IEC 60950-1 Ed:2.2
EN 60950-1:2006/A2:2013
標準介紹

- 主講人：Miller Chang
- 2014-01-16

- Previous Standard:
  - IEC 60950-1:2005+A1: 2009
  - EN 60950-1:2006+A11: 2009+A1: 2010+A12: 2011

- Newest Standard:
  - IEC 60950-1:2005+A1: 2009+A2: 2013
  - EN 60950-1:2006+A11: 2009+A1: 2010+A12: 2011 +A2: 2013
  - Date of Withdrawal (DOW) (Previous Standard) : 2016.07.02

1.5.1 General

增加條文敘述:

> Components and subassemblies that comply with IEC 62368-1 are acceptable as part of an equipment covered by this standard without further evaluation other than to give consideration to the appropriate use of the component or subassembly in the end-product.

[差異]:

符合IEC62368-1認可的零件以及配件可以被接受, 且使用在合適的終端產品上, 可不需額外評估.

Table 1C

增加表格敘述:

Table 1C – Capacitor ratings according to IEC 60384-14

Capacitor subclass according to IEC 60384-14	RATED VOLTAGE of the capacitor V r.m.s.	TYPE TEST impulse voltage of the capacitor kV peak	TYPE TEST r.m.s voltage of the capacitor kV r.m.s
Y1	Up to and including 500	8	4
Y2	Over 150 up to and including 300	5	1,5
Y4	Up to and including 150	2,5	0,9
X1	Up to and including 760	4 [a]	-
X2	Up to and including 760	2,5 [a]	-

[差異]:

- 增加**X1**以及**X2**電容的額定電壓規格
- 增加電容**type test**的電壓規格

IEC 60384-14

Table 10 – Voltage proof

Class	Range of rated voltages	Test A	Test B or test C
X1 X2	≤ 760 V	4,3 U_R (d.c.)	2 U_R + 1 500 V (a.c.) with a minimum of 2 000 V (a.c.) [a]
X3			
Y1	≤ 500 V	4 000 V (a.c.)	4 000 V (a.c.)
Y2	≥ 150 V ≤ 300 V	1 500 V (a.c.) [b]	U_R + 1 500 V (a.c.) with a minimum of 2 000 V (a.c.) [b]
Y3	≤ 250 V	1 500 V (a.c.) [b]	
Y4	< 150 V	900 V (a.c.) [b]	900 V (a.c.) [b]

[a]) For delta and T-connected capacitor units according to Figures 5b and 5c, the test voltage for terminals to case shall be the appropriate test voltage for the Y-capacitors.

[b]) For lot-by-lot tests of Class Y2-, Y3- and Y4-capacitors, the a.c. test voltage may be replaced by a d.c. voltage of 1,5 times the prescribed a.c. voltage.

Table 1C

修改條文敘述:

For a single capacitor bridging FUNCTIONAL INSULATION, BASIC INSULATION, SUPPLEMENTARY INSULATION or REINFORCED INSULATION, the voltage rating of the single capacitor shall be at least equal to the RMS WORKING VOLTAGE across the insulation being bridged, determined according to 2.10.2.2.

[差異]:

單顆跨接跨接在FI, BI SI or RI的電容, 則電容的額定電壓至少需要符合跨接此絕緣的工作電壓.

1.5.9.4 Bridging of basic insulation by a VDR

修改條文敘述:

1.5.9.4 Bridging of basic insulation by a VDR

It is permitted to bridge BASIC INSULATION by a VDR complying with the requirements of Annex Q, with or without a GDT in series, provided that one side of the ~~VDR~~ circuit is earthed in accordance with 2.6.1 a).

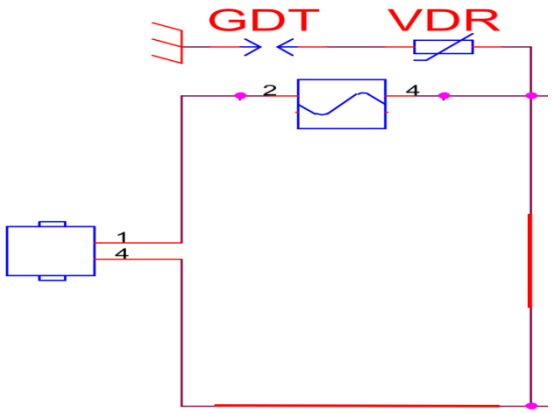
Equipment with such a VDR bridging BASIC INSULATION shall be one of the following:

- PLUGGABLE EQUIPMENT TYPE B; or
- PERMANENTLY CONNECTED EQUIPMENT; or
- equipment that has provision for a permanently connected PROTECTIVE EARTHING CONDUCTOR and is provided with instructions for the installation of that conductor.

1.5.9.4 Bridging of basic insulation by a VDR (cont.)

修改條文敘述:

For all other equipment, it is permitted to bridge BASIC INSULATION by a VDR in series with a GDT provided that:



- the VDR complies with the requirements of Annex Q; and
- the GDT complies with:
  - the electric strength test for BASIC INSULATION; and
  - the external CLEARANCE and CREEPAGE DISTANCE requirements for BASIC INSULATION.

Compliance is checked by inspection and, if necessary, by measurement and test.

1.7.1.3 Use of graphical symbols

增加條文敘述:

> 1.7.1.3 Use of graphical symbols
>
> Graphical symbols placed on the equipment, whether required by this standard or not, shall be in accordance with IEC 60417 or ISO 3864-2 or ISO 7000, if available. In the absence of suitable symbols, the manufacturer may design specific graphical symbols.
>
> Symbols placed on the equipment shall be explained in the user manual.

[差異]

- 位在產品上的圖形符號, 無論是否為本標準所要求, 必須符合IEC 60417 or ISO 3864-2 or ISO 7000. 如果沒有合適的圖形符號, 製造商可自行設計且定義.
- 在產品上的圖形符號, 必須在使用者手冊上加以解釋說明

Table 2B Limits for power sources without an overcurrent protective device

修改表格敘述:

Output voltage [a] (U_{oc})		Output current [b d] (I_{sc})	Apparent power [c d] (S)
V a.c.	V d.c.	A	VA
≤ 30	≤ 30	≤ 8,0	≤ 100
–	30 < U_{oc} ≤ 60	≤ 150/U_{oc}	≤ 100

a U_{oc}: Output voltage measured in accordance with 1.4.5 with all load circuits disconnected. Voltages are for substantially sinusoidal a.c. and ripple free d.c. For non-sinusoidal a.c. and d.c. with ripple greater than 10 % of the peak, the peak voltage shall not exceed 42,4 V.

b I_{sc}: Maximum output current with any non-capacitive load, including a short-circuit.

c S (VA): Maximum output VA with any non-capacitive load.

d Measurement of I_{sc} and S are made 5 s after application of the load if protection is by an electronic circuit and 60 s for a positive temperature coefficient device~~, and 60 s~~ or in other cases.

[差異]

使用PTC或者其他保護(除了electronic circuit)作為保護時, 測試時間變更為60秒

2.6.2 Functional earthing

刪除條文敘述:

~~– in a power supply cord where a conductor having green-and-yellow insulation is used only to provide a FUNCTIONAL EARTHING connection:~~

- ~~the equipment shall not be marked with the symbol~~  ~~(IEC 60417-5172 (DB:2003:02)); and~~
- ~~there are no requirements other than those in 3.1.9 regarding the termination of this conductor at the equipment end.~~

[差異] 刪除條文

2.6.2 Functional earthing (cont.)

增加條文敘述:

For equipment having a power supply cord where a conductor with green-and-yellow insulation is used only to provide a FUNCTIONAL EARTHING connection:

- the equipment shall not be marked with the symbol  , IEC 60417-5172 (2003-02); and
- the equipment may be marked with:
  - the symbol  , IEC 60417-5018 (2011-07); or
  - the symbol  , IEC 60417-6092 (2011-10).

These symbols shall not be used for CLASS I EQUIPMENT.

There are no requirements other than those in 3.1.9 regarding the termination of this FUNCTIONAL EARTHING conductor at the equipment end.

[差異] 增加條文, 使用綠滾黃的電源線, 且僅提供功能性接地連接, 則:

- 產品不可標示 
- 產品僅能標示  or 
- 上述的符號不得標示在Class I的產品

2.9.2 Humidity condition

修改條文敘述:

2.9.2 Humidity conditioning

Where required by 2.9.1, 2.10.8.3, 2.10.10 or 2.10.11, humidity conditioning is conducted for 48 h in a cabinet or room containing air with a relative humidity of ~~91 % to 95 %~~ (93 ± 3) %. The temperature of the air, at all places where samples can be located, is maintained within ~~1 °C~~ ± 2°C of any convenient value t between 20 °C and 30 °C such that condensation does not occur. During this conditioning the component or subassembly is not energized.

For equipment designated for use in tropical conditions, the time duration shall be 120 h at a temperature of (40 ± 2) °C and a relative humidity of (93 ± 3) %.

[差異]

- 變更測試的溫度誤差條件以及濕度條件
- 增加對於熱帶氣候的測試條件

3.4.11 Multiple power sources

修改條文敘述:

3.4.11 Multiple power sources

Where a unit receives power from more than one source (for example, different voltages or frequencies or as backup power), there shall be a prominent marking at each disconnect device giving adequate instructions for the removal of all power from the unit.

If the disconnect device is not in the equipment, the marking shall be on the equipment and located close to the MAINS input terminals.

[差異]

如果"斷接裝置"不在產品上, 可在"產品上"並且"靠近市電輸入端子"的地方標示

4.3.8 Batteries

增加條文敘述:

Portable secondary sealed cells and batteries (other than button) containing alkaline or other non-acid electrolyte shall comply with IEC 62133.

Equipment containing batteries shall be designed to reduce the risk of fire, explosion and chemical leaks under normal conditions and after a single fault in the equipment (see 1.4.14)~~, including a fault in circuitry within the equipment battery pack~~. For USER-replaceable batteries, the design shall reduce the likelihood of reverse polarity installation if this would create a hazard.

[差異]

- 新增: 可攜式的可充電池(除了鈕扣電池, 例如: RTC Battery), 包含了鹼性以及非酸性電池, 皆須符合IEC 62133: 2012 (參考Annex P)

4.3.8 Batteries (cont.)

修改條文敘述:

- ~~***Overcharging of a rechargeable battery**. The battery is charged under each of the following conditions in turn.*~~

- ~~*The battery charging circuit is adjusted with the battery disconnected to give 106 % of the rated output voltage of the charger, or the maximum charging voltage available from the charger (without simulation of faults), whichever is the higher attainable value. The battery is then charged for 7 h.*~~

- ~~*The battery charging circuit is adjusted, with the battery disconnected, to 100 % of the rated output voltage of the charger. The battery is charged while briefly subjected to the simulation of any single component failure that is likely to occur in the charging circuit and that results in overcharging of the battery. To minimize testing time, the failure is chosen that causes the highest overcharging current. The battery is then charged for a single period of 7 h with that simulated failure in place.*~~

- ***Overcharging of a rechargeable battery.** The battery is charged while briefly subjected to the simulation of any SINGLE FAULT CONDITION that is likely to occur in the charging circuit and that results in overcharging of the battery. To minimize testing time, the failure is chosen that causes the worst-case overcharging condition. The battery is then charged for a single period of 7h with the simulated failure in place.*

[差異]

刪除106%以及100%的測試過充測試要求, 並且重新定義可重複充電電池的"過充測試"要求

4.3.13.5.2 Light emitting diodes (LEDs)

增加條文敘述:

NOTE 3 If optical radiation is broadband visible and IR-A radiation and the luminance of the source does not exceed 10^4 cd/m^2, it is expected that the radiation does not exceed the exposure limits given in 4.3 of IEC 62471:2006 (see 4.1 of IEC 62471:2006).

[差異]
新增: LED光學(可見光)的輻射要求.

若LED的流明(luminance)未超過10000 cd/m^2, 即無須提供IEC 62471的認證或者隨機測試.

7.4.1 General

增加條文敘述:

If an equipment is intended for connection to both an outdoor antenna and another CABLE DISTRIBUTION SYSTEM, it shall pass the tests of 7.4.2 and 7.4.3.

- to equipment where:
  - the circuit under consideration is a TNV-1 CIRCUIT; and
  - the common or earthed side of the circuit is connected to the screen of the coaxial cable and to all accessible parts and circuits (SELV, accessible metal parts and LIMITED CURRENT CIRCUITS, if any); and
  - the screen of the coaxial cable is intended to be connected to earth in the building installation.

[差異]

新增不適用7.4.2(Surge) & 7.4.3 (Impulse)的產品的規則.

Annex Q Voltage dependent resistors (VDRs)

修改條文敘述:

A VDR shall comply with IEC 61051-2, whether a FIRE ENCLOSURE is provided or not, taking into account all of the following:

- Preferred climatic categories (2.1.1 of IEC 61051-2:1991):
  - lower category temperature: – 10 °C
  - upper category temperature: + 85 °C
  - duration of damp heat, steady state test: 21 days.
- Maximum continuous voltage
  - at least 1,25 times the rated voltage of the equipment or
  - at least 1,25 times the upper voltage of the rated voltage range.

Annex Q Voltage dependent resistors (VDRs) (cont.)

[差異]

- 原本僅定義在一次側VDR, 需要符合IEC 61051-2的相關測試.
- 修改最大連續電壓之定義為1.25倍.
  影響VDR應用在產品的額定電壓, 例如: 產品的額定電壓為100-240Vac, 則原本VDR的最大連續電壓至少需要288Vac (240 x 1.2), 但A2的版本至少需要300Vac(240 x 1.25).

Annex Q Voltage dependent resistors (VDRs) (cont.)

[範例]:

Varistor
Varistor

Typ(en) / *Type(s)*:	Max. Spitzenstrom Puls 8/20 µs) *Max. peak current time 8/20 µs)*	(1 Max. Spitzenstrom Puls 8/20 µs) *(1 Max. peak current time 8/20 µs)*	(1 Max. Dauerspannung (1 *Max. continuous voltage*
180K14D/14D180K bis/to 680K14D/14D680K	1000 A	10 A	AC 11-40 V DC 14-56 V
820K14D/14D820K bis/to 911K14D/14D911K	1000 A	50 A	AC 50-550 V DC 66-745 V
102K14D/14D102K bis/to 112K14D/14D112K	1000 A	50 A	AC 625-680 V DC 725-895 V

Annex Q Voltage dependent resistors (VDRs) (cont.)

修改條文敘述:

The body of the VDR shall comply with the needle flame according to IEC 60695-11-5, with the following test severities:

- duration of application of the test flame: 10 s;
- after flame time: 5 s.

If the body of the VDR complies with V-1 CLASS MATERIAL, the needle flame test does not need to be performed.

