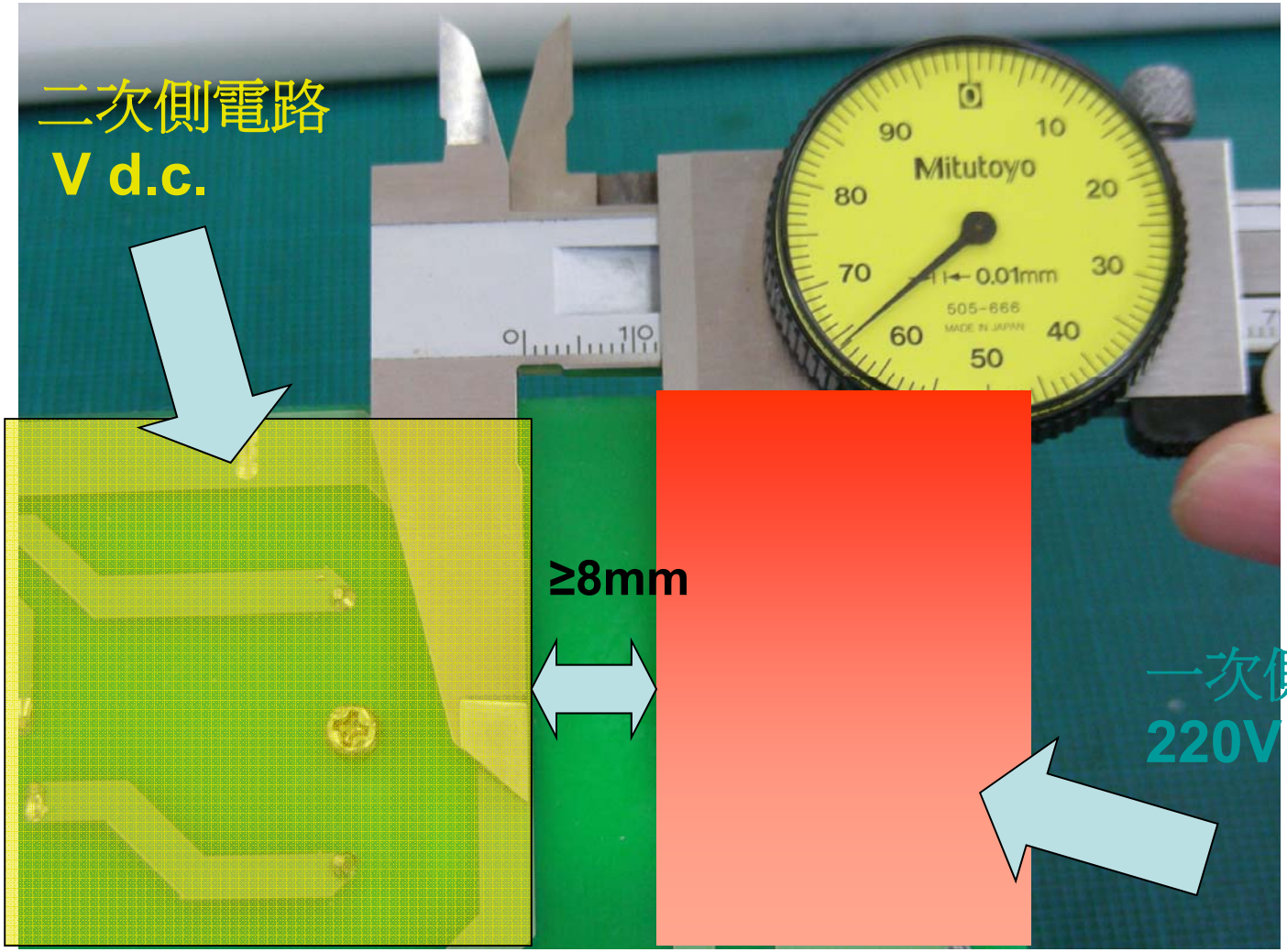
絕緣距離與空氣距離之作用：

確保帶電導體之距離以避免跳電電弧**(Arc)**情形發生

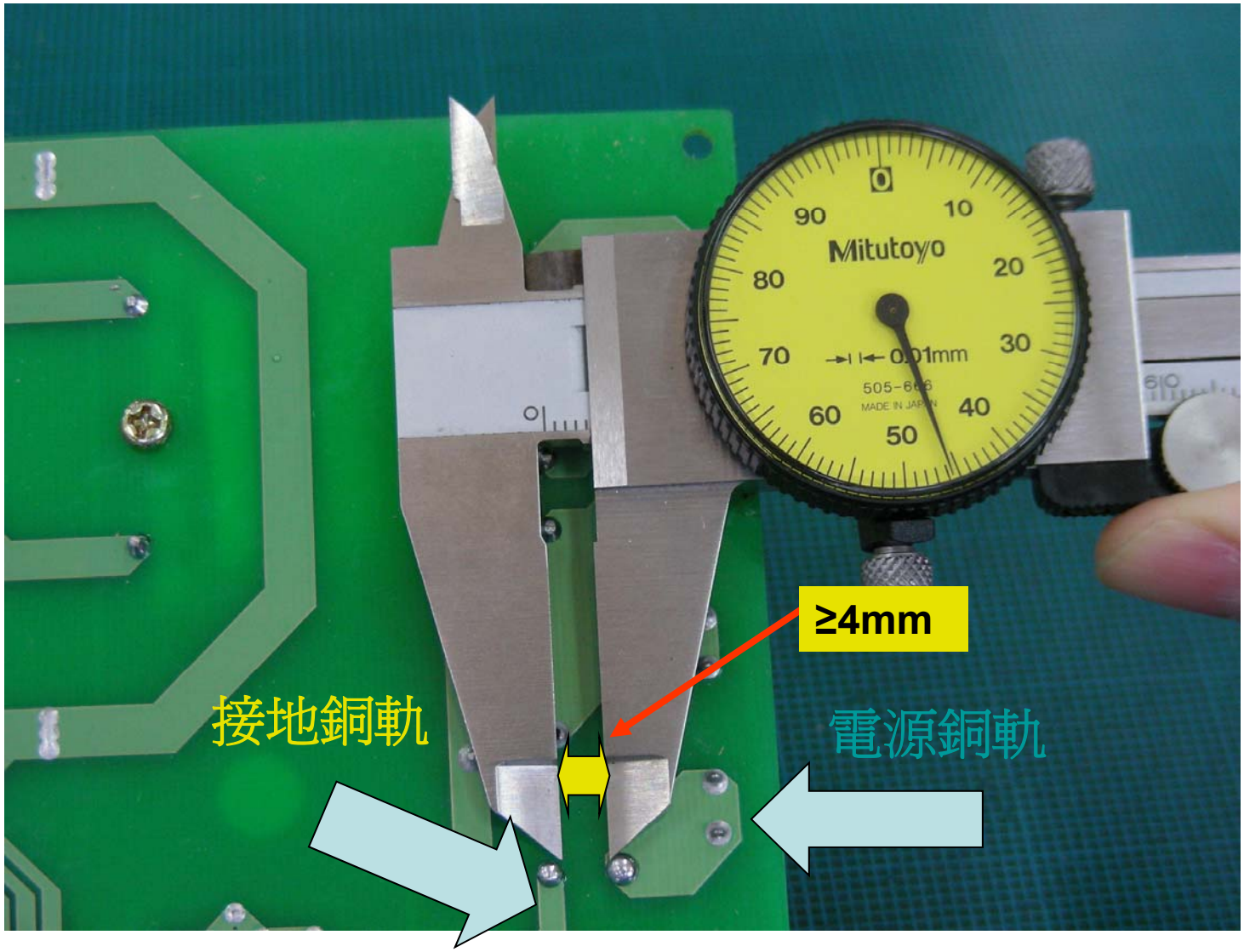
MOPP之估算範例

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s. up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing WORKING two MEANS OF PATIENT PROTECTION	
		CR mm	**AC** mm	**CR** mm	**AC** mm
177	125	3	1.6	6	3.2

電路板之絕緣距離量測範例(一)



電路板之絕緣距離量測範例(二)