[差異]

VDR的外皮需有防燃等級V-1以上的要求, 或者符合IEC 60695-11-5 (針焰測試 needle flame test)

Thank You

Introduction of IEC 62368-1/Ed 2: Audio/Video, Information And Communication Technology Equipment

Prepare by Stephen Lin
2014-01-16

大綱

- 標準版本及現行要求
- Scope
- 標準內容簡述
- 實例解說

Cerpass Technology Corp.

標準版本及現行要求

- **IEC 62368-1: 1st Edition**
  - Publication date: 2010-01-21
  - CENELEC no publication accordingly
  - UL 62368-1:1st edition issued at 2012-02-17
- **IEC 62368-1: 2nd Edition**
  - Publication date: 2014-02-28 (forecast) (目前為FDIS版本, 2013/11)
  - EN 62368-1 to be issued at Q1 of 2014
  - UL 62368-1:2nd edition to be issued at Q2 of 2014
- **Enforcement:**

Today	2013/2014	2018 & beyond
60065 60950 62368-1 Ed 1.0	60065 60950 62368-1 Ed 1.0 62368-1 Ed 2.0	62368-1 Ed 2.0

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Cerpass
Technology Corp.

標準版本及現行要求

TC 108 Safety of electronic equipment within the field of audio/video, information technology and communication technology

Scope | Structure | Projects / Publications | Documents | Votes | Meetings | Collaboration Tools

Working Documents | Other Documents | Log in | En | Fr

TC 108 Working Documents since 2013-01-02

Reference, Title	Downloads	Circulation Date	Closing Date	CENELEC	Voting / Comment	Authorized Committees
108/522/INF Background on the development of IEC 62368-1	89 kB	2013-11-22				
108/521/FDIS IEC 62368-1/Ed2:Audio/video, information and communication technology equipment - Part 1: Safety requirements	3038 kB 3063 kB	2013-11-08	2014-01-10	yes		

皆在2014-1-10投票

CENELEC Documents open for vote/comment

Documents

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Reference	Project Number	Type	Technical Body	Closing Date	IEC	Downloads
FprEN 62368-1:2013	23361	parallel vote on FDIS	CLC/TC 108X	2014-01-10	Y	3038 kB 3063 kB
FprEN 62368-1:2013/FprAA:2013	23362	formal vote	CLC/TC 108X	2014-01-10	N	EN

Scope

適用範圍

- 涵蓋目前IEC 60950-1與IEC 60065下的所有產品範圍
- 額定輸入電壓低於600V的產品
- 分別對於一般使用者、受指示的人員、專業技術人員需提供規定之安全防護措施, 並涵蓋孩童可能接觸或使用之產品
- 除非製造商另行定義，此標準評估將假設產品使用於海拔2000m以下
- 不針對產品性能或功能性作評估
- 不適用安裝於潮濕環境使用的產品
- 安裝於戶外使用的產品需加評估IEC 60950-22
- 不適用於UPS產品, 馬達發電機, 配電用之變壓器

IEC 62368-1簡述

IEC 60950-1+IEC 60065
= IEC 62368-1?

制定觀念不同, 但測試方式大致相同

IEC 62368-1目前直接接受符合IEC 60950-1 or IEC 60065之認可零件或組件

IEC 62368-1簡述

基本制定觀點

- IEC 62368-1是不同於現行IEC 60950-1以及IEC 60065的概念下考量安全，是基於產品設計時就必須考量到危害人體各種傷害的一種安全工程流程設計的概念-
  HBSE (Hazard-Based Safety Engineering)

IEC 62368-1簡述

What is HBSE

- 產品具有或提供會造成疼痛或傷害的能量經過傳導後到人體

This concept is represented by a three-block model (see Figure 1).

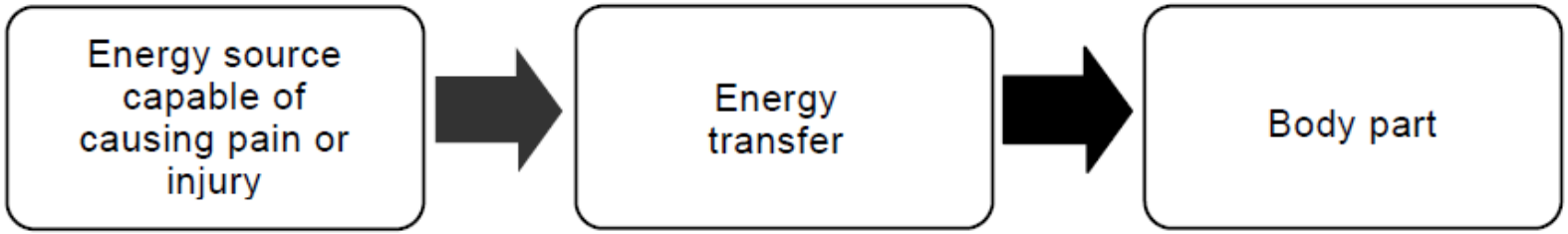


Figure 1 – Three block model for pain and injury

IEC 62368-1簡述

Energy source

能量形式	人體反應或財產損失的狀況
Electrical energy (ES, Clause 5) (電能, 例如帶電的導體)	痛覺, 心室顫動, 心跳停止, 呼吸停止, 皮膚及器官的燒傷
Thermal energy (PS, Clause 6) (熱能, 例如電氣起火, 或是火的蔓延)	由電氣起火所導致的燒燙傷或財產損失
Chemical reaction (CS, Clause 7) (化學反應, 例如電解液, 有毒物質)	皮膚傷害, 肺及其他器官的傷害, 中毒, 細胞傷害
Kinetic energy (MS, Clause 8) (動能, 例如產品之移動件, 風扇)	撕裂傷, 刺傷, 擦傷, 撞傷, 壓傷, 截肢或喪失四肢, 眼, 耳
Thermal energy (TS, Clause 9) (熱能, 例如高溫可被接觸之部件)	皮膚燙傷
Radiated energy (RS, Clause 10) (放射能, 例如輻射, 光, 聲音之能量)	喪失視覺, 聽覺,皮膚病變燒傷

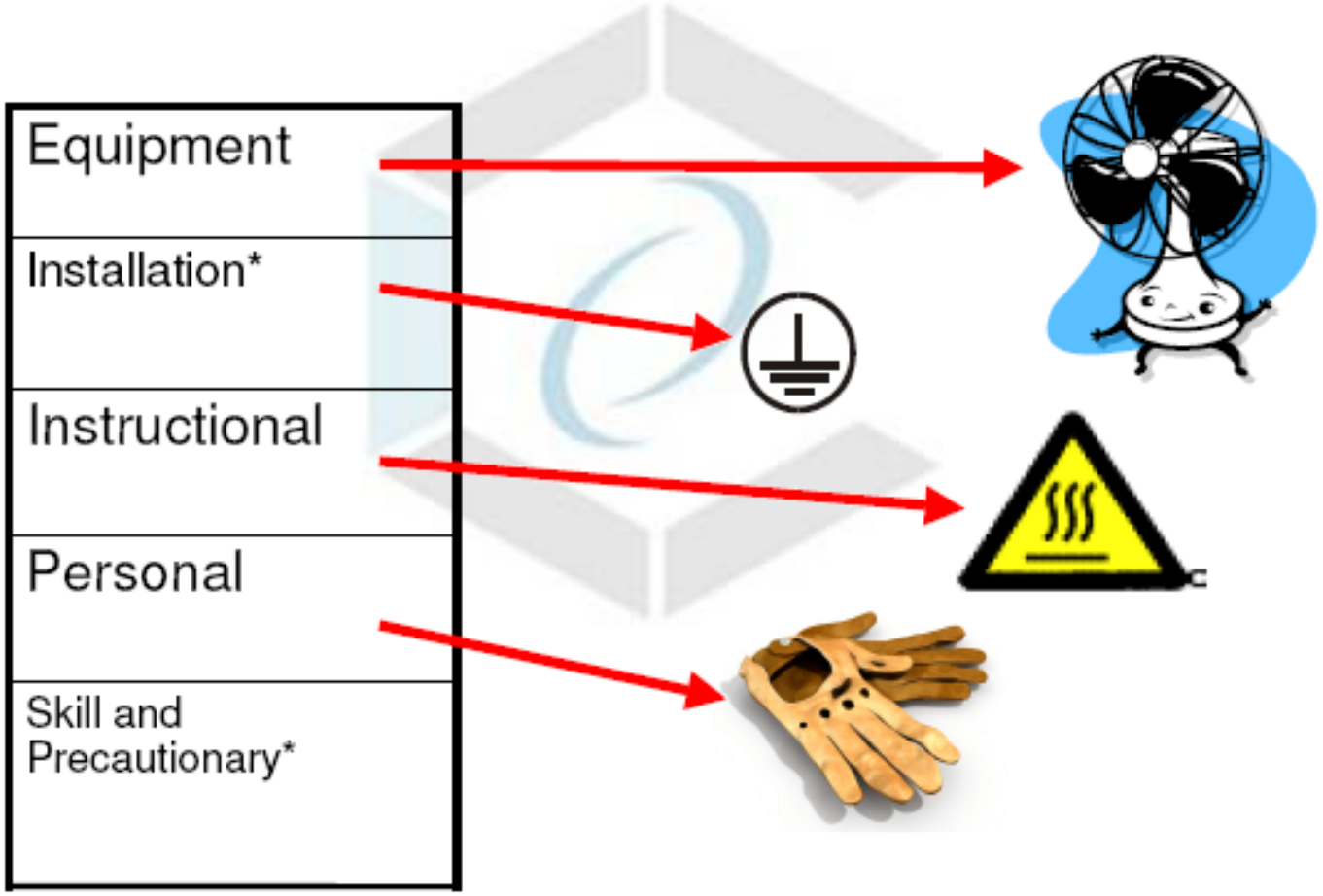
IEC 62368-1簡述

How to protect those Energy source capable of causing pain or injury??

Figure 2 – Three block model for safety

IEC 62368-1簡述

- **Safeguards**



IEC 62368-1簡述

Safeguards (Cont.)

- 設備防護(Equipment Safeguard): 設備外殼或內部元件提供之防護, 包含
  - 基本防護(Basic Safeguard)
  - 附加防護(Supplementary Safeguard)
  - 雙重防護(Double Safeguard)
  - 加強防護(Reinforced Safeguard)

- 安裝防護(Installation Safeguard): 依照安裝條件以增加安全性, e.g., 產品接地; 上栓子; 室內使用; 放置於地面上使用以防止傾倒…等

IEC 62368-1簡述

Safeguards (Cont.)

- 指導防護(Instructional Safeguard): 提供防止受傷的訊息或符號, 包含使用手冊
- 個人防護(Personal Safeguard): 對個人外加防護設備, 例如帶手套
- 預防防護(Precautionary Safeguard): 在技術人員指導及監督下使用產品
- 技能防護(Skill Safeguard): 操作人員受過訓練或有相當經驗之專業知識可以防止受到傷害

IEC 62368-1簡述

操作人員區分

- 一般使用者(Ordinary Person): 不僅包含設備使用者，也包括可能會接觸設備或者設備附近的任何人
- 受指示的人員(Instructed Person): 經由技術人員或被監督情況下操作之人員
- 專業技術人員(Skilled Person): 有相關的教育或經驗的人員,其具有之專業知識能避免設備所產生之危險或降低其危險

IEC 62368-1簡述

- 能量等級區分

Table 1 – Response to energy class

Energy source	Effect on the body	Effect on combustible materials
Class 1	Not painful, but may be detectable	Ignition not likely
Class 2	Painful, but not an injury	Ignition possible, but limited growth and spread of fire
Class 3	Injury	Ignition likely, rapid growth and spread of fire

IEC 62368-1簡述

Energy source classifications

- Class 1 energy source
  - 正常及異常操作下不會超過Class 1限制值**以及**單一失效的狀況下不會超過Class 2限制值
- Class 2 energy source
  - 超過Class 1限制值, 但正常操作, 異常操作或單一失效的狀況下不超過Class 2限制值; **受指示人員可以接觸Class 2 energy source**
- Class 3 energy source
  - 在正常操作, 異常操作或單一失效的狀況下超過Class 2限制值; **專業技術人員可以接觸Class 3 energy source**

註: 異常操作(abnormal)與單一失效(Single fault)定義不同

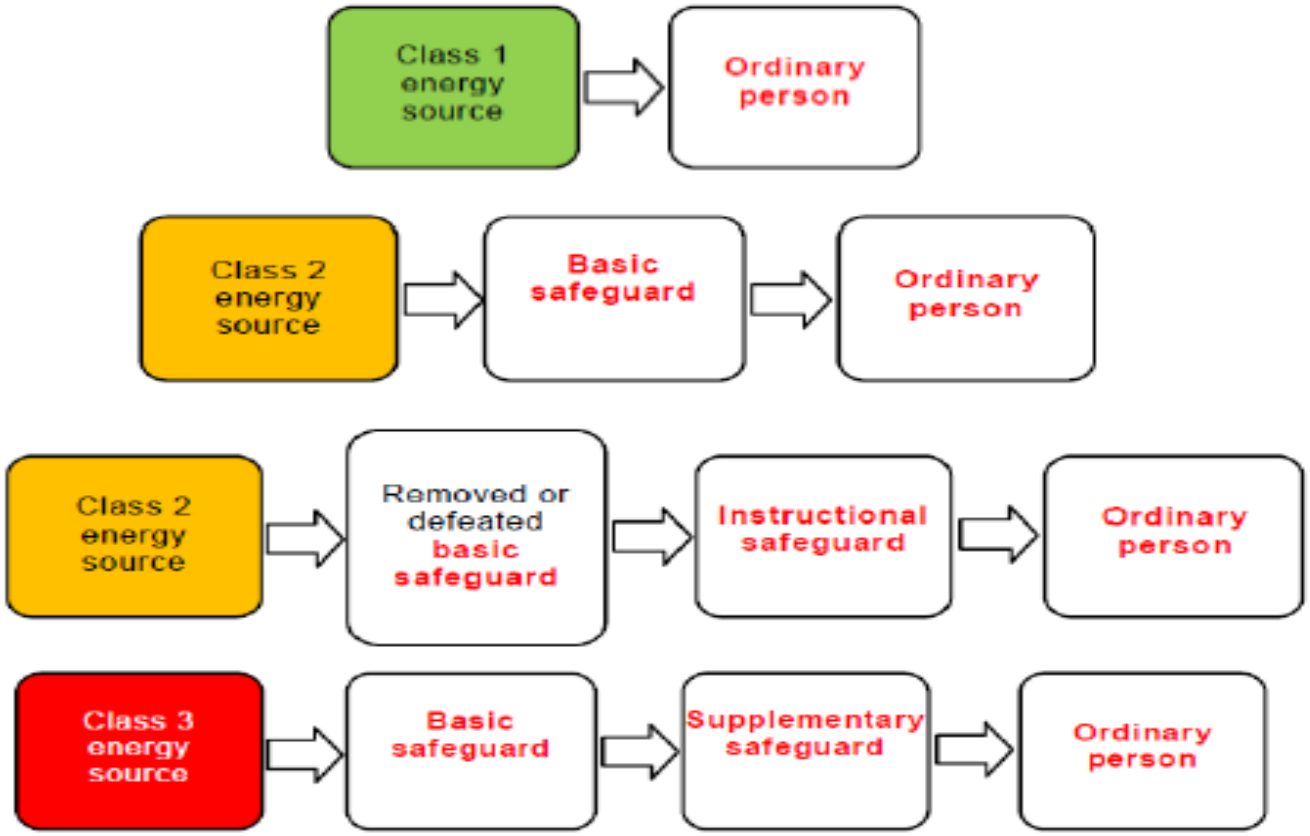
IEC 62368-1簡述

Energy source abbreviations

ES	Electrical energy source
ES1	Electrical energy source class 1
ES2	Electrical energy source class 2
ES3	Electrical energy source class 3
PS	Power source
PS1	Power source class 1
PS2	Power source class 2
PS3	Power source class 3
TS	Thermal energy source
TS1	Thermal energy source class 1
TS2	Thermal energy source class 2
TS3	Thermal energy source class 3
MS	Mechanical energy source
MS1	Mechanical energy source class 1
MS2	Mechanical energy source class 2
MS3	Mechanical energy source class 3
RS	Radiation energy source
RS1	Radiation energy source class 1
RS2	Radiation energy source class 2
RS3	Radiation energy source class 3