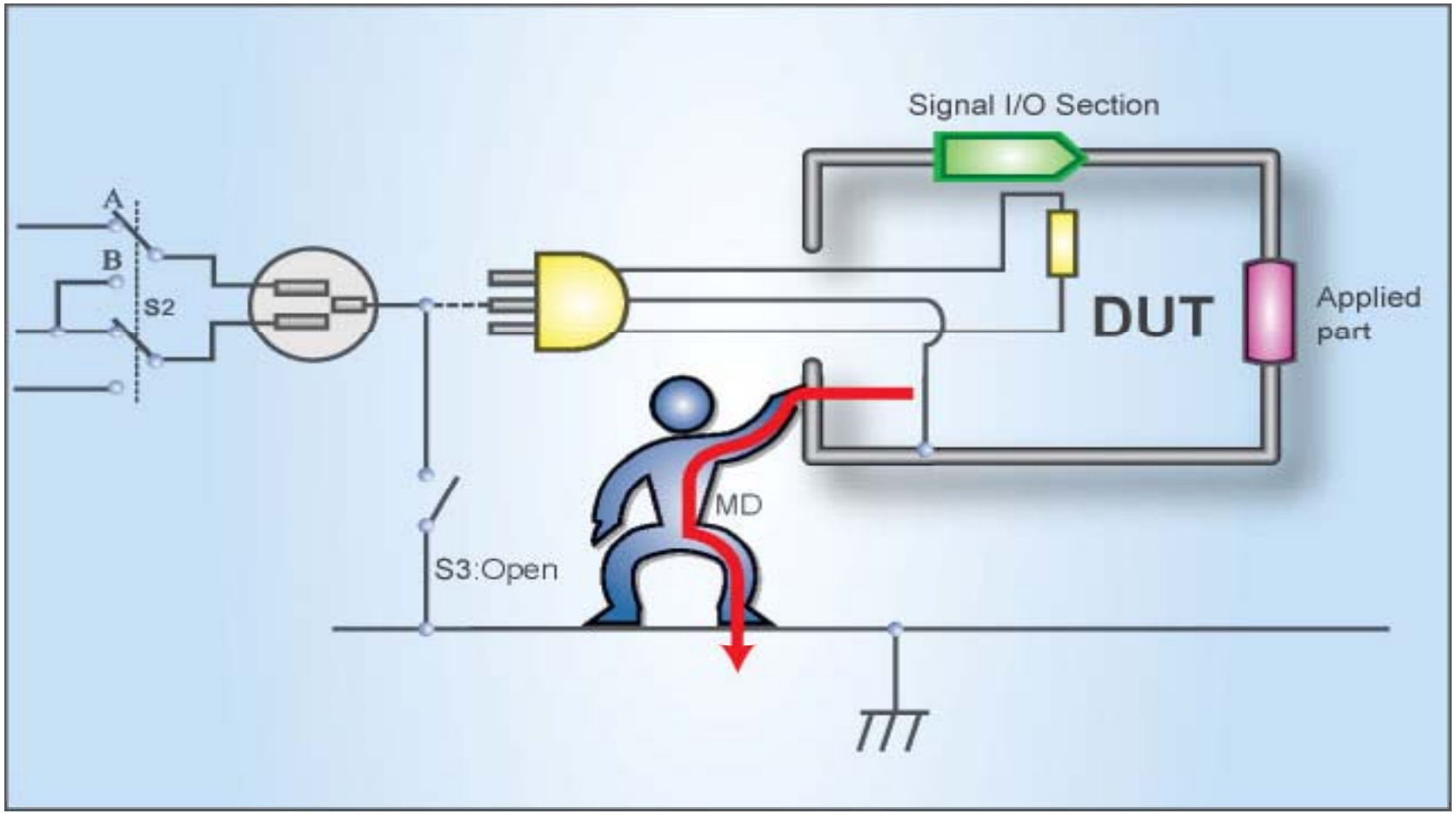
洩漏電流之量測與評估

Electrical Shock, Hazardous Current

	Harm	**Thresholds**
①	無感覺	below 0,5 mA
②	驚嚇 (鬆脫)	over 0,5 mA, 50/60 Hz
③	無法自行鬆脫	over 10 mA, 15-100 Hz
④	心室顫動	over 35 mA, 15-100 Hz
		0,01 mA, 50/60 Hz (Heart direct)

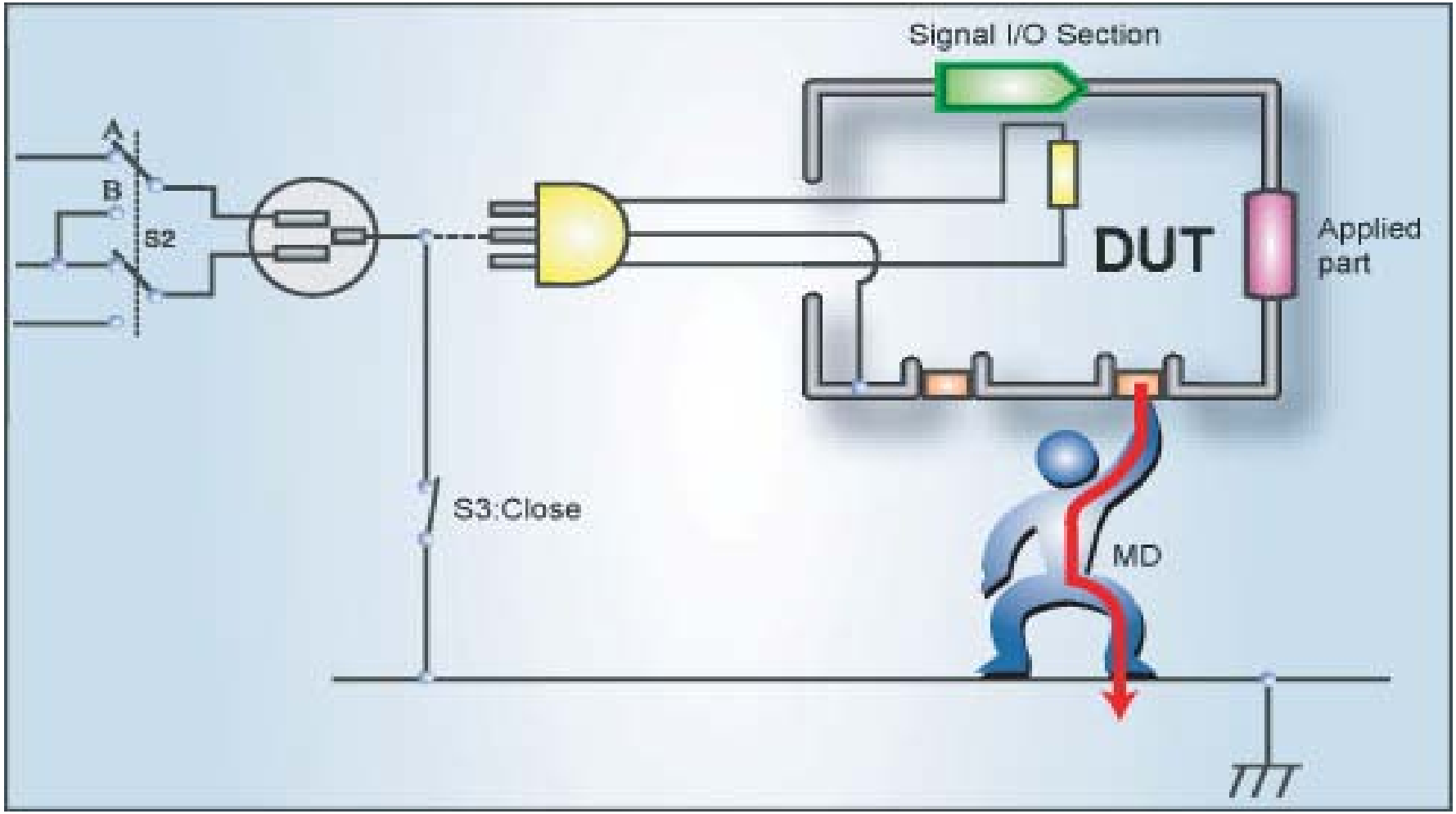
Remark: 上述數據爲正常人的統計數據
(參考 IEC 60479-1, -2, -3)

接地漏電流傳導路徑



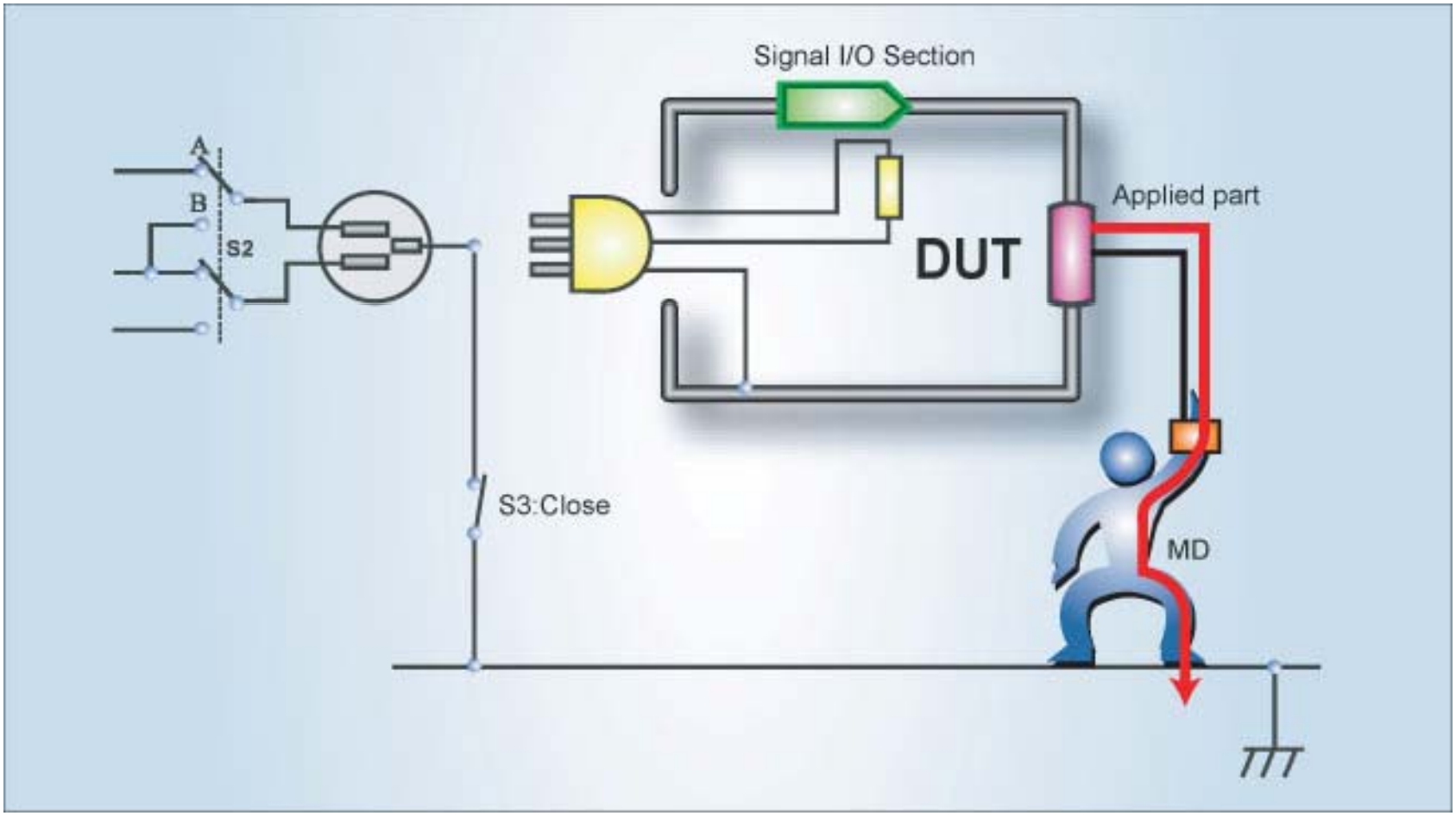
資料來源:華儀

接觸漏電流之傳導路徑



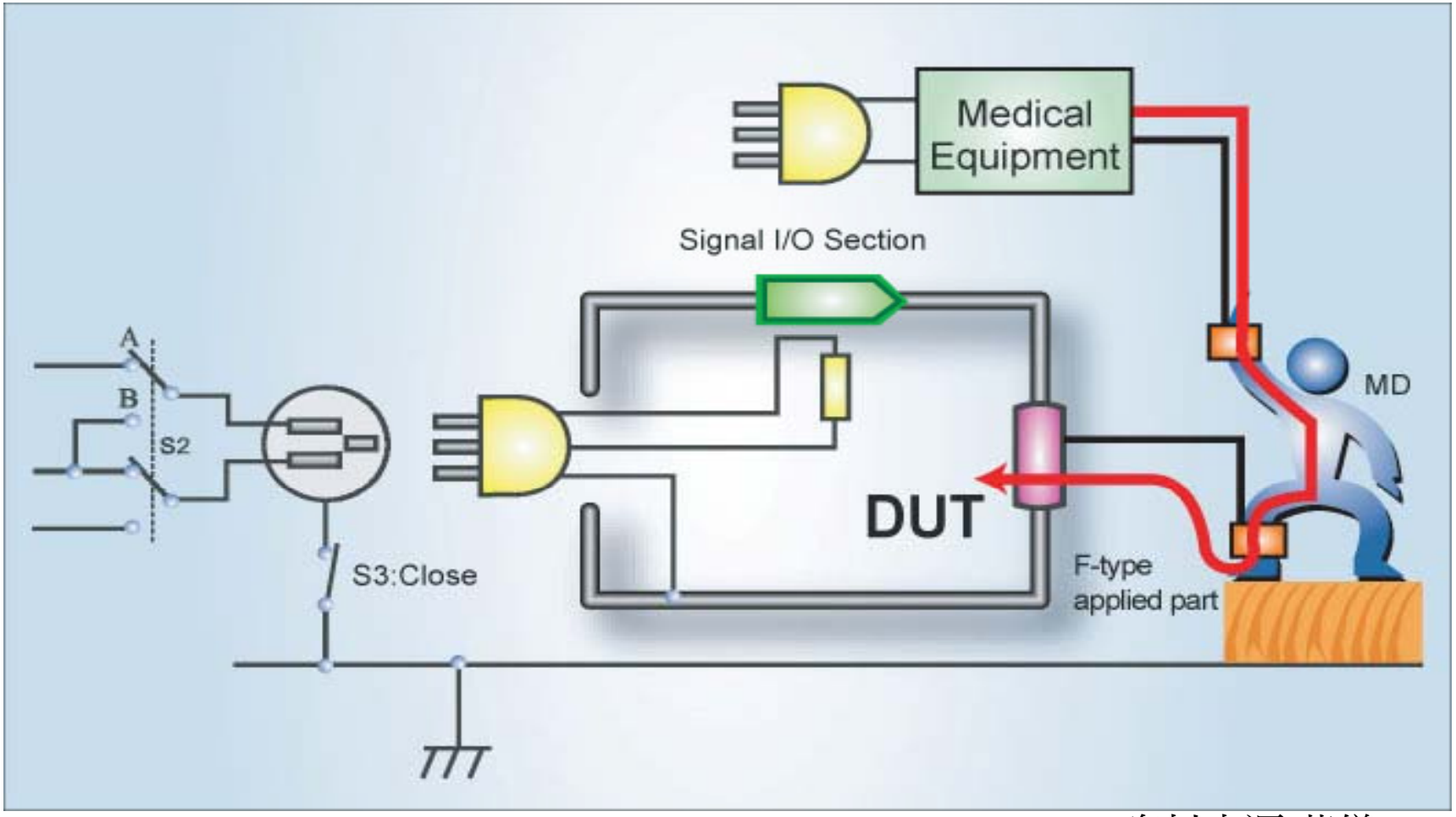
資料來源:華儀

患者洩漏電流傳導路徑



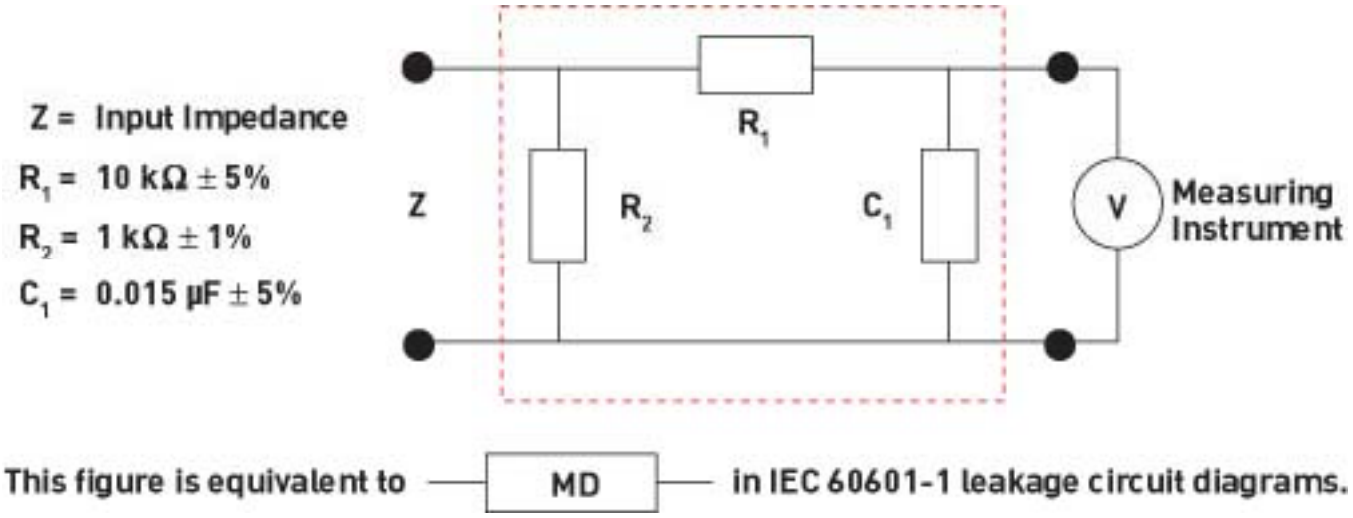
資料來源:華儀

具F型 applied part異常狀況傳導路徑



資料來源:華儀

測試洩漏電流之人體阻抗模型



Limited of ME with TYPE B and/or BF APPLIED PART(AC)

Touch current	100uA(NC),500uA(SFC)
Earth leakage current	5mA(NC) 0.5mA for 2nd 10mA(SFC) 1.0mA for 2nd
Patient Auxiliary current	100uA(NC),500uA(SFC)
Patient leakage current	100uA(NC),500uA(SFC)
Total Patient leakage current	500uA(NC),1000uA(SFC)

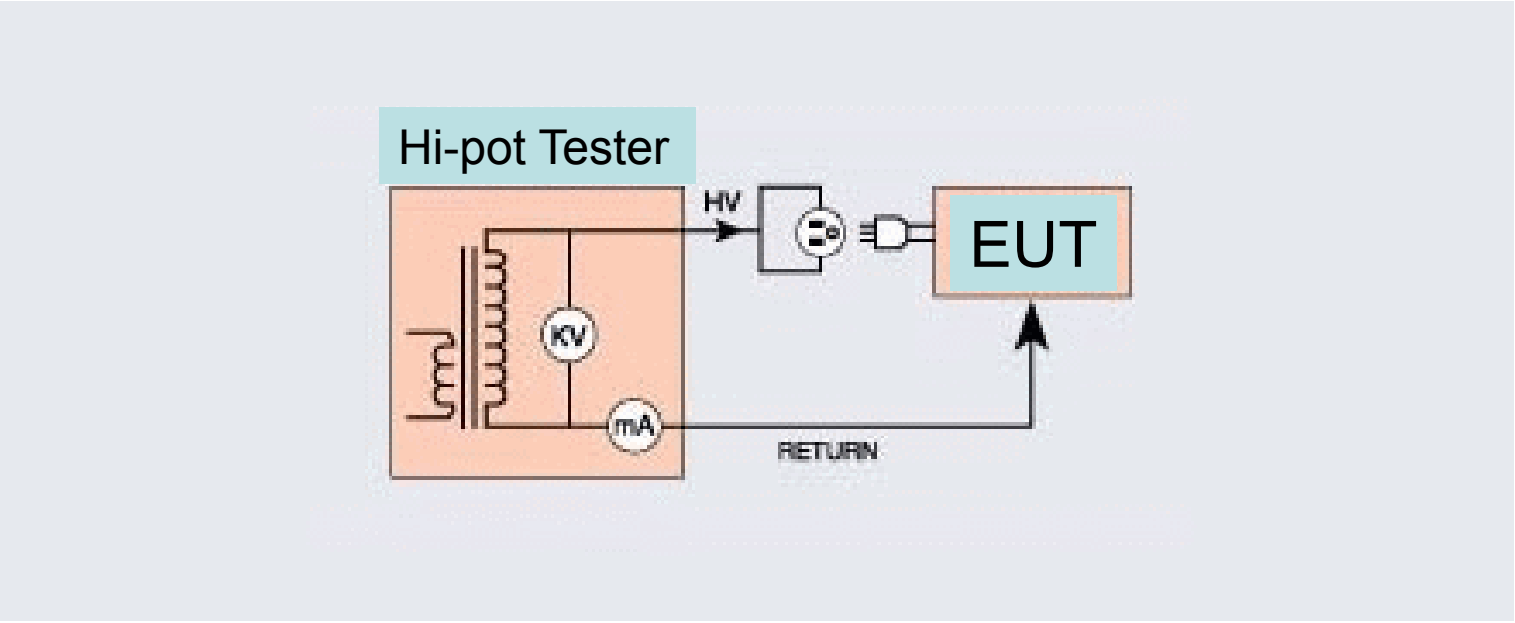
Limited of ME with TYPE CF APPLIED PART (AC)