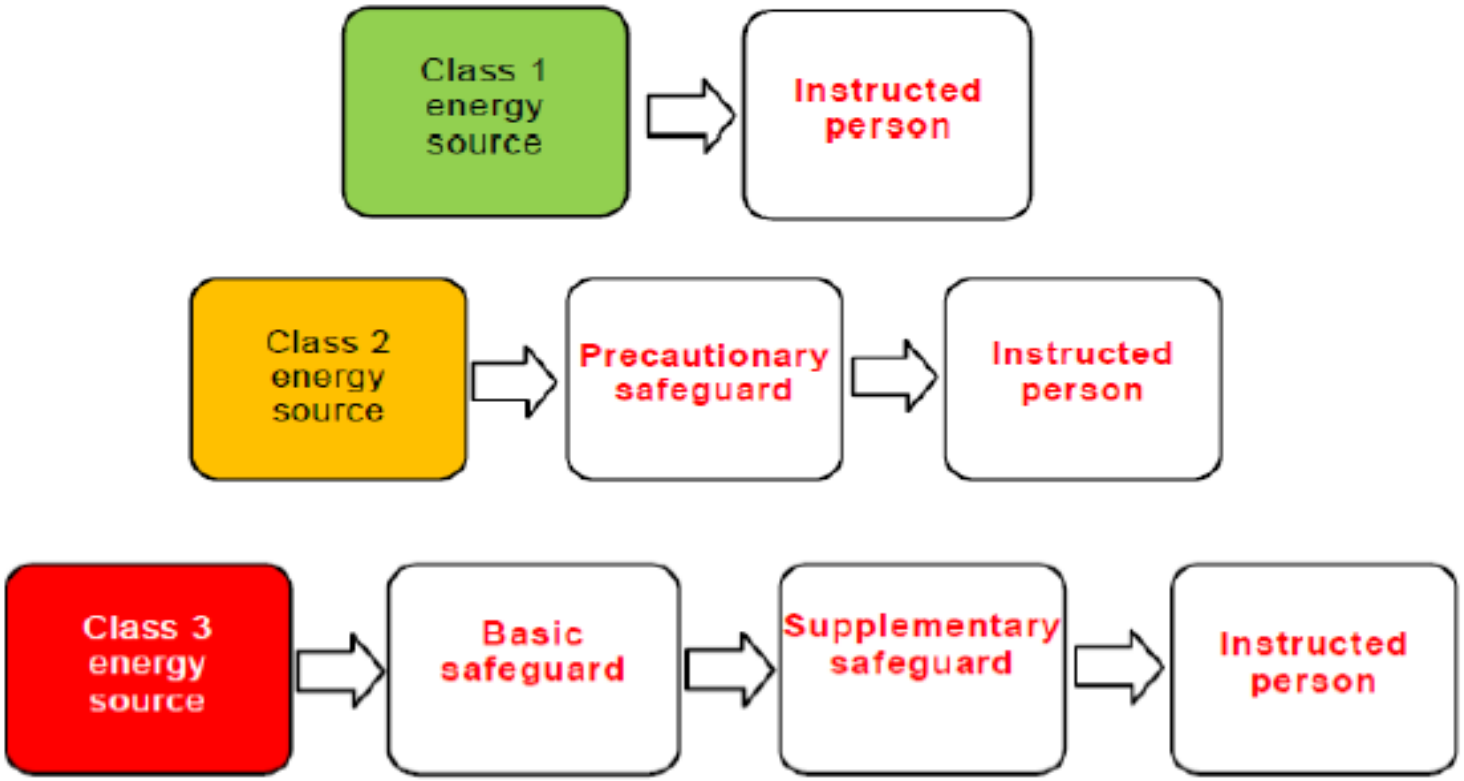
IEC 62368-1簡述

- 不同使用者針對不同等級之危險防護需求
  - 一般使用者(Ordinary Person)



IEC 62368-1簡述

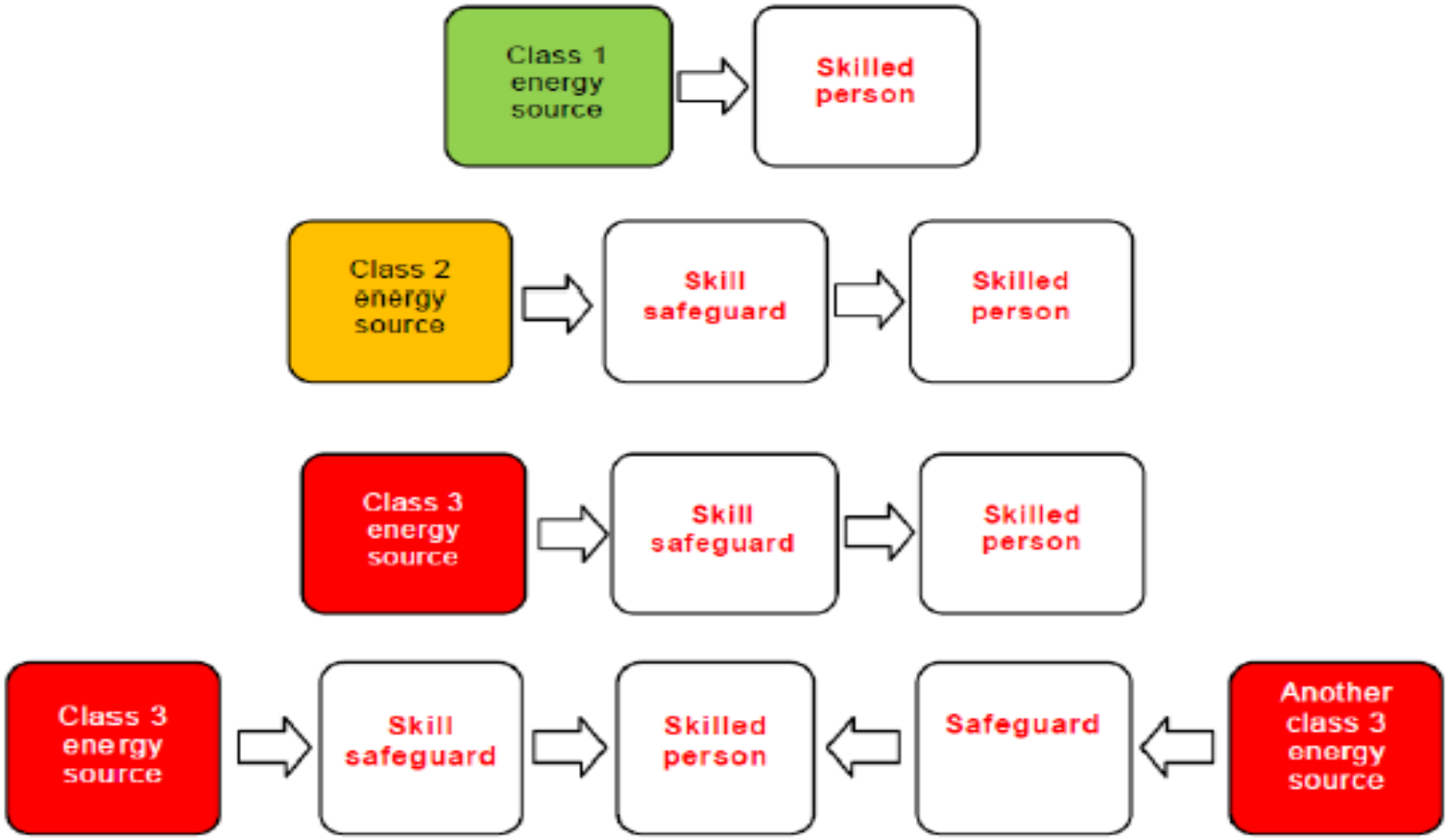
- 不同使用者針對危險之防護需求
  - 受指示的人員(Instructed Person)



IEC 62368-1簡述

不同使用者針對危險之防護需求

- 專業技術人員(Skilled Person)



IEC 62368-1簡述

Energy source classifications(Cont.)

- 製造商如有特殊考量, 可自行宣稱Class 1為Class 2 or 3或者Class 2為Class 3 (只能往高危險等級宣告)
- 中性線導體視作ES Class 3
- 保護接地導體直接視作ES Class 1

IEC 62368-1簡述

HBSE小結

- 各種能量危險皆區分為Class 1/2/3, 並針對不同操作人員分別可接觸相對的能量等級

- Class I/II/III產品分別包含各類(ES, PS, TS……)的Class 1/2/3

e.g., Class III的產品, 其產品可能同時具有energy source為ES1, PS2, MS2

- Energy source包含前述定義之各類能量形式, 注意不要跟 **Electrical energy source (ES)** 搞混.

IEC 62368-1簡述

■ 廠商設計流程

IEC 62368-1簡述

各類Energy source說明

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IEC 62368-1簡述

Electrical energy source classifications (ES)

Energy source	ES1 limits		ES2 limits		ES3
	Voltage	Current [a, c]	Voltage	Current [b, c]	
d.c.	60 V	2 mA	120 V	25 mA	> ES2
a.c up to 1 kHz	30 V r.m.s. 42,4 V peak		50 V r.m.s. 70,7 V peak		
a.c. > 1 kHz up to 100 kHz	30 V r.m.s. + 0,4 f	0,5 mA r.m.s 0,707 mA peak	50 V r.m.s. + 0,9 f	5 mA r.m.s. 7,07 mA peak	
a.c above 100 kHz	70 V r.m.s.		140 V r.m.s.		
Combined a.c. and d.c.	$\frac{U_{dc}\ V}{60} + \frac{U_{ac}\ V\ r.m.s.}{30} \le 1$ $\frac{U_{dc}\ V}{60} + \frac{U_{ac}\ V\ peak}{42,4} \le 1$	$\frac{I_{dc}\ mA}{2} + \frac{I_{ac}\ mA\ r.m.s.}{0,5} \le 1$ $\frac{I_{dc}\ mA}{2} + \frac{I_{ac}\ mA\ peak}{0,707} \le 1$	See Figure 23	See Figure 22	

The formulation below as a function of frequency may be of interest to designers for sinusoidal waveforms

Energy source	ES1 limits	ES2 limits	ES3
	Current [c] r.m.s.	Current [c] r.m.s.	
a.c up to 1 kHz	0,5 mA	5 mA	> ES2
a.c. > 1 kHz up to 100 kHz	0,5 mA x f [d]	5 mA + 0,95 f [e]	
a.c above 100 kHz	50 mA [d]	100 mA [e]	

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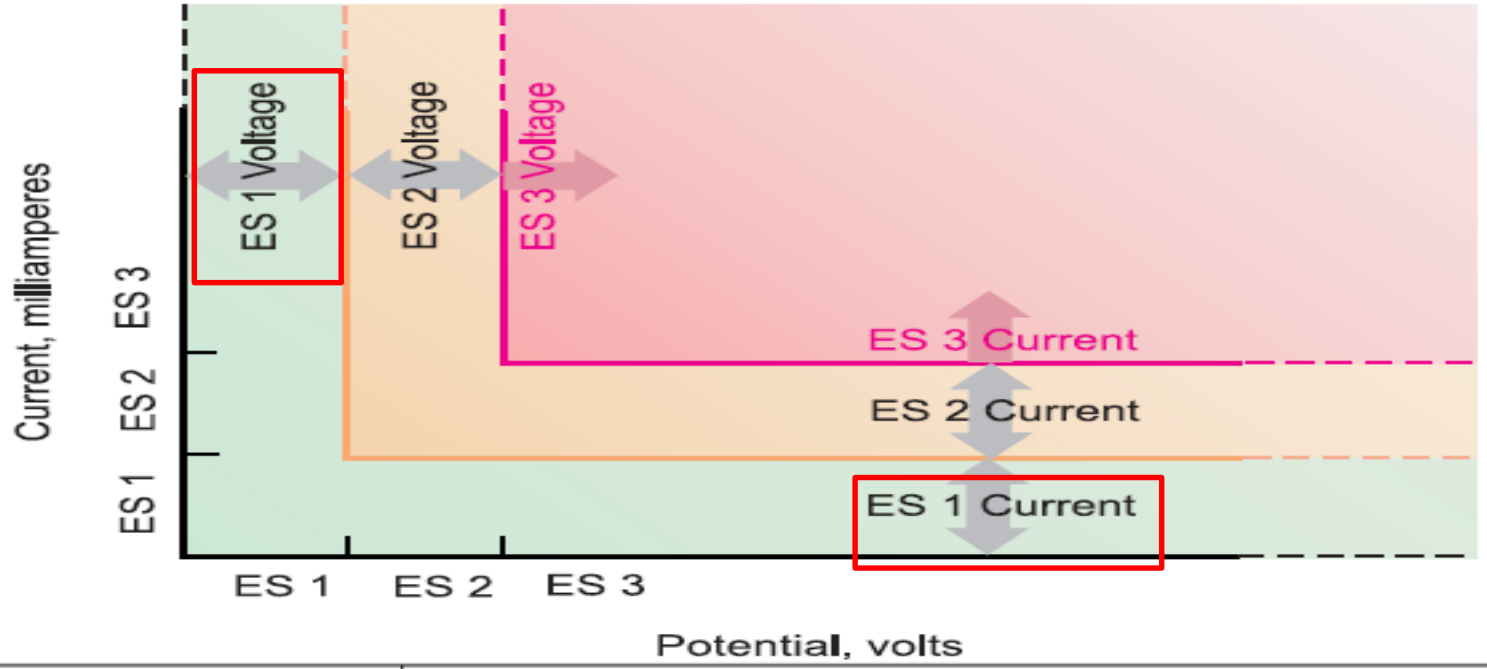
IEC 62368-1簡述

- **Electrical energy source classifications (ES)**



Person	Required number of equipment safeguards interposed between an electrical energy source and persons		
	ES1	ES2	ES3
Ordinary person	0	1	2
Instructed person	0	0	2
Skilled person	0	0	0 or 1 [a]

IEC 62368-1簡述

Power source circuit classifications (PS)

6.2.2.4 PS1

PS1 is a circuit where the power source, (see Figure 36) measured according to 6.2.2, does not exceed 15 W measured after 3 s.