Touch current	100uA(NC),500uA(SFC)
Earth leakage current	5mA(NC) 0.5mA for 2nd 10mA(SFC) 1.0mA for 2nd
Patient Auxiliary current	10uA(NC),50uA(SFC)
Patient leakage current	**10uA(NC),50uA(SFC)**
Total Patient leakage current	50uA(NC),100uA(SFC)

介電強度

- 介電強度測試之目的:確認設備絕緣之品質
- 測試時樣品需先經過濕度處理(93% RH)
- 測試用電源 50Hz/60Hz 交流電
- 測試電壓：見表6及表7

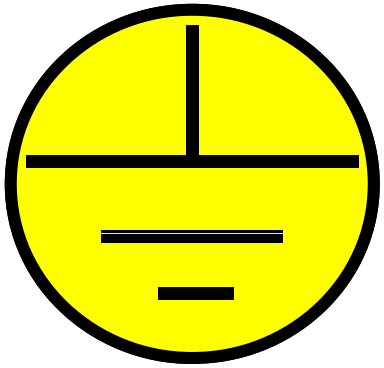
介電強度測試線路



介電強度測試值舉例

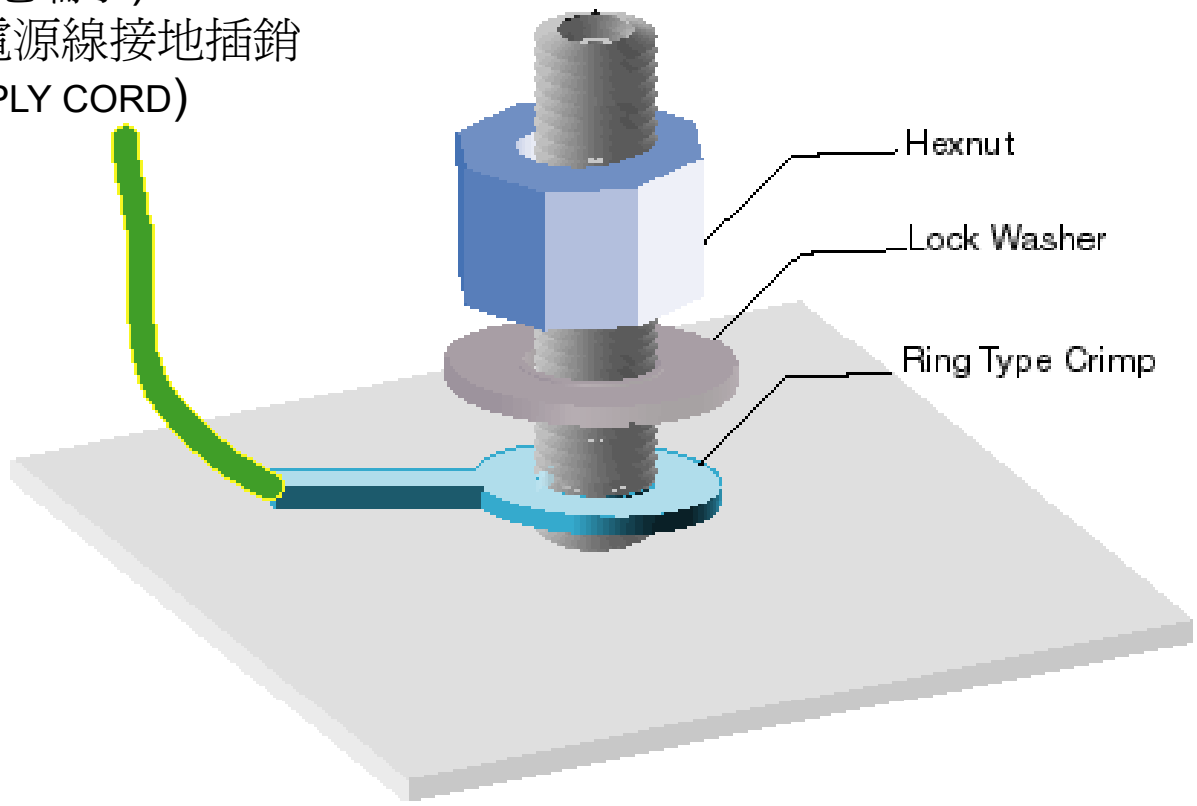
工作電壓（U）	1 MOPP	1 MOPP
115V	1500V	3000V
230V	1500V	4000V

接地端子之要求與測試

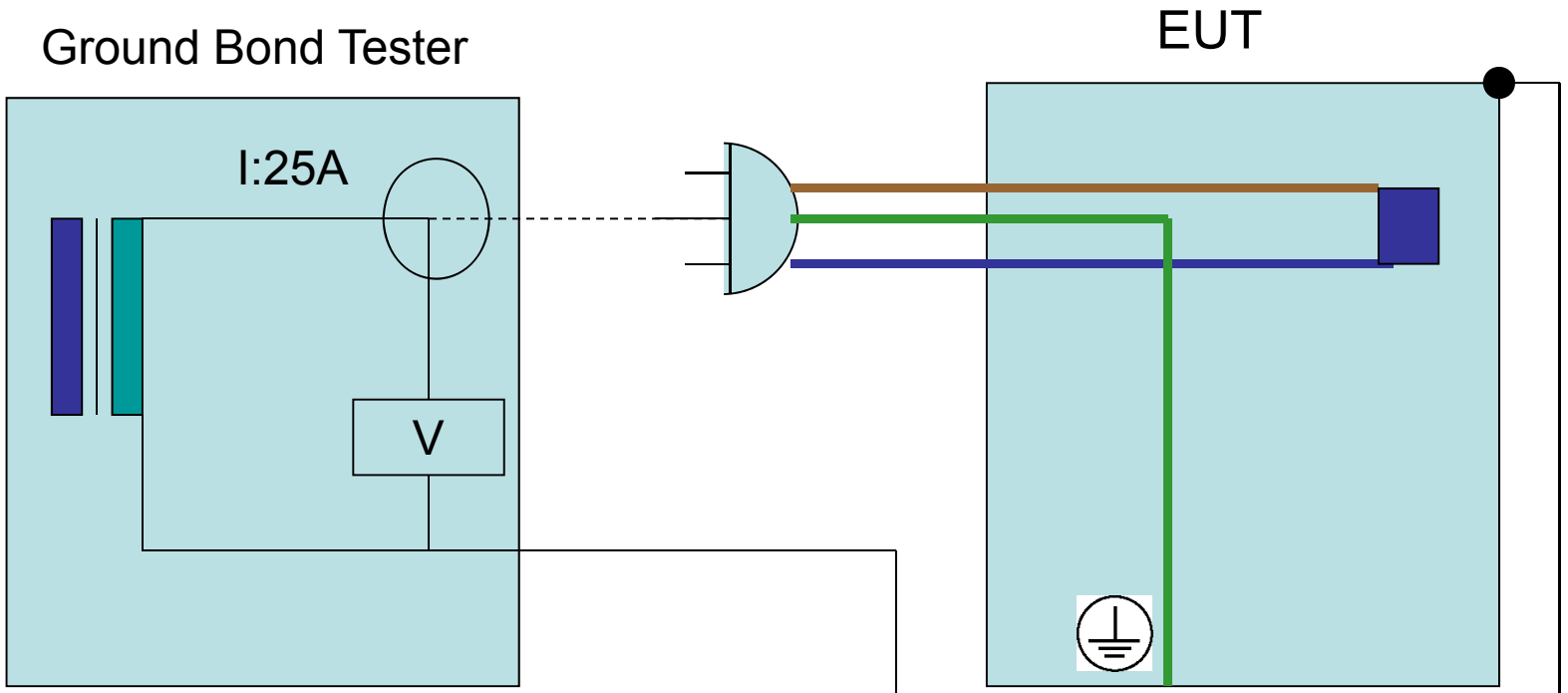


保護接地端子之要求

1.保護接地端子不得從設備外部鬆脫
2.必須使用工具才能接觸
3.不能作爲外殼之連接用途
4.接地阻抗值:100mΩ(至接地端子)
200m Ω(至電源線接地插銷
non-DETACHABLE POWER SUPPLY CORD)

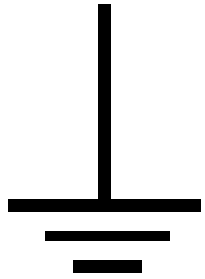


接地阻抗之量測方法



R=V/I

接地端子之標示

- 保護性接地 
- 功能性接地 

醫電設備結構要求

外殼機械強度之要求

測試項目	測試目的	測試值
Push Test	機械外殼剛性	**250N±10N 5s**
Impact Test	機械外殼抗衝擊能力	**500g鐵球, 1.3m高度**
Drop test	外殼抗摔強度	手持式:**1m高度落下** 可移動式： **m≤10kg➔ 5 cm** **10kg<m ≤50kg➔3cm** **50kg<m➔2cm**
Rough Handling Test	可移動設備之機械強度	**40mm上下階梯及跨障礙測試** 測試
Mould Stress test	可塑性材質 內應力	**70˚C (or 10˚C+Tnc), 7hr**

移動部位（ 陷阱區）

- Gaps 缺口大小符合ISO 13852之要求
  Body >500mm, Head>300mm or <120mm
  Hand >100mm, Finger >25mm or <8mm
- 具有足夠之安全距離可避免使用者及患者接觸
- 具有防護設施(Guard)➔其強度需通過15.3規定之測試
- 由使用者控制設備之移動＋急停裝置

移動部位（急停裝置）

- 必須在操作人員能接觸到之範圍
- 不能爲正常操作之部分
- 必須能切斷相關電路之所有負載
- 必須能用單一動作產生停止移動之結果
- 其制動器需用紅色標示
- 標示”STOP”或 

- 釋放之動作必須與原急停動作不同

邊,角,面之危險

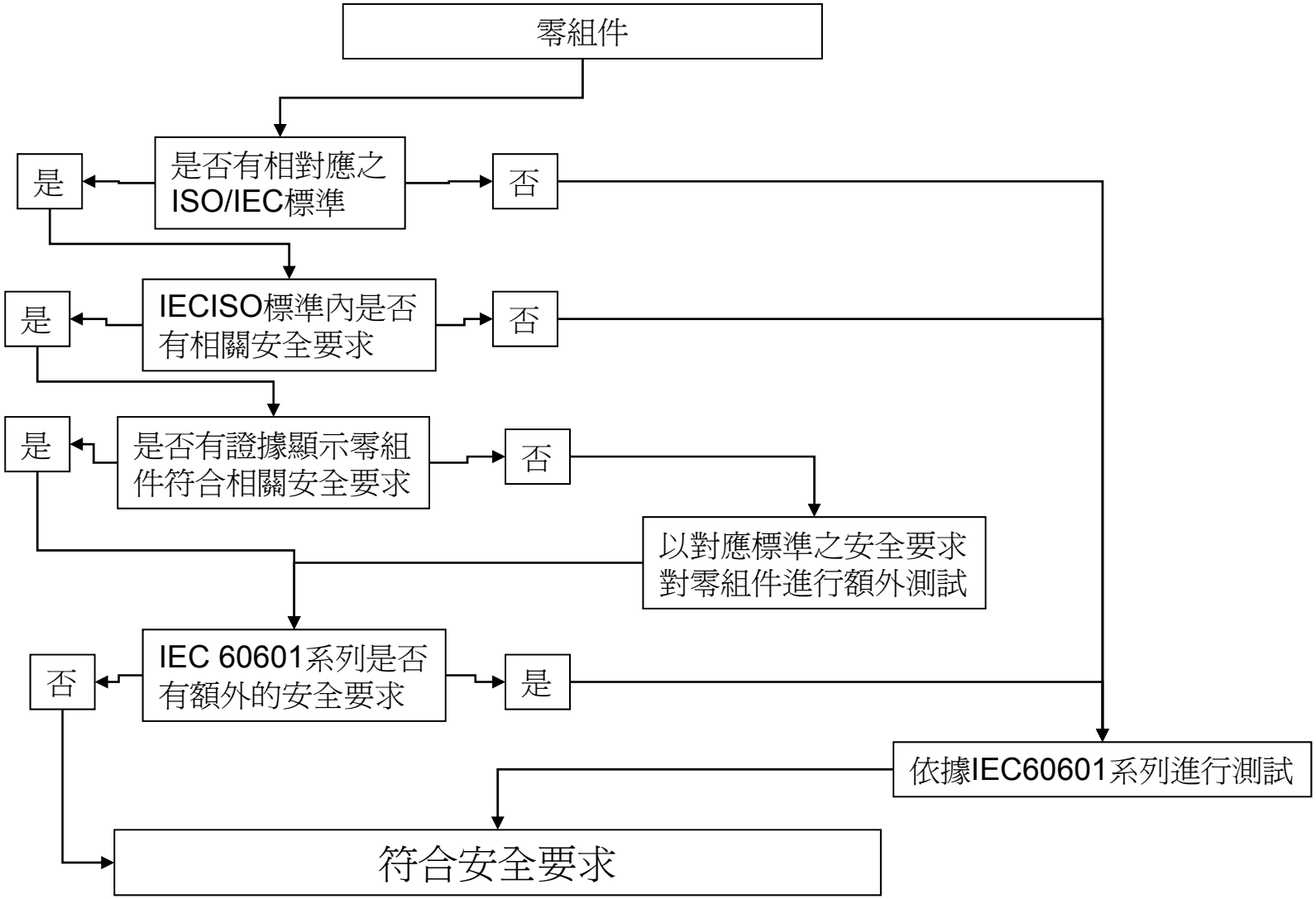
- 針對突出邊緣,框角,毛邊等進行測試
- 利用UL 1439規定之Sharp Edge Tester進行評估

穩定性

- 10°傾斜測試(搬運狀態)
- 5°傾斜測試(非搬運狀態)
- 220N推力測試
- 800N下壓力測試
- 20mm 門檻測試(重量超過45kg之可移動設備,速度 0.4m/s

主電源部件，零件與布局要求

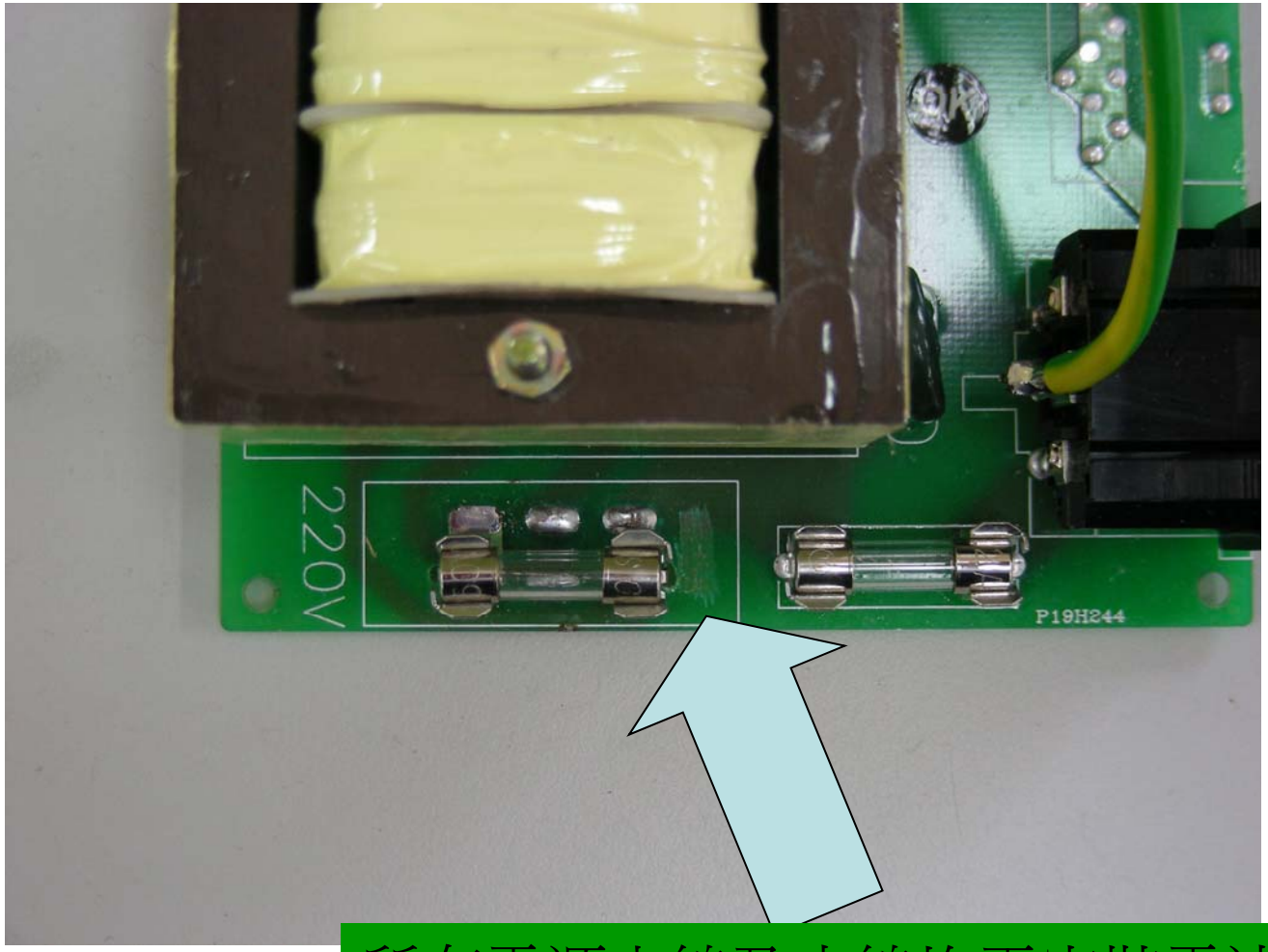
安全零組件之符合規則


零組件
是否有相對應之ISO/IEC標準
是
否
IECISO標準內是否有相關安全要求
是
否
是否有證據顯示零組件符合相關安全要求
是
否
以對應標準之安全要求對零組件進行額外測試
IEC 60601系列是否有額外的安全要求
否
是
依據IEC60601系列進行測試
符合安全要求