6.2.2.5 PS2

PS2 is a circuit where the power source, (see Figure 36) measured according to 6.2.2:

– exceeds PS1 limits; and

– does not exceed 100 W measured after 5 s.

6.2.2.6 PS3

PS3 is a circuit whose power source exceeds PS2 limits, or any circuit whose power source has not been classified (see Figure 36).

IEC 62368-1簡述

- **Power source circuit classifications (PS)**

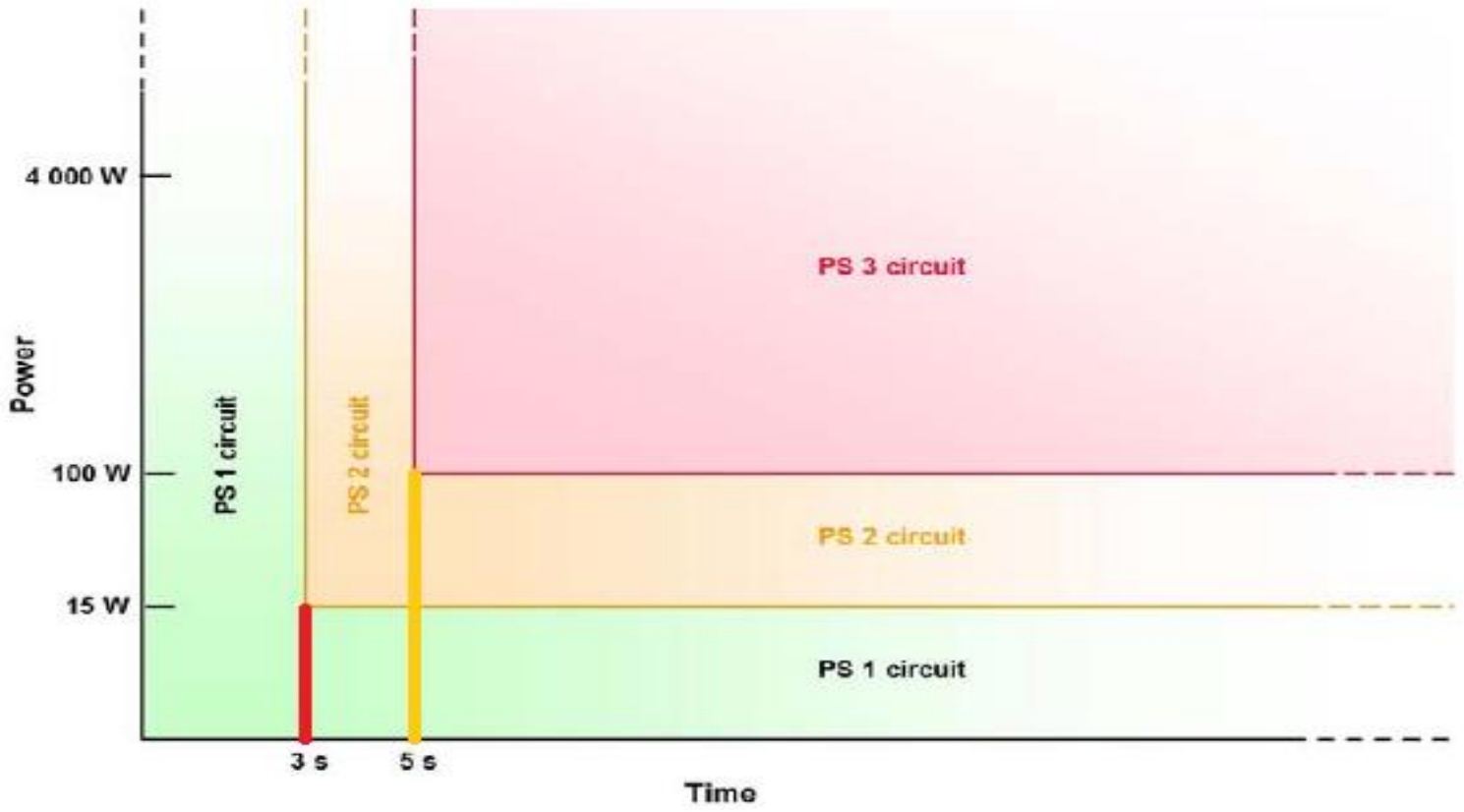


Figure 36 – Illustration of power source classification

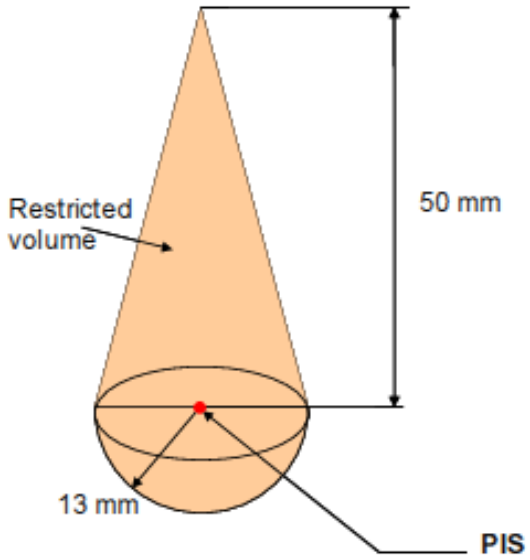
IEC 62368-1簡述

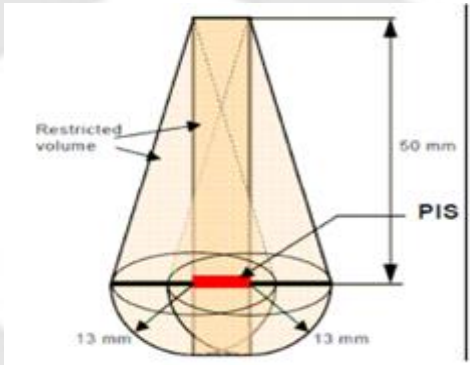
- **Power source circuit classifications (PS)**
  - The electrically-caused fire including power sources(PS) and **potential ignition sources(PIS, 潛在起火源)**
- **PIS**
  - PS2以及PS3線路直接視作具有潛在起火源

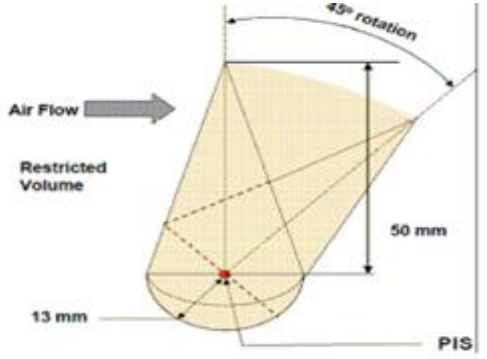
IEC 62368-1簡述

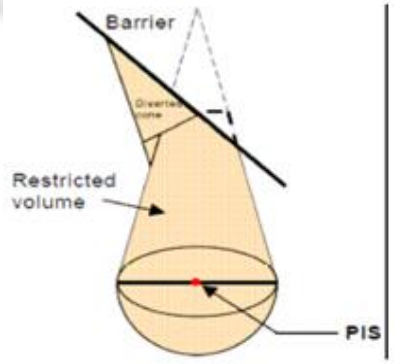
PIS (Cont.)

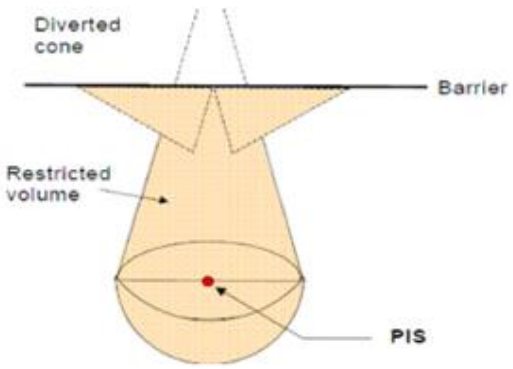
- The **Combustible material** shall be separated from the "restricted volume" of PIS, unless the material is V-1







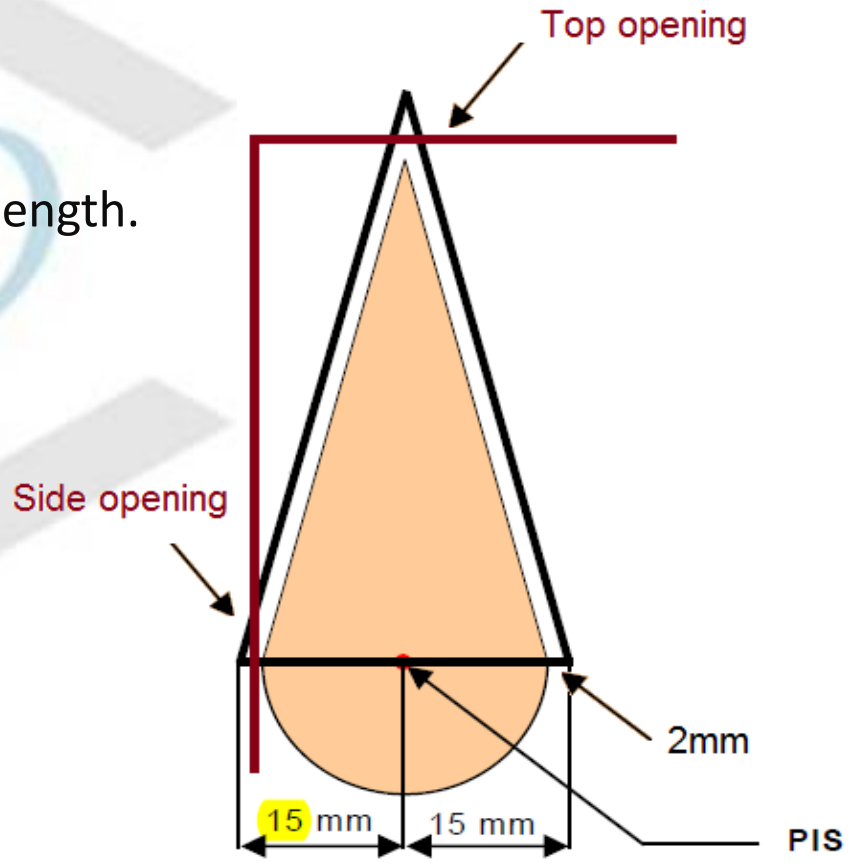




IEC 62368-1簡述

PIS (Cont.)

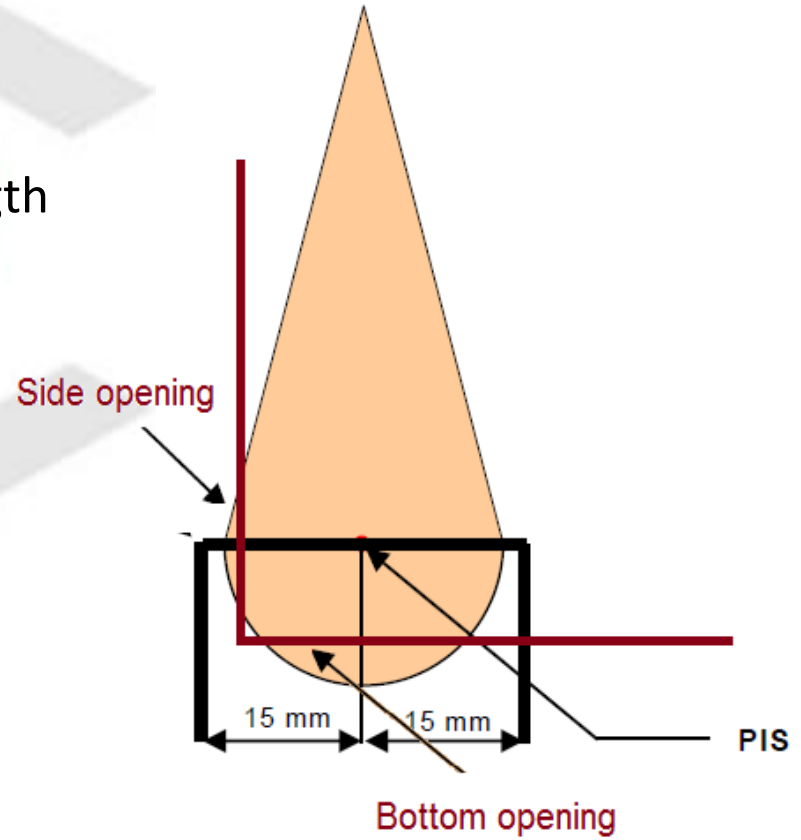
- Requirements for **top /side openings** of a fire enclosure and a fire barrier
  - 5 mm in any dimension, or
  - 1 mm in width regardless of length.



IEC 62368-1簡述

PIS (Cont.)

- Requirements for **bottom /side openings** of a fire enclosure and a fire barrier
  - 3 mm in any dimension, or
  - 1 mm in width regardless of length



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IEC 62368-1簡述

Mechanical energy source classifications(MS)

Table 35 – Classification for various categories of mechanical energy sources

Line	Category	MS1	MS2	MS3
1	Sharp edges and corners	Does not cause pain or injury [b]	Does not cause injury [b] but may be painful	May cause injury [c]
2	Moving parts	Does not cause pain or injury [b]	Does not cause injury [b] but may be painful	May cause injury [c]
3a	Plastic fan blades [a]	$\frac{N}{15\ 000} + \frac{K}{2\ 400} \leq 1$	> MS1; and $\frac{N}{44\ 000} + \frac{K}{7\ 200} \leq 1$	> MS2
3b	Other fan blades [a] See Figure 43.	$\frac{N}{15\ 000} + \frac{K}{2\ 400} \leq 1$	> MS1; and $\frac{N}{22\ 000} + \frac{K}{3\ 600} \leq 1$	> MS2
4	Loosening, exploding or imploding parts.	NA	NA	See [d]
5	Equipment mass	≤ 7 kg	7 kg < mass ≤ 25 kg	> 25 kg
6	Wall/ceiling mount	Equipment mass ≤ 1 kg mounted ≤ 2 m [e]	Equipment mass > 1 kg mounted ≤ 2 m [e]	All equipment mounted > 2 m

[a] The K factor is determined from the formula $K = 6 \times 10^{-7} (m\ r^2\ N^2)$ where m is the mass (kg) of the moving part of the fan assembly (blade, shaft and rotor), r is the radius (mm) of the fan blade from centre line of the motor (shaft) to the tip of the outer area likely to be contacted, N is the rotational speed (rpm) of the fan blade.

In the end product, the fan maximum operational voltage can be different than the **rated voltage** of the fan and this difference should be taken into account.

[b] The phrase "Does not cause injury" means that a doctor or hospital emergency attention is not needed.

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IEC 62368-1簡述

Thermal energy source classifications(TS)

9.2.6 Touch temperature levels

Table 38 – Touch temperature limits for accessible parts

	Accessible parts [a]	Maximum temperature (T_{max}) °C			
		Metal [f]	Glass, porcelain and vitreous material	Plastic and rubber	Wood
TS1	Handles, knobs, grips, etc., and external surfaces either held, touched or worn against the body in normal use (> 1 min) [b, c]	48	48	48	48
	Handles, knobs, grips, etc., and external surfaces held for short periods of time or touched occasionally (> 10 s and < 1 min) [c]	51	56	60	60
	Handle, knobs, grips etc., and external surfaces touched occasionally for very short periods (>1 s and < 10 s) [c]	60	71	77	107
	External surfaces that need not be touched to operate the equipment (<1 s) [c]	70 [d]	80 [d]	94 [d]	140
TS2	Handles, knobs, grips, etc., and external surfaces held in normal use (> 1 min) [c]	58	58	58	58
	Handles, knobs, grips, etc., and external surfaces held for short periods of time or touched occasionally (> 10 s and < 1 min) [d]	61	66	70	70
	Handle, knobs, grips etc., and external surfaces touched occasionally for very short periods (> 1 s and < 10 s) [d]	70	81	87	117
	External surfaces that need not be touched to operate the equipment (< 1 s) [d]	80 (100) [e]	90 (100) [e]	104	150
TS3	Higher than the TS2 limits				

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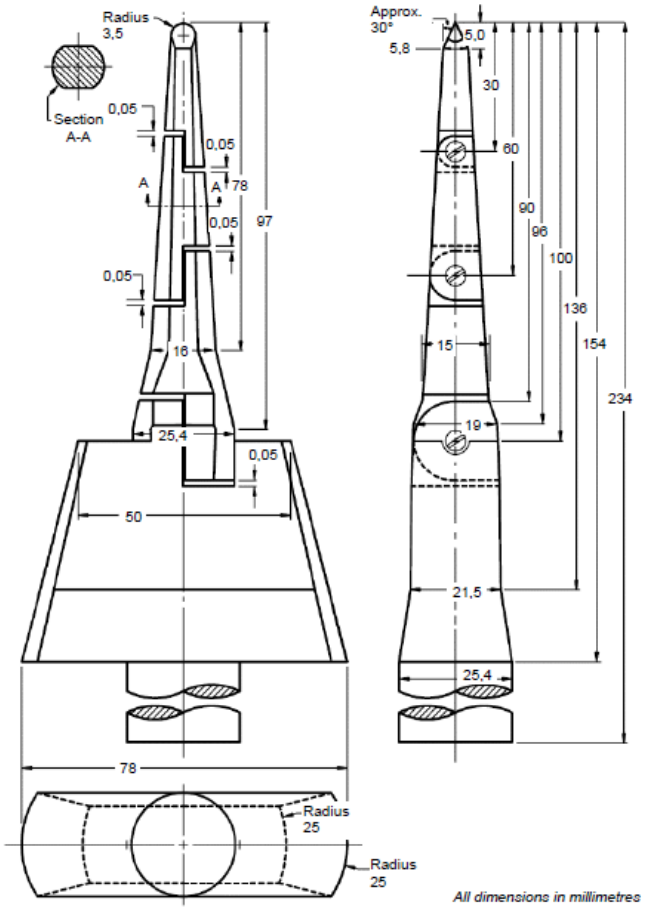
IEC 62368-1簡述

與IEC 60950/IEC 60065
須注意之差異

IEC 62368-1簡述

安全防護增加條文-針對孩童

- Test finger for child
- 設備可能會被孩童接觸的情況
  - 設備含有一前控制面板
  - 設備含有一顯示螢幕提供圖像
  - **設備定義使用在家中或類似之環境**



IEC 62368-1簡述

安全防護增加條文-針對孩童(Cont.)

- Lithium coin / button cell batteries **(如可自行替換)**
  - 產品(包含遙控器)可能會被孩童接觸, 以及
  - lithium coin/button cell battery with diameter of **< 32mm** shall:
    - 必須使用工具才能打開電池蓋; or
    - 必須同時對兩個以上的獨立卡榫或類似開關動作才能開啟電池蓋 (用手開啟)
    - 除以上方式外, 還必須加上相關警語以及評估機械性測試, 如掉落, 應力, 以及**擠壓測試**

IEC 62368-1簡述

固態絕緣使用增加要求

- Solid insulation requirements at **>30 kHz**
  - Ep x Kr x d > 1.2 x Vpw

where:

Ep: breakdown strength at mains frequency 60Hz (table 21)

Kr: reduction factor (tables 22 and 23)

d: total thickness, in mm

Vpw: peak working voltage at high frequency

IEC 62368-1簡述

固態絕緣使用增加要求(Cont.)

Table 21 – Electric field strength E_P for some commonly used materials

Material	Breakdown electric field strength E_P kV/mm				
	Thickness of the material mm				
	0,75	0,08	0,06	0,05	0,03
Porcelain [a]	9,2	-	-	-	-
Silicon-glass [a]	14	-	-	-	-
Phenolic [a]	17	-	-	-	-
Ceramic [a]	19	-	-	-	-
Teflon® [a]	27	-	-	-	-
Melamine-glass [a]	27	-	-	-	-
Mica [a]	29	-	-	-	-
Paper phenolic [a]	38	-	-	-	-
Polyethylene [b]	49	-	-	52	-
Polystyrene [c]	55	65	-	-	-
Glass [a]	60	-	-	-	-
Kapton® [a]	303	-	-	-	-
FR530L [a]	33	-	-	-	-
Mica-filled phenolic [a]	28	-	-	-	-
Glass-silicone laminate [a]	18	-	-	-	-
Cellulose-acetobutyrate [d]	-	-	120	-	210
Polycarbonate [d]	-	-	160	-	270
Cellulose-triacetate [d]	-	-	120	-	210

IEC 62368-1簡述

■ 固態絕緣使用增加要求(Cont.)

Table 22 – Reduction factors for the value of breakdown electric field strength E_P at higher frequencies

Material [a]	Frequency kHz										
	30	100	200	300	400	500	1 000	2 000	3 000	5 000	10 000
	Reduction factor K_R										
Porcelain	0,52	0,42	0,40	0,39	0,38	0,37	0,36	0,35	0,35	0,34	0,30
Silicon-glass	0,79	0,65	0,57	0,53	0,49	0,46	0,39	0,33	0,31	0,29	0,26
Phenolic	0,82	0,71	0,53	0,42	0,36	0,34	0,24	0,16	0,14	0,13	0,12
Ceramic	0,78	0,64	0,62	0,56	0,54	0,51	0,46	0,42	0,37	0,35	0,29
Teflon	0,57	0,54	0,52	0,51	0,48	0,46	0,45	0,44	0,41	0,37	0,22
Melamine-glass	0,48	0,41	0,31	0,27	0,24	0,22	0,16	0,12	0,10	0,09	0,06
Mica	0,69	0,55	0,48	0,45	0,41	0,38	0,34	0,28	0,26	0,24	0,20
Paper phenolic	0,58	0,47	0,40	0,32	0,26	0,23	0,16	0,11	0,08	0,06	0,05
Polyethylene	0,36	0,28	0,22	0,21	0,20	0,19	0,16	0,13	0,12	0,12	0,11
Polystyrene	0,35	0,22	0,15	0,13	0,13	0,11	0,08	0,06	0,06	0,06	0,06
Glass	0,37	0,21	0,15	0,13	0,11	0,10	0,08	0,06	0,05	0,05	0,04
Other materials	0,43	0,35	0,30	0,27	0,25	0,24	0,20	0,17	0,16	0,14	0,12

IEC 62368-1簡述

■ 固態絕緣使用增加要求(Cont.)

Table 23 – Reduction factors for the value of breakdown electric field strength E_P at higher frequencies for thin materials

Thin material	Frequency kHz										
	30	100	200	300	400	500	1 000	2 000	3 000	5 000	10 000
	Reduction factor K_R										
Cellulose-acetobutyrate (0,03 mm)	0,67	0,43	0,32	0,27	0,24	0,20	0,15	0,11	0,09	0,07	0,06
Cellulose-acetobutyrate (0,06 mm)	0,69	0,49	0,36	0,30	0,26	0,23	0,17	0,13	0,11	0,08	0,06
Polycarbonate (0,03 mm)	0,61	0,39	0,31	0,25	0,23	0,20	0,14	0,10	0,08	0,06	0,05
Polycarbonate (0,06 mm)	0,70	0,49	0,39	0,33	0,28	0,25	0,19	0,13	0,11	0,08	0,06
Cellulose-triacetate (0,03 mm)	0,67	0,43	0,31	0,26	0,23	0,20	0,14	0,10	0,09	0,07	0,06
Cellulose-triacetate (0,06 mm)	0,72	0,50	0,36	0,31	0,27	0,23	0,17	0,13	0,10	0,10	0,06
Other thin foil materials	0,68	0,46	0,34	0,29	0,25	0,22	0,16	0,12	0,10	0,08	0,06

IEC 62368-1簡述

Touch Current Test

- Normal condition
  - Limit : ES1 (0.5mArms)
  - Test condition: **connecting with PE terminal** to the earth of mains

- Single fault condition
  - Limit: ES2 (5mArms)
  - Test condition:
    - disconnect PE terminal, and;
    - open the Neutral

IEC 62368-1簡述

Steady Force Test

- 100N for Transportable Equipment, Hand-held Equipment and Direct Plug-in Equipment (formerly 250N)

Discharge Test

- Below ES1 (<42.4Vp) after 2s the disconnection from mains
- The disconnection is made at its peak charging voltage

IEC 62368-1簡述

Electric Strength Test

*Unless otherwise specified elsewhere in this standard, the test voltage for the electric strength of **basic insulation**, **supplementary insulation** or **reinforced insulation** is the highest value of the following three methods:*

*Method 1: Determine the test voltage according to Table 27 using the **required withstand voltage** (based on transient voltages from the a.c. **mains** or d.c. **mains** or from **external circuits**).*

*Method 2: Determine the test voltage according to Table 28 using the **peak working voltage**.*

*Method 3: Determine the test voltage according to Table 29 using the nominal **mains** voltage (to cover **temporary overvoltages**).*

The insulation is subjected to the highest test voltage as follows:

- *by applying an a.c. voltage of substantially sine-wave form having a frequency of 50 Hz or 60 Hz; or*
- *by applying a **d.c. voltage** in one polarity and then in reverse polarity.*

*The voltage applied to the insulation under test is gradually raised from zero to the prescribed voltage and maintained at that value for 60 s (for **routine tests** see 5.4.9.2).*

IEC 62368-1簡述

Electric Strength Test (Cont.)

Table 27 – Test voltages for electric strength tests based on transient voltages

Required withstand voltage up to and including	Test voltage for basic insulation or supplementary insulation	Test voltage for reinforced insulation
kV peak	kV peak or d.c.	
0,33	0,33	0,5
0,5	0,5	0,8
0,8	0,8	1,5
1,5	1,5	2,5
2,5	2,5	4
4	4	6
6	6	8
8	8	12
12	12	18
U_R [a]	U_R [a]	1,5 × U_R [a]
Linear interpolation may be used between the nearest two points.		

IEC 62368-1簡述

Electric Strength Test (Cont.)

Table 28 – Test voltages for electric strength tests based on peak working voltages

Peak working voltage up to and including	Test voltage for basic insulation or supplementary insulation	Test voltage for reinforced insulation
kV peak	kV peak or d.c.	
0,33	0,43	0,53
0,5	0,65	0,8
0,8	1,04	1,28
1,5	1,95	2,4
2,5	3,25	4
4	5,2	6,4
6	7,8	9,6
8	10,4	12,8
12	15,6	19,2
U_P [a]	1,3 × U_P [a]	1,6 × U_P [a]
Linear interpolation may be used between the nearest two points.		

IEC 62368-1簡述

防火外殼要求

- PS3線路必須要符合fire enclosure不能只使用fire barrier
- Fire enclosure or fire barrier需使用V-1以上的材質, 但假設與PIS距離不符合以下要求則必須升級使用到V-0材質

A **fire enclosure** or fire barrier made of **combustible material** shall:

– have a minimum distance of 13 mm to an **arcing PIS**; and

– have a minimum distance of 5 mm to a **resistive PIS**.

IEC 62368-1簡述

■ 防火外殼要求(Cont.)

- 內部線材要求

6.5 Internal and external wiring

6.5.1 Requirements

In PS2 circuits or PS3 circuits, the insulation on internal or external wiring shall pass the test methods described below.

For conductors with a cross-sectional area of 0,5 mm^2 or greater, the test methods in IEC 60332-1-2 and IEC 60332-1-3 shall be used.

For conductors with a cross-sectional area of less than 0,5 mm^2, the test methods in IEC 60332-2-2 shall be used.

For both internal and external wiring, the test method described in IEC/TS 60695-11-21 may be used instead of the test methods in IEC 60332-1-2, IEC 60332-1-3 or IEC 60332-2-2.

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實例解說

ENERGY SOURCE CLASSIFICATIONS:

(Note: 1: Identify the following six (6) energy source forms based on the origin of the energy source.)
(Note: 2: The identified classification e.g., ES2, TS1, should be with respect to an ordinary person.
Additionally identify where an energy source is declared to be operating at the most onerous level.)