元件與電線之要求

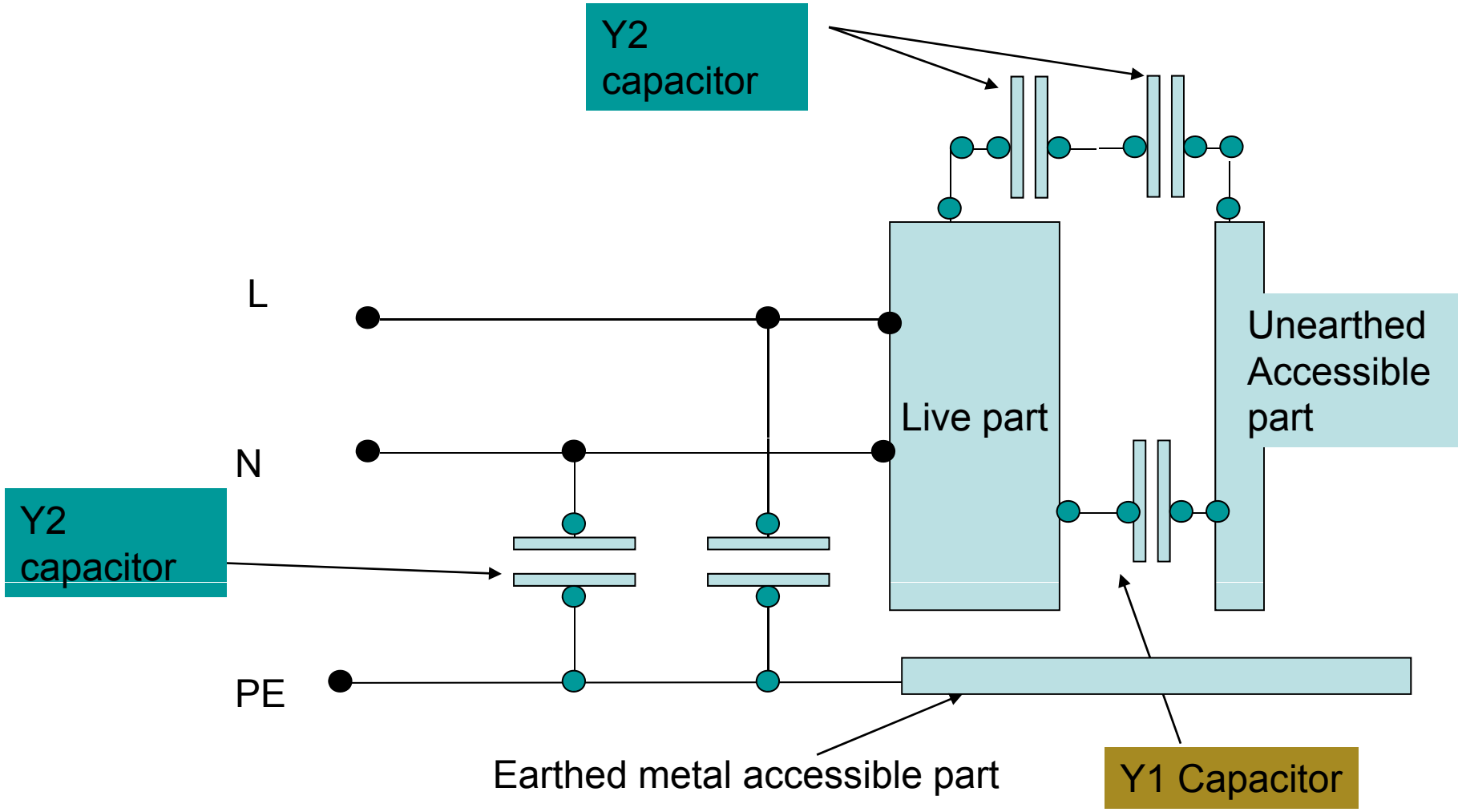
元件之固定	會影響安全之元件必須確實固定
電線之固定	利用鉗夾方式固定之絞線錶面不得上焊錫
設備不同部位之連接	中繼連接線於鬆脫時不得有違反8.4節之情形
手控及足控裝置	手動裝置操作電壓需小於42.4Vpeak或60V d.c，且須與市電間具雙重保護 兩端均須有固線裝置(以8.11.3電源線之要求測試)
電線之機械保護	內部配線不可接觸移動部位及銳邊銳角 組裝及開關access cover時不可有破壞內部配線之可能
絕緣電線之捲線盤	電線收整時纏繞之直徑須大於5倍電線外徑
內部配線之絕緣	絕緣護套必須確實固定 超過機械及熱應力條件之絕緣電現需視爲裸線 正常操作時溫度超過70℃之電線需爲耐熱絕緣披覆

I類電氣之保險絲要求



所有電源火線及水線均需安裝電流保險絲

跨接於MOP之電容器要求



電池之要求

- 防止電池短路之空間
- 充電電池➔防止過度充電,並考量通風避免起火
- 充電狀態必須有指示燈指示充電狀態
- 鋰電池必須符合IEC 60086-4 ：Safety of lithium batteries之要求

足動或手持式控制裝置

Type	requirement
Hand-held control device	1m掉落測試
Foot-operated control device	IPX1防水測試IPX6(急診室/開刀房用) 1350N 重力測試

電源變壓器之要求

Overheating:

- short circuit test (directly after output)

- output overload test

Dielectric strength:

5×rated voltage, 5×rated frequency (Rated voltage≤500V or Rated frequency≤60Hz)

2×rated voltage, 2×rated frequency (Rated voltage>500 or Rated frequency>60Hz)

變壓器overheating條件下之最高允許溫度

繞組絕緣物之等級	允許最高溫度
Class A	150
Class B	175
Class E	165
Class F	190
Class H	210

對溫度及火等危害之保護

溫昇測試之條件

- 在正常使用之 worst-case條件下進行操作包含在允許可操作之最高室溫下進行測試
- 待測物放置於黑色木製（2公分厚之夾板）測試角隅中,
- 整體測試需達到Thermal stability狀態

溫昇測試輸入電壓條件

醫電設備之型態	輸入電壓條件
具加熱元件	額定電壓之110%
具馬達	額定電壓之90%至110%之間最不利者
同時具加熱元件及馬達	額定電壓之90%與110%

正常使用下之溫度限制

- 醫電設備之各部位溫度限制值依據表 22 及表23之規定
- Test Corner之表面溫度不得超過90 ˚C;
- 正常條件下溫度斷路器不得動作

Table 22 – Allowable maximum temperatures of parts

Parts	Maximum Temperature °C
Insulation, including winding insulation [a]	
- of Class A Material	105
- of Class E Material	120
- of Class B Material	130
- of Class F Material	155
- of Class H Material	180
Parts with T marking	T [b]
Other components and materials	[c]
Parts in contact with flammable liquid with flash-point of T °C	T-25
Wood	90

[a] The classification of insulating materials is in accordance with IEC 60085. Any incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered.

[b] T marking refers to the marked maximum operating temperature.

[c] For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.8.4.1 should be performed.

From IEC 60601-1 3rd

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	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

[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.

From IEC 60601-1 3rd

APPLIED PARTS之溫度要求

Applied part	要求
預期對患者提供熱能之**applied part**	使用說明書中須註明溫度及臨床效應
不預期對患者提供熱能之**APPLIED PARTS**	須符合表Table 24 之要求(最高溫度須註明於說明書) 或不超過 41 ˚C,

Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS

APPLIED PARTS of ME EQUIPMENT		Maximum temperature [a] [b] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
APPLIED PART having contact with the PATIENT for a time "*t*"	*t* < 1 min	51	56	60
	1 min ≤ *t* < 10 min	48	48	48
	10 min ≤ *t*	43	43	43

[a] These temperature limit values are applicable for 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. They are not applicable 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.

[b] Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.

From IEC 60601-1 3rd

量測溫度之方法

1.Resistance method (for windings):

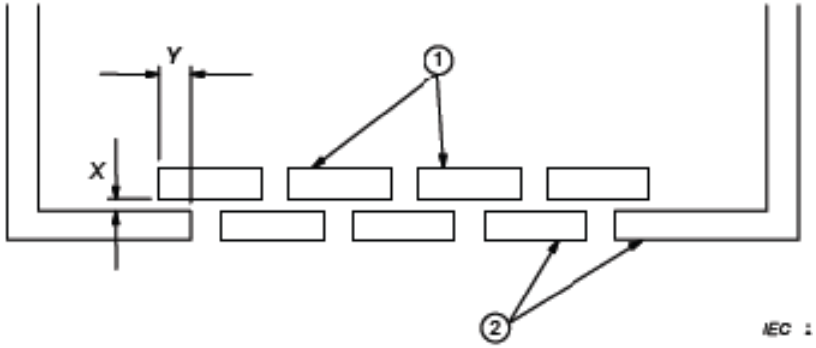
$$\Delta T = \frac{R_2 - R_1}{R_1}(234{,}5 + T_1) - (T_2 - T_1)$$

2.Thermocouple methods :

Table 22 are to be reduced by 10 ˚C.to determine the temperature of windings,

防火外殼之結構要求

- 防火外殼內之絕緣披覆電線需達FV-1 (94V-1)
- 連接器，印刷電路板及安裝零件之材料需達FV-2(94V-2)
- 底部不可開口，如有開口須符合圖38及圖39之要求，如爲金屬底部，開孔不可超過表25之規定，如爲金屬網則金屬線徑至少需0.45mm，中心點形成面積不得大於4mm^2。



Y = twice X but never less than 25 mm

(1) Baffle plates (may be below the bottom of the ENCLOSURE)