Electrically-caused injury: (Note: Identify type of source, list sub-assembly or circuit designation and corresponding energy source classification.) Example: DC and low frequency sources:	+5 V dc input – ES1
Source of injury	**Corresponding classification**
100-240V AC mains	ES3
+12Vdc SELV circuit	ES1
Electrically- caused fire (Note: List sub-assembly or circuit designation and corresponding energy source classification.) Example: Battery pack (maximum 85 watts):	PS2
Source of fire	**Corresponding classification**
100-240V AC mains	PS3
+12Vdc, 2.5A SELV circuit	PS2
Chemically-caused injury (Note: Specify hazardous chemicals, whether produces ozone or other chemical construction not addressed as part of the component evaluation.) Example: Liquid in filled component:	Glycol
Source of hazardous chemicals	**Corresponding chemical**
None	
Mechanically-caused injury (Note: List moving part(s), fan, special installations, etc. and corresponding MS classification based on Table 4D.) Example: Wall mount unit: – mass 11 kg	MS2
Source of injury	**Corresponding classification**
Sharp edge	MS1
Thermal burn injury (Note: Identify the surface or support, and corresponding energy source classification based on type of part, location, operating temperature and contact time in Table 4C.) Example: Hand-held scanner – thermoplastic enclosure	TS1 (when operating temperature < 45°C)
Source of injury	**Corresponding classification**
Metal enclosure (<70°C)	TS2
Radiation (Note: List the types of radiation present in the product and the corresponding energy source classification.) Example: DVD – Class 1 Laser Product	RS1
Type of radiation	**Corresponding classification**
None	

Service

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醫療器材設備(Medical Electrical Equipment)的EMC電磁相容檢驗




IEC 60601-1-2:2007 Ed.3

Medical Electrical Equipment - Part 1 - 2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

IEC 60601-1-2

Emission Testing:

CISPR 11	工業、科學和醫療類產品電磁干擾檢測
IEC 61000-3-2	電源諧波干擾檢測
IEC 61000-3-3	電壓變動閃爍干擾檢測
CISPR 22	資訊類產品電磁干擾檢測
CISPR 15	燈具類產品電磁干擾檢測
CISPR 14-1	電器類產品及系統電磁干擾檢測(家用、可攜型工具等)

Immunity Testing:

IEC 61000-4-2	**ESD**	Electrostatic Discharge
IEC 61000-4-3	**RS**	RF Radiated Immunity
IEC 61000-4-4	**EFT**	Electrical Fast Transients/Burst Surge Immunity
IEC 61000-4-5	**Surge**	Surge Immunity
IEC 61000-4-6	**CS**	Conducted RF Immunity
IEC 61000-4-8	**PFMF**	Power Frequency Magnetic Field Immunity
IEC 61000-4-11	**Dips**	Voltage Dips & Interruptions on Supply Line

EMISSIONS

- Protection of radio services — Requirements and Tests
- Protection of the PUBLIC MAINS NETWORK — Requirements and Tests

IEC 60601-1-2

- Protection of radio services — Requirements
- 設備的分組
  - 1組：為發揮其自身功能的需要而有意產生和（或）使用傳導耦合射頻能量的所有工科醫設備。
  - 2組：為材料處理、電火花腐蝕等功能的需要而有意產生和（或）使用電磁幅射射頻能量的所有工科醫設備。

IEC 60601-1-2

- Protection of radio services — Requirements
- 設備分類
  - A類：非家用和不直接連接到住宅低壓供電網設施中使用的設備。
  - B類：家用和直接連接到住宅低壓供電網設施中使用的設備。

IEC 60601-1-2

- Protection of radio services — Requirements
- 簡單電氣器件
  - 只包括簡單電氣器件(如：電動機、開關)、工作頻率低於9kHz的設備，可根據CISPR 14-1 進行分類及測試。
  - 該項允許對簡單的設備根據較寬鬆要求的CISPR 14-1 進行測試，該標準主要針對較低頻傳導發射的要求。

IEC 60601-1-2

- Protection of radio services — Requirements
- 照明設備
  - 對於獨立照明設備（例如：手術室的照明裝置），可根據 CISPR 15 進行分類和測試。
  - 該項允許此類照明設備可根據較寬鬆要求的 CISPR 15 進行測試，同上一項一樣，它也是標準中可放寬要求的一部分。

IEC 60601-1-2

- Protection of radio services — Requirements
- 資訊設備（ITE）
  - 與設備和系統連接的ITE可按CISPR 22分類，但受下列限制：

    CISPR 22的B類設備可與CISPR 11的A類或B類系統一起使用，但是CISPR 22的A類設備僅可與CISPR 11的A類系統一起使用。

IEC 60601-1-2

- Protection of radio services — Requirements
- **規定僅用於遮罩場所的設備和系統**
  - 對於規定僅用於遮罩場所的設備和系統，當在試驗場進行試驗時，只有最低RF遮罩效能的技術要求滿足5.2.2.3 b中所規定的要求，CISPR 11的電磁幅射限值才可增加，該增加值最多可達到相應最低RF遮罩效能的規定值。
  - 對於規定僅用於遮罩場所的設備和系統，當在試驗場進行試驗時，只有最小RF濾波衰減的技術要求滿足5.2.2.3 b中所規定的要求，CISPR 11的電源端電壓限值才可增加，該增加值對於從遮罩場所引出的所有電纜最多可達到相應最小到濾波衰減的規定值。

IEC 60601-1-2

- Protection of radio services — Requirements
- 含有無線電設備的設備和系統
  - 對於含有已進行了試驗的無線電設備、且該無線電設備符合適用的國家無線電法規的設備和系統，如果適用的國家無線電法規的發射限值小於或等於CISPR相對應的國家標準的電磁騷擾限值，該設備和系統可免予測試。含有RF發射機的設備和系統，在發射機的專用發射頻段裡免予本標準的發射要求。否則本標準的發射要求應適用，對於僅用在沒有國家無線電法規的國家中的設備和系統，本本標準的發射要求應適用。

IEC 60601-1-2

- Protection of radio services — Tests
- 應採用CISPR相對應的國家標準的測試方法。但有下列規定的說明和例外。
  - 患者電纜
    - 患者耦合電纜應視為互連電纜，所用的任何患者耦合電纜終端應在測試文件中說明。
    - 如果需要模擬患者生理信號來模擬設備或系統的正常運行，則應該提供。
    - 在測試期間，患者耦合點對地不應有刻意的導體或電容連接。患者耦合點與地之間的分佈電容量應不大於250pF。

IEC 60601-1-2

- Protection of radio services — Tests
- 應採用CISPR相對應的國家標準的測試方法。但有下列規定的說明和例外。
  - 子系統
    - 通過提供模擬正常運行條件對系統的每個子系統進行測試，可驗證其是否符合CISPR 11的要求。
    - 任何用來替代實際設備的模擬器應完全模擬介面的電氣特性和在某些情況下的機械特性，尤其要注意RF信號和阻抗以及電纜的配置和型號。

IEC 60601-1-2

- Protection of radio services — Tests
- 應採用CISPR相對應的國家標準的測試方法。但有下列規定的說明和例外。
  - 大型永久安裝設備和系統
    - 結構上不宜進行子系統模擬運行的大型永久安裝設備和系統，可在典型的使用場所進行型式測試。

Protection of the PUBLIC MAINS NETWORK — Requirements and Tests

- Harmonic distortion(諧波失真)的要求和試驗方法
- Voltage fluctuations and flicker 的要求和試驗方法

Harmonic distortion的要求和試驗方法

- 要求
  - 每相額定輸入電流小於等於16A且預期與公共電網連接的設備和系統，應符合IEC 61000-3-2中諧波失真的限值要求。
  - 如果設備和系統既有長期又有瞬時電流額定值，則應使用較高的額定值來確定是否適用IEC 61000-3-2。
- 測試方法
  - 依IEC 61000-3-2規定的測試方法和測試設備。
- 注意：指定在醫院或其它場所、使用自有配電系統（通過變壓器從公共電網中隔離出來）的設備，豁免於本要求。

Voltage fluctuations and flicker 的要求和試驗方法

- 要求
  - 每相額定輸入電流小於等於16A且預期與公共電網連接的設備和系統，應符合IEC 61000-3-3中關於電壓的波動和閃爍的要求。
  - 如果設備和系統既有長期又有瞬時電流額定值，則應使用較高的額定值來確定是否適用IEC 61000-3-3 。
- 測試方法
  - 依IEC 61000-3-3規定的測試方法和測試設備。
- 注意：注意：指定在醫院或其它場所、使用自有配電系統（通過變壓器從公共電網中隔離出來）的設備，豁免於本要求。

Immunity

IEC 61000-4-2	ESD	Electrostatic Discharge
IEC 61000-4-3	RS	RF Radiated Immunity
IEC 61000-4-4	EFT	Electrical Fast Transients/Burst Surge Immunity
IEC 61000-4-5	Surge	Surge Immunity
IEC 61000-4-6	CS	Conducted RF Immunity
IEC 61000-4-8	PFMF	Power Frequency Magnetic Field Immunity
IEC 61000-4-11	Dips	Voltage Dips & Interruptions on Supply Line

IEC 60601-1-2

- Compliance criteria (**6.2.1.10**)
  - 若干與基本性能有關的降級模式是被禁止的，包括：
    - 器件故障；
    - 可程式設計參數的改變；
    - 工廠初始值的復位（製造商的預設值）；
    - 工做模式改變；
    - 錯誤警報；
    - 任何預期運行的終止或中斷，即使伴有警報；
    - 任何非預期運行的產生，包括非預期或非受控的動作，即使伴有警報；
    - 顯示數值的誤差大到足以影響診斷或治療；
    - 波形上的雜訊，妨礙診斷, 診療與監測；
    - 圖像上的偽影或失真，妨礙診斷, 診療與監測；
    - 自動診斷, 診療設備和系統在進行診斷, 診療時失效，即使伴隨著警報。

– 性能降級但與符合性判據一致的例子：

- 影像系統顯示的可能是變更過的圖像，但是它在某種程度上是可識別的，且不會對診斷或治療產生影響。

IEC 60601-1-2

Electrostatic Discharge

- IEC 61000-4-2
  - 2kV, 4kV, 6kV contact discharge
  - 2kV, 4kV, 8 kV air discharge

靜電放電（ESD）IEC 61000-4-2

- 試驗方法
  - 適用IEC 61000-4-2規定的試驗方法和設備，但有以下修改：
    - 放電間隔時間起始值應為1s，為了能夠區分單次放電回應和多次放電回應，可能要求更長的放電間隔時間。
    - 接觸放電應適用於設備或系統的可觸及導電部件和耦合平面。
    - 空氣放電應適用於設備或系統的非導電的可觸及部件和可觸及部件中導電的不可觸及部分，如果設備或系統的連接器附近標有IEC 60417-5134符號，則該連接器免予此項試驗。

Radiated Immunity
IEC 61000-4-3

- 要求
  - 一般對非生命支援設備,測試頻率80 MHz to 2,5 GHz, 3 V/m的場強。
  - 對生命支持設備,測試頻率80 MHz to 2,5 GHz, 10 V/m的場強。
  - 規定僅用於遮罩場所的生命支援設備可以以低於10 V/m的場強，非生命支援設備以低於3V/m的場強進行測試。該場強取決於設備的技術描述中指定的遮罩效能和濾波衰減。
  - 帶射頻通信接收器的設備不應以其接收該類信號的頻帶進行測試。

Electrical Fast Transients
IEC 61000-4-4

- 要求
  - 設備基本性能應可承受 ±2kV 的 ac.及 dc.電源線湧沖以及超過3米長度的信號電纜和互連電纜 ±1kV 的湧沖。

患者耦合電纜不直接測試但應保留在測試過程中

Surge
IEC 61000-4-5

- 要求
  - 應就 ±0.5 kV、±1 kV和 ±2 kV（交流電源線對地）以及 ±0.5 kV和 ±1 kV（交流電源線對線）進行測試。
  - 設備和系統的所有其他電纜不直接測試。
  - 在初級電源電路中沒有surge保護裝置的設備和系統，可只做 ±2 kV線對地和 ±1 kV線對線的測試。
  - 沒有任何接地互連的Ⅱ類設備和系統免予線對地測試。

Conducted RF Immunity
IEC 61000-4-6

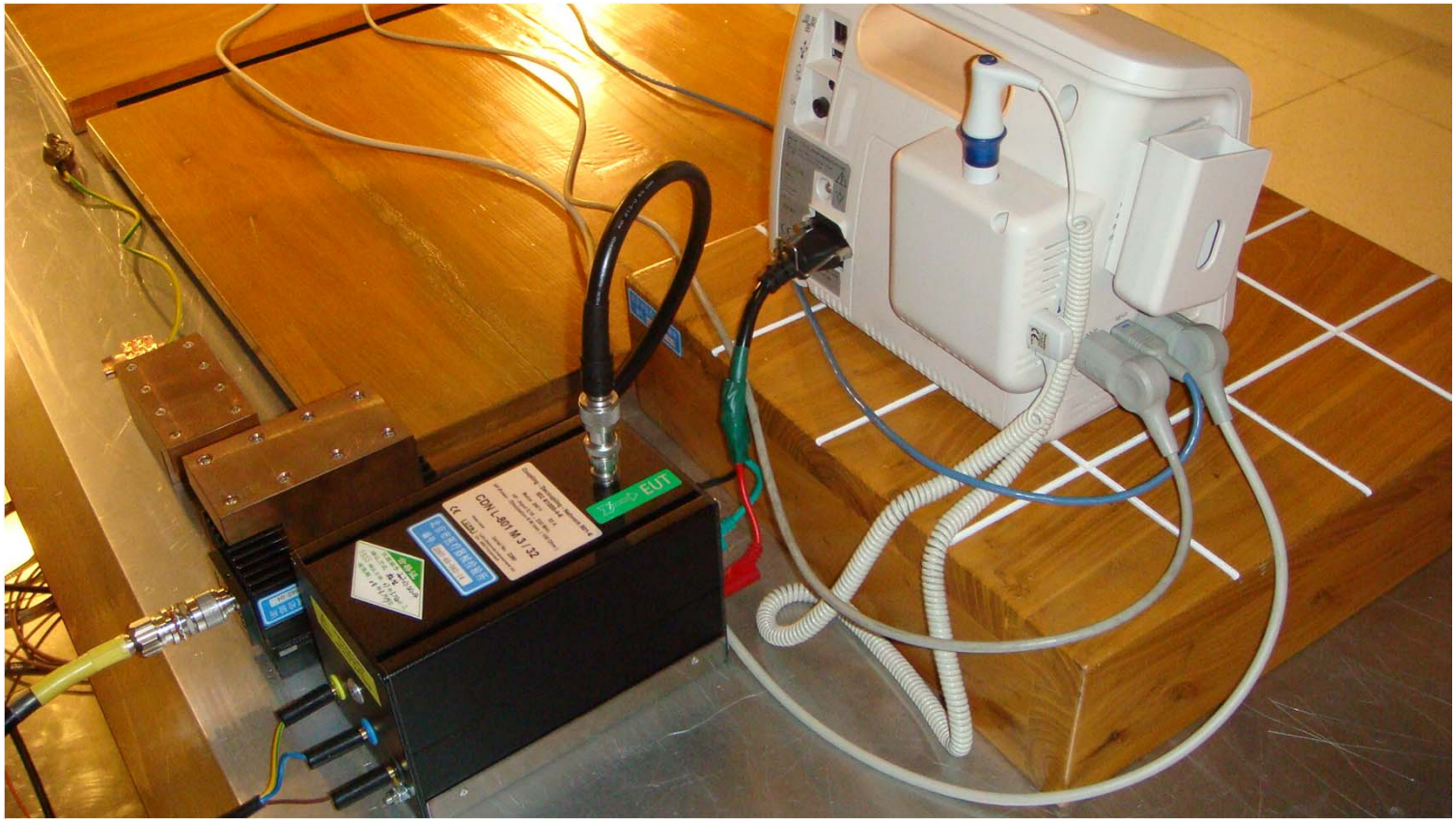
- 要求

應對設備起始頻率至80 MHz頻率範圍內以3 V rms進行測試。對於生命支援設備，還應在起始頻率至80 MHz之間的工科醫（ISM）頻段內以10 V rms進行測試。

Conducted RF Immunity
IEC 61000-4-6

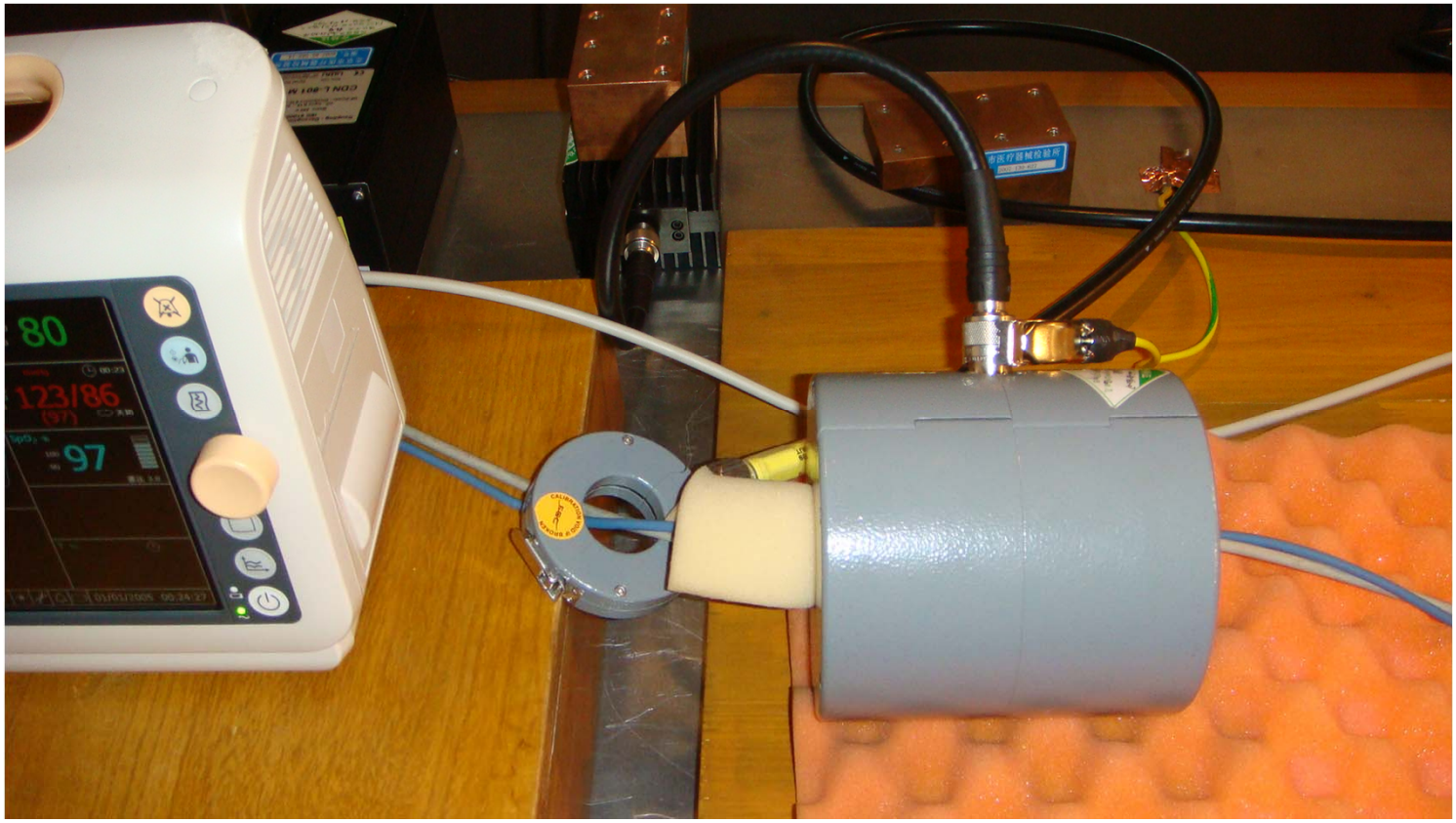
CDN

Conducted RF Immunity
IEC 61000-4-6



CDN

Conducted RF Immunity
IEC 61000-4-6

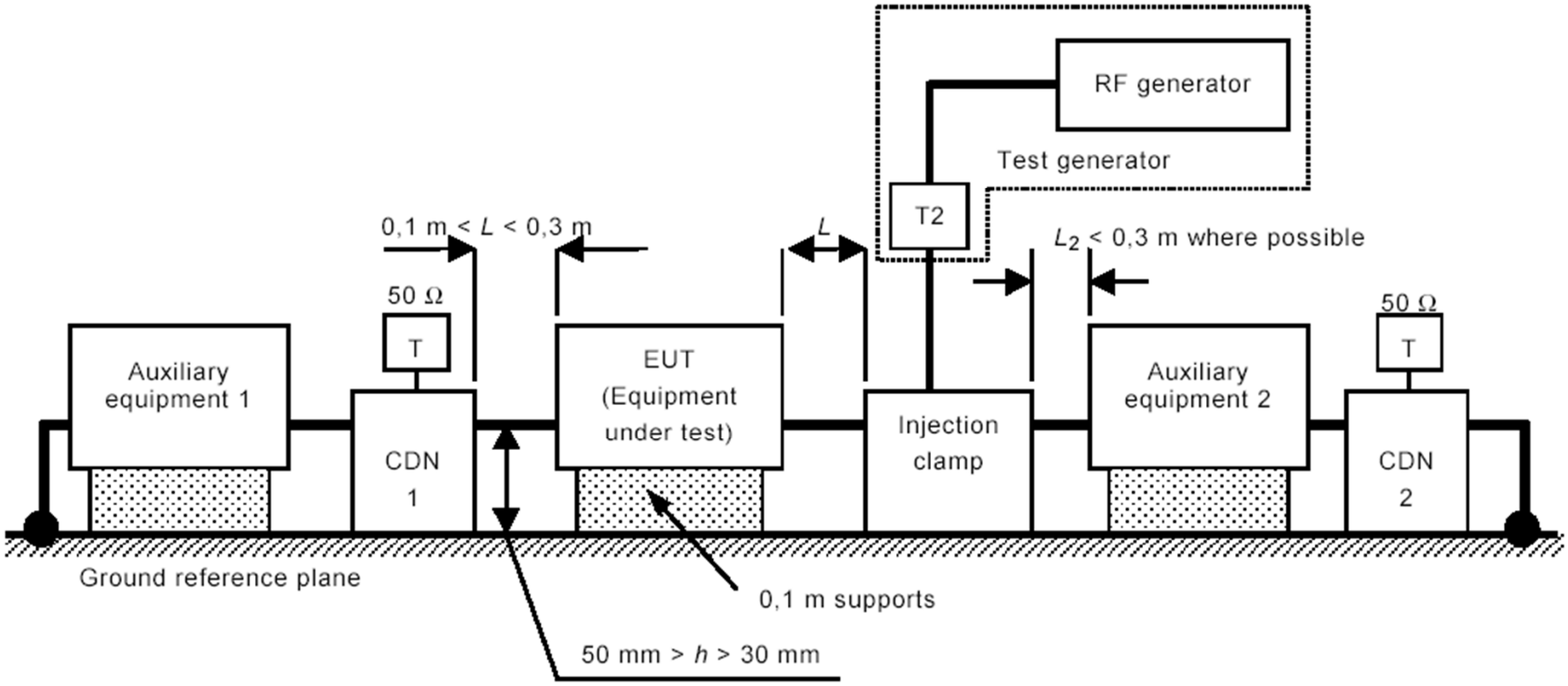


電流鉗

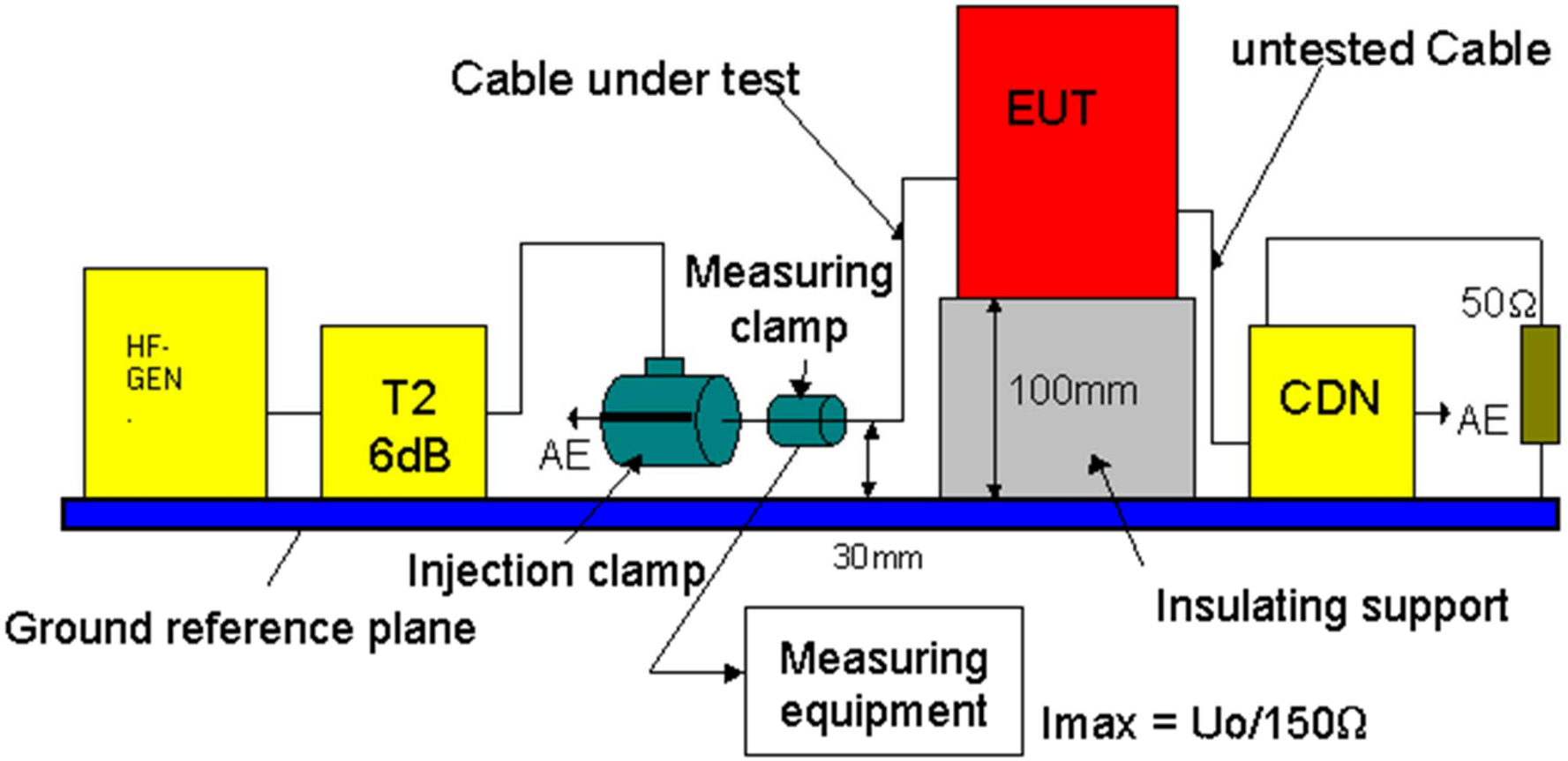
Conducted RF Immunity
IEC 61000-4-6

Clamp

Conducted RF Immunity
IEC 61000-4-6



Conducted RF Immunity
IEC 61000-4-6



Power frequency magnetic field IEC 61000-4-8

- 要求
  - 應根據IEC 61000-4-8，就3 A/m在所有工作電源頻率中的磁場，對設備進行其基本性能的測試。

Voltage Dips
IEC 61000-4-11

- 要求
  - 額定輸入功率為1kVA或低於1kVA的設備和系統以及所有生命支持的設備和系統，應依表 10 規定測試以符合6.2.1.10的要求。
  - 對於額定輸入功率大於1 kVA和額定輸入電流小於或等於每相16A的非生命支援設備和系統，只要設備和系統保持安全，不發生組件損壞並通過操作者干預可恢復到測試前狀態，則允許在表依表 10 規定偏離6.2.1.10的要求。

Voltage Dips
IEC 61000-4-11

- 要求（續）
  - 額定輸入電流超過每相16A的非生命支援設備和系統，免除表10 規定的測試。
  - 只要設備和系統保持安全，不發生組件損壞並通過操作者干預可恢復到測試前狀態，則允許在表依表11 規定偏離6.2.1.10的要求。
  - 生命支援設備和系統在使用時，如果偏離6.2.1.10要求的允差，應提供適用的符合國際標準警報，以指示與基本性能有關的預期運行的終止或中斷。

Voltage Dips
IEC 61000-4-11

Table 10 – IMMUNITY TEST LEVELS for voltage dips

Voltage test level % U_T	Voltage dip % U_T	Duration periods
< 5	> 95	0.5
40	60	5
70	30	25

NOTE U_T is the a.c. MAINS VOLTAGE prior to application of the test level.

Voltage Dips
IEC 61000-4-11

Table 11 - IMMUNITY TEST LEVEL for voltage interruption

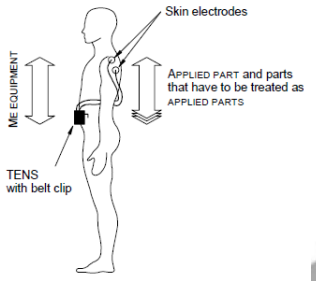
Voltage test level % U_T	Voltage dip % U_T	Duration s
< 5	> 95	5
NOTE U T is the a.c. MAINS VOLTAGE prior to application of the test level.		