(2) Bottom of the ENCLOSURE

Fig 38 construction of baffle

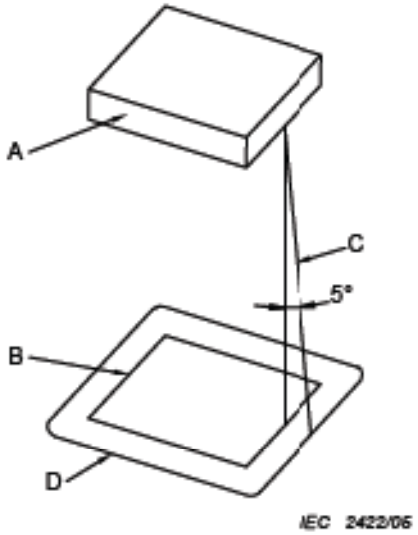
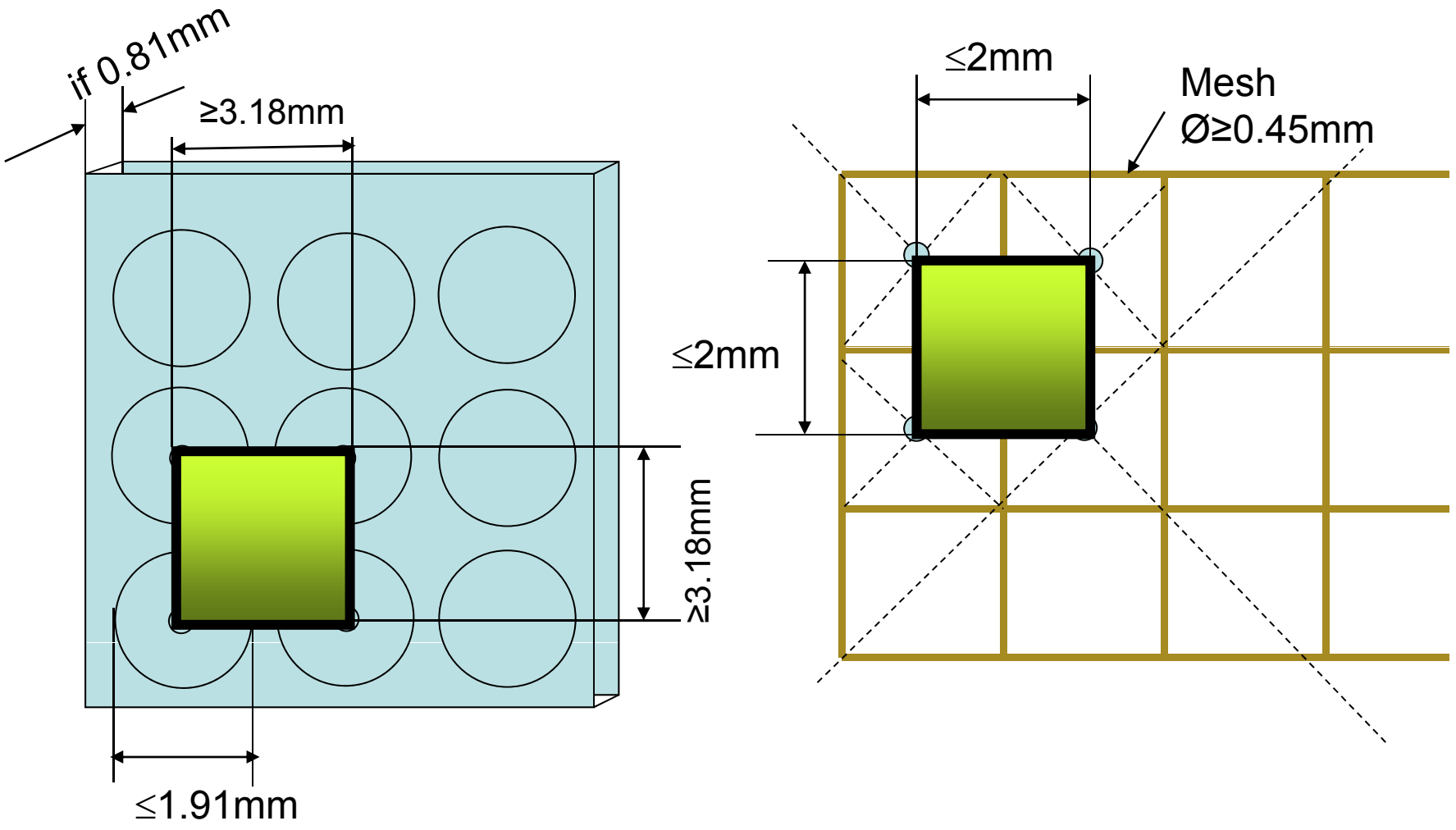


Fig 39-Area of the bottom of an fire enclosure with baffle

金屬底部開口與網底結構要求



防火外殼之耐燃要求

- 可移動設備-最少爲 FV-2等級材質
- 固定或大型設備-最少爲FV-1等級材質

耐然等級區分

UL	IEC
94-5VA or B	5V
94V-0	VF-0
94V-1, 94HF-1	VF-1
94V-2,94HF-2	VF-2
94HB,94HBF	HB,HBF

IEC60601-1 3rd標示與說明

應標示在設備外部之標示

7.2.2	**name or trademark of the manufacturer** **model or type reference**
7.2.3	 **or**  **(better)**
7.2.4	**name or trademark of the manufacturer** **model or type reference of accessories**
7.2.5	**ME intended to receive power from other equipment (model or type reference)**
7.2.6	**connection to the supply mains:** **•rated supply voltage(s) or rated voltage range(s)** **• nature of supply** **•the RATED supply frequency or RATED frequency range (Hz)** **•symbol of class II**

電業供電電壓週率標準

- 第四條 交流電之週率，定爲60Hz，其相數定爲單相及三相兩種。
- 第五條 交流電之電壓，應以各輸電線或配電之標稱電壓爲標準，其各級伏數規定 如左：

  1.110V 單相二線

  2.110V 及220V 單相三線

  3.220V單相二線及三相三線

  4.220V及380V 三相四線

  5.380V 三相三線…….

練習 下列哪些電源供應標示符合台灣地區之規定

- 100V~,50Hz
- 110V~,60Hz
- 100-120V~,50/60Hz
- 110/220V~,60Hz
- 220V~,50Hz
- 110-240V~,47-63Hz
- 380V~,60Hz

應標示在設備外部之項目

7.2.7	**electrical input power from the supply mains** **A or VA or W (if power factor >0.9)**
7.2.8	**output connectors**
7.2.9	**IP classification (IPX0 or IP0X avoid)**
7.2.10	**Applied part**
7.2.11	**mode of operation(no marking for continuous operation.)** **On time/off time for non-continuous operation**

應標示在設備外部之項目

7.2.12	**the type and full rating of the fuse (voltage,current, operating speed and breaking capacity)**
7.2.13	**safety sign for physiological effects**
7.2.14	**high voltage terminal devices** 
7.2.15	**cooling conditions**
7.2.16	**mechanical stability** 

應標示在設備外部之項目

7.2.17	protective packaging（special handling measures, environmental conditions for transport and storage ）
7.2.18	external pressure source rated maximum supply pressure adjacent to each input connector.
7.2.19	functional earth terminals 
7.2.20	removable protective means

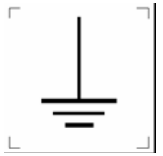
於設備本體內應標示之項目

7.3.1	**heating elements or lampholders** __w max. on lampholder, type of lamp on AD
7.3.2	**high voltage parts**  **or** 
7.3.3	**batteries :** type of battery and the mode of insertion
7.3.4	**fuses, thermal cut-outs and over-current releases (voltage, current, operating speed and breaking capacity) ex. T1.6AL250V**
7.3.5	**protective earth terminals** 

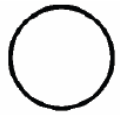
IEC 127之保險絲規格

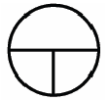
- FF: Very quick acting
- F: Quick acting
- M: Medium time –lag
- T: Time lag
- TT: Long time-lag
- L: Low breaking capacity :35A or 10In
- H: High breaking capacity :1500A

於設備本體內應標示之項目

7.3.6	**functional earth terminals** 
7.3.7	**supply terminals** **“N” for neutral conductor exculsive.**
7.3.8	**temperature of supply terminals** “For supply connections, use wiring materials suitable for at least X ˚C.” if T of temp>75 ˚C in normal use

開關之標示

- “on” (power) “off” (power) 

- push button with bistable positions 
- push button with momentary 
- “on” for part of equipment 
- “off” for part of equipment 
- Emergency Stop 

標示擦拭試驗要求

分別以下列液體

- 蒸餾水
- 變性酒精 (methylated spirit)
- 異丙醇 (isopropyl alcohol)

沾在棉布上對標籤擦拭15秒後, 在1m之距離(30度視角)觀察標示是否清楚易見

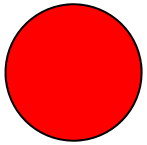
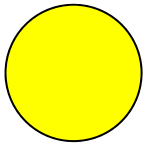
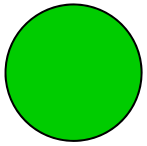
符號類型

警告標示

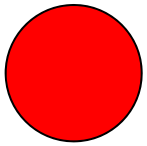
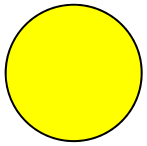
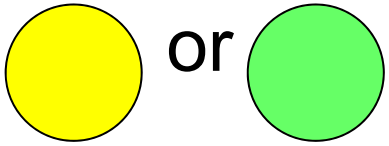
禁制標示

強制標示

醫電設備指示燈之規定顏色代表意義

顏色	代表意義
	警告-操作人員必須立即反應（HIGH PRIORITY）
	警告-操作人員必須做適當之反應（ MEDIUM PRIORITY ）
	可使用
其他顏色	非上述三種燈色代表之意義

IEC60601-1-8對警報指示燈之規定

警報類別	指示燈顏色	閃爍頻率	週期
High priority		1.4Hz 至 2.8Hz	20% to 60% on
Medium Priority		0.4Hz至 0.8Hz	20% to 60% on
Low Priority		固定不變	100% on

ACCOMPANYING DOCUMENTS

- 基本資料應包含：

製造廠名稱或商標

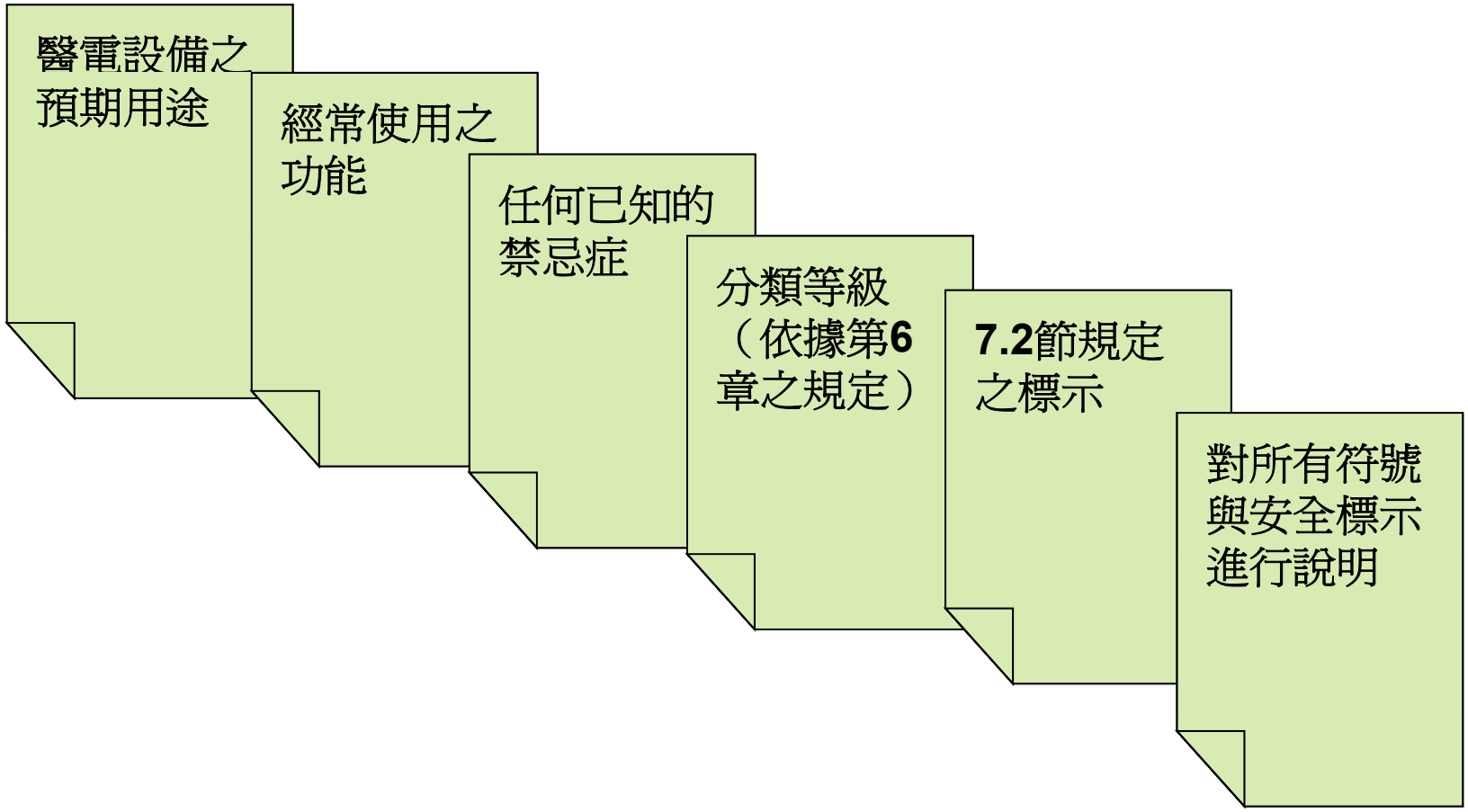
型式/型號

任何操作者或使用單位應具備之特定技能,訓練及知識

任何有關設備於使用時之環境或地點限制

ACCOMPANYING DOCUMENTS
使用手冊

- 基本內容應包含:



ACCOMPANYING DOCUMENTS

使用手冊

警語及安全性公告

Class I 醫電設備:

WARNING:

To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth

ACCOMPANYING DOCUMENTS
使用手冊

- 警語與安全性公告

-有關在特定診察或處置時因醫電設備之存在可能之交叉干擾而產生之風險

-醫電設備與其他器材在一起時可能造成之電磁場或其他干擾,使用時應盡量避免已將干擾降至最低

ACCOMPANYING DOCUMENTS
使用手冊

- 需與特定獨立電源連接之醫電設備:

-power supply shall be specified as part of the me equipment or

-the combination shall be specified as an me system

ACCOMPANYING DOCUMENTS
使用手冊

- **Electrical power source**

  -對額外電源進行定期檢查或更換

  -當電池漏液可能會造成危險時,應說明當設備依段時間不使用實應將電池取下

  -如電池是可更換的,則應說名電池之規格

  -如果失去電源會造成危險,則應警告設備應連接到適當之電源(如**UPS)**

ACCOMPANYING DOCUMENTS
使用手冊

- 有關醫電設備之描述

-醫電設備簡介

–作用原理

–物理及性能特徵.

-對操作者,患者或其他在正常使用中會接近設備之人員預期之姿勢/位置

-患者或操作人員會接觸到之材質或成分（假如有潛在風險）

-與其他儀器/網路/資料耦合器之連結限制

-所有Applied Part

ACCOMPANYING DOCUMENTS

使用手冊

- 需要安裝之醫電設備

-說明何處可取得安裝指導書

-製造廠指定之合格安裝人員之聯絡方法

ACCOMPANYING DOCUMENTS
使用手冊

- 與電源之隔離方式

-利用插接器或插頭者：

設備放置地點不要在難以將插接器或插頭拔開之處

ACCOMPANYING DOCUMENTS
使用手冊

- 啓動程序：

-起始控制設定

-與患者之連接方式

-患者的姿勢或位置

ACCOMPANYING DOCUMENTS

- 操作說明
- 各項控制之功能說明
- 顯示及訊號
- 操作次序
- 可拆部位及附件之連接與斷接方法
- 因使用中消耗而需更換之材料
- 任何圖形,符號,警語,聲明,縮寫即指示燈之意義

ACCOMPANYING DOCUMENTS
使用手冊

- **Messages**
- 所有系統資訊,錯誤資訊及失效資訊
- 必須包含對上述資訊之解釋,含重要肇因,操作者去解決資訊指示之狀態之可能的動作

ACCOMPANYING DOCUMENTS
使用手冊

- **關機程序**
- 如何安全地終止醫電設備之操作

ACCOMPANYING DOCUMENTS
使用手冊

- 清潔,消毒與滅菌方式

– 有關清潔及消毒之細節,
或滅菌之方法

-含滅菌參數（ 溫度,壓
力,濕度,時間限制及滅
菌次數）

ACCOMPANYING DOCUMENTS
使用手冊

- 保養

-使用者執行預防檢查,保養及校正之細節,包含保養之週期.

-說明定期保養對持續確保醫電設備安全之必要性.

-鑑別必須由服務人員進行預防檢查或保養之部件,包含實施週期

-具不需服務人員進行保養之可充電電池之醫電設備,需提供適當之保養方法

ACCOMPANYING DOCUMENTS

使用手冊

- 附件,補充設備,使用材料(耗材)

-應檢附附件,可拆式部件及耗材之清單

練習5

- 舉例一下一台震波碎石機可能包含哪些附件/耗材?

1.耗材:coil,水囊,spark gap, Jelly,熱感紙,

2.附件:printer, connecting wire, power cord set., CRT monitor, key board, mouse, PC, tool box, calibrator,

3.選配:X 光機(含foot switch),超音波(foot switch) ,ECG monitor,

ACCOMPANYING DOCUMENTS
使用手冊

- **環境保護**

-鑑別廢棄物,殘留物拋棄時之任何風險

-鑑別產品及其附件於生命週期終了後丟棄時任何可能之風險

-提供將該風險降至最低之建議.

ACCOMPANYING DOCUMENTS
Technical description

一般要求：

- 7.2節要求事項
- 允許之使用環境條件,包含運送及儲存
- 所有醫電設備之特性,包含範圍,準確度,顯示值之精度
- 任何安裝之特別要求,如供應電源之最大允許內阻

ACCOMPANYING DOCUMENTS
Technical description

-用於冷卻之液體if liquid is used for cooling, the permissible range of values of inlet pressure and flow, and冷卻義肢化學成分;

- – 醫電設備與供電電源隔離之方法,（該隔離之方法不在醫電設備之內);
- – 部分密封之充油醫電設備或部件,應說明查核油位之方法

ACCOMPANYING DOCUMENTS
Technical description

- 對未經授權而修改而造成危險之警語:

"WARNING: No modification of this equipment is allowed."

"WARNING: Do not modify this equipment without authorization of the manufacturer."

"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."

ACCOMPANYING DOCUMENTS
Technical description

- 若技術文件與使用說明爲不同一份文件,則必須包含：

- 7.2節規定之資訊
- 所有第6章規定之適用分類
- 所有警語與安全公告
- 安全符號之解釋
- 醫電設備簡述
- 醫電設備之功能
- 醫電設備之物理及性能特性

ACCOMPANYING DOCUMENTS
Technical description

- **電流熔線,電源線及其他部件之更換：**

-針對永久連接醫電設備,在設備外用於供應電源之電流熔線之型號與完整的額定值

–具有非可分離式電源線之醫電設備,需說明電源線是否需由服務人員更換,並提供 正確連接暨固定之方式

– 針對製造廠指定由服務人員進行更換之部件,需提供正確的更換說明

–當更換某部件會造成不可接受之風險時,需提供鑑別該項危險之警語,當製造廠指定該零件由服務人員更換時,需提供所有有關安全的更換該零件有關之資訊

ACCOMPANYING DOCUMENTS
Technical description

-電路圖,零部件清單,

-與電源隔離之方法

means used to comply with the requirements of 8.11.1.

可程式醫電系統(PMES)要求

14.3 RISK MANAGEMENT plan

14.4 PEMS DEVELOPMENT LIFE-CYCLE

14.5 Problem resolution

14.6 RISK MANAGEMENT PROCESS

14.7 Requirement specification

14.8 * Architecture

14.9 Design and implementation

14.10 VERIFICATION

14.11 PEMS VALIDATION

14.12 Modification

14.13 Connection of PEMS by NETWORK/DATA COUPLING to other equipment

問題與討論

Thank you for your patience

Contact me:
e-mail: malta@etc.org.tw
Tel:03-3276195