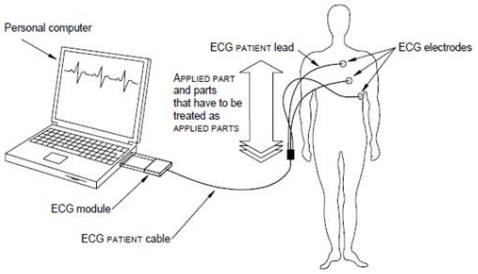
世 騰 認 證 集 團
Cerpass Group

Briefing on Differences Between 60950 and 60601

1. Applied Parts 的位置定義:

Part of ME equipment that in normal use necessarily comes into physical contact with the patient for ME equipment or an ME system to perform its function.





2. MOPP 及 MOOP 的分等要求:

- MEANS OF PATIENT PROTECTION (MOPP) (For patient contact parts)
- MEANS OF OPERATOR PROTECTION (MOOP) (For operator contact parts)
- 2 MOOP/MOPP = Double/Reinforced Insulation
- 1 MOOP/MOPP = Basic Insulation

3. Comparison:

Item	60950	60601 MOOP (for Power and IT)	60601 MOPP (for Power and IT)
Insulation Class	I, II, III	I, II and Internally powered (Internally powered equipment that also connect to a supply mains shall comply with the requirements for class I or class II while so connected, and with the requirements for internally powered equipment while not so connected.)	
Hipot	B/I: 1500Vac D/I:3000Vac	Same as 60950	B/I: 1500Vac D/I:4000Vac
Creepage Distance (Interpolation is allowed)	Working voltage: 300Vrms B/I: 3.2mm D/I: 6.4mm	Same as 60950	Working voltage: 250Vrms B/I: 4.0mm D/I: 8.0mm
			Working voltage: 300Vrms B/I: 4.7mm D/I: 9.4mm
Clearance (Interpolation is **NOT** allowed for 60601)	Working voltage: 300Vrms B/I: 2.0mm D/I: 4.0mm	Same as 60950	Working voltage: 250Vrms B/I: 2.5mm D/I: 5.0mm
			Working voltage: 300Vrms B/I: 3.5mm D/I:7.0mm
Opposite Polarity (L to N)	Creepage: 2.5mm Clearance: 1.5mm	Creepage: 3.0mm Clearance: 1.6mm	
Y Capacitor across Pri to Sec	One Y1 or Two Y2	Same as 60950	Two Y1
Leakage Current (Touch current)	Class I: 0.75mA/ 3.5mA Class II: 0.25mA	NC: 100uA (PE connected) SFC: 500uA (PE open, same as test condition of 60950) (No patient circuit involved)	

Item	60950	60601 MOOP (for Power and IT)	60601 MOPP (for Power and IT)
Heating (External Surface)	Limit: 75°C or 95°C max.	Limit: 48°C max. (Risk Analysis Allowed)	
Fuse	One is OK	One for Class II Two for Class I	
Class II USA Plug (1-15P)	Polarized or not	Polarized (unless both L and N have fuse)	
Color	No limit	Red for urgent only Yellow for caution	
外殼防火要求:	移動式產品 : V-1 固定式產品 : 5VB	移動式產品 : V-2 固定式產品 : V-1	
Discharge Test	After 1s：< 37% of initial voltage	After 1s：< 60V	
Triple Insulated Wire	Accepted 950 tested wire (3000V for B/I) (6000V for D/I)	Same as 60950	Tested per 60601-1 or else consider as basic insulation (3000V for B/I) (8000V for D/I)
Insulation Sheet	1 layer: S/I or R/I: >0.4mm 3 layers: By Hipot test	Same as 60950	
Input Marking of A, VA, or W	Max. only	Mark the upper and lower limits of the range(s), if the range(s) is > ± 10 % of the mean value of the given range	
Accessibility of Live part	Check by finger, pin and 50mm probe	Check by finger, pin, 4mm probe, hook	
Signal I/O e.g. RS232, USB, COM Port, etc.	No isolation required	No isolation required but the applicant could declare the isolation and we will test it accordingly	
Risk Management File (ISO 14971)	No need	● Power may or may not need to provide the RMF ● Other ITE or MEE need to provide the RMF	
Display	-	Need to specify in manual regarding the medical purpose	
PC / Tablet	-	If measuring function is involved, it needs to apply GMP (ISO 13485). Not a medical device if use for analyzing an image on a computer that is not connected to a patient and is located in an office.	

4. <u>UL CCN:</u>

QQHM2 for Medical Power

PIDF for Medical Devices

KFCV for Television/Video Equipment for Use in Health Care Facilities (UL 1492 or UL 60065)

Revision: E

IEC/EN 61010-1,-2-030, -2-032, -2-033, -2-081 & -2-101

安 規 簡 介

- 主講人：Jasson Shiu
- 日　　期：2014/1/16

Version Note

- **EN 61010-1:2010**

  Safety requirements for electrical equipment for measurement, control, and laboratory use

- **EN 61010-2-030:2010**

  Particular requirements for testing and measuring circuits

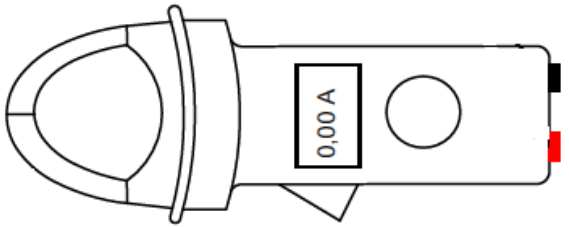
- **EN 61010-2-032:2012**

  Particular requirements for hand-held and hand-manipulated current sensors for electrical test and measurement

Version Note

- **EN 61010-2-033:2012**

  Particular requirements for HAND-HELD MULTIMETERS and other METERS, for domestic and professional use, capable of measuring MAINS voltage



- **EN 61010-2-081:2002/A1:2003**

  Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

  - FprEN 61010-2-081:2012 (Non-DOR)

- **EN 61010-2-101:2002**

  Particular requirements for in vitro diagnostic (IVD) medical equipment

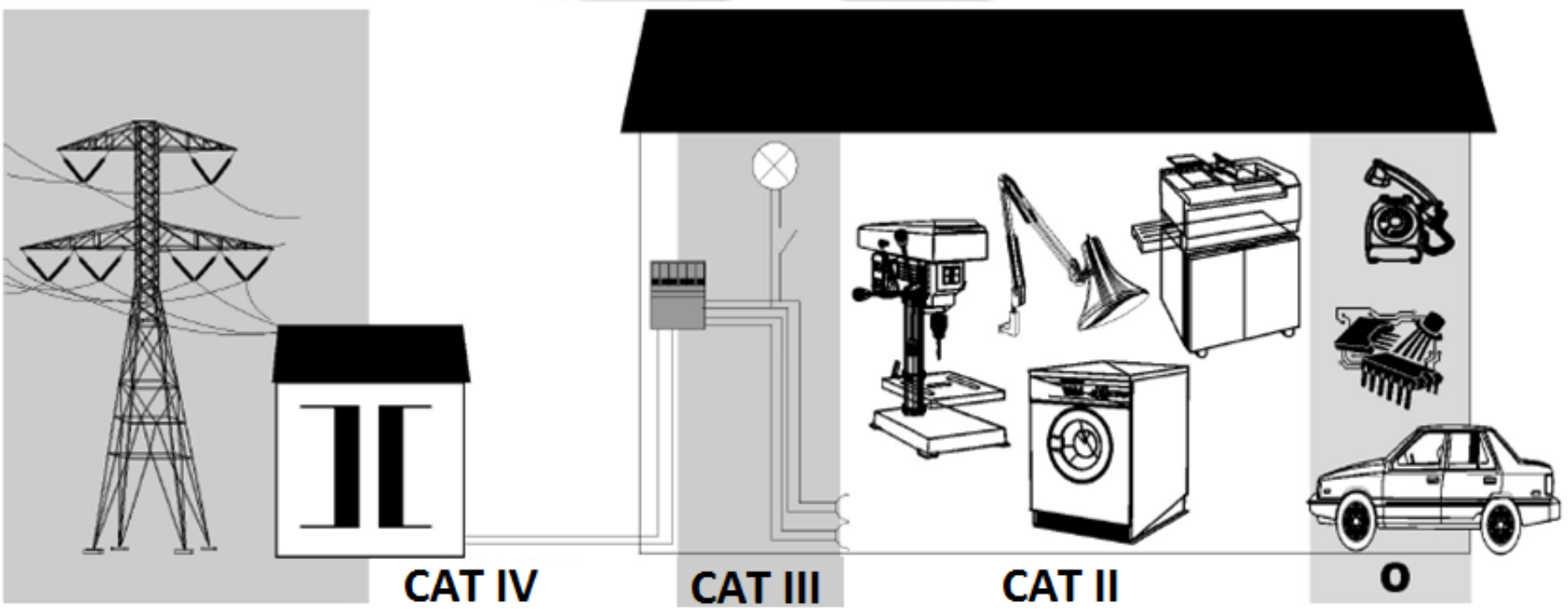
  - FprEN 61010-2-101:2012 (Non-DOR)

Version Note

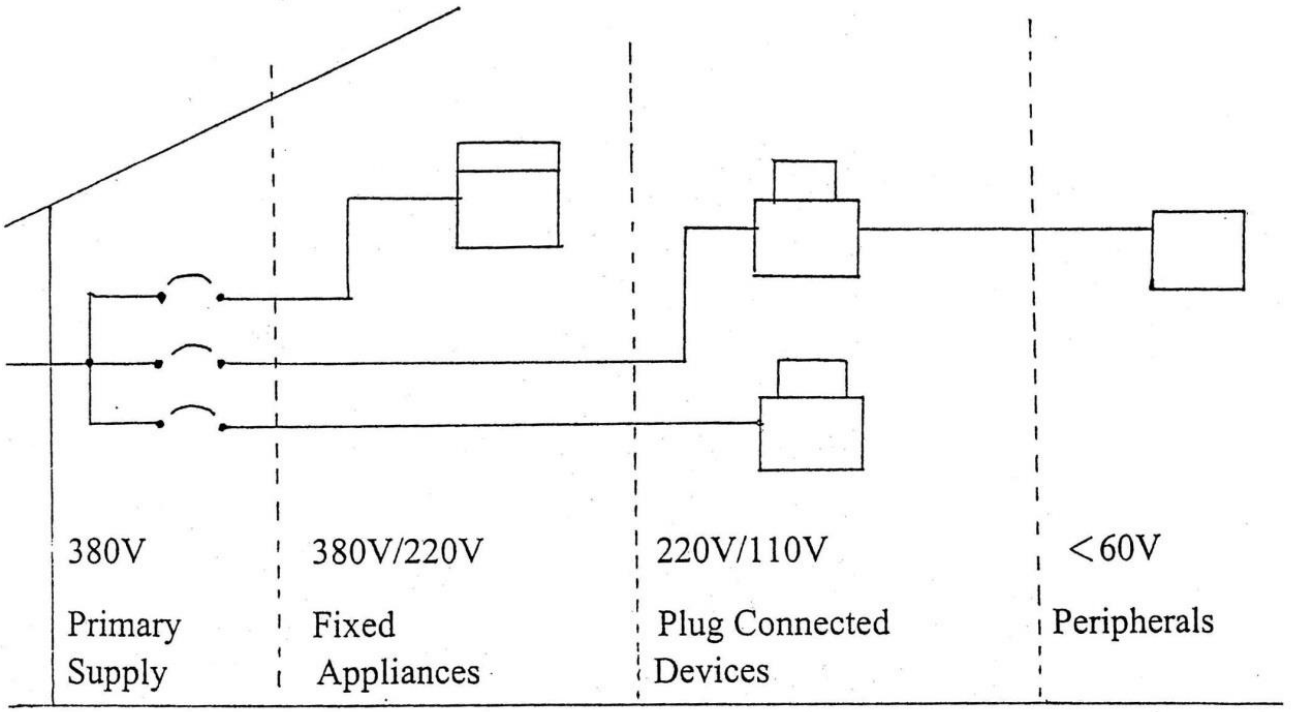
- For equipment with testing and measuring circuit, -2-030 should be used.
- If -2-032 is applicable, no -2-030 is needed.
- For meters that measuring the mains circuit, -2-033 should be used.
- But for a hand-held clamp meter with V/COM terminals, both -2-033 and -2-032 are needed

Installation Category (CAT)

- **Installation Category (CAT) (-2-030)**



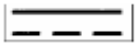
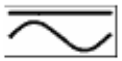
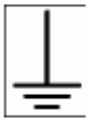
Installation Category (CAT)



Category:	IV	III	II	I
Surge Voltage:	6000V	4000V	2500V	500V

Marking Symbol

Table 1 – Symbols

Number	Symbol	Reference	Description
1		IEC 60417-5031 (2002-10)	Direct current
2		IEC 60417-5032 (2002-10)	Alternating current
3		IEC 60417-5033 (2002-10)	Both direct and alternating current
4		IEC 60417-5032-1 (2002-10)	Three-phase alternating current
5		IEC 60417-5017 (2006-08)	Earth (ground) TERMINAL
6		IEC 60417-5019 (2006-08)	PROTECTIVE CONDUCTOR TERMINAL
7		IEC 60417-5020 (2002-10)	Frame or chassis TERMINAL
8			Not used

Marking Symbol

9		IEC 60417-5007 (2009-02)	On (Power)
10		IEC 60417-5008 (2009-02)	Off (Power)
11		IEC 60417-5172 (2003-02)	Equipment protected throughout by DOUBLE INSULATION or REINFORCED INSULATION
12			Caution, possibility of electric shock
13		IEC 60417-5041 (2002-10)	Caution, hot surface
14		ISO 7000-0434B (2004-01)	Caution [a]
15		IEC 60417-5268 (2002-10)	In position of a bi-stable push control
16		IEC 60417-5269 (2002-10)	Out position of a bi-stable push control
17		ISO 361	Ionizing radiation

Number	Symbol	Publication	Description
101	 Background colour – yellow; symbol and outline – black.	ISO 7000 – 0659	Biohazard
102	LOT	EN 980, subclause 4	Batch code

Marking

■ 在產品的本體上須標示：

- 商標;
- 型號;
- 電氣規格 :

  (如: 100-120 / 220-240 V ~, 50/60 Hz, 100 W, 110 VA)

  - 註1: 可以只標W值、A值或VA值
  - 註2: 實測的W值、A值或VA值不能大於額定值的110%
  - 註3: 電池操作的產品不必標示W值、A值或VA值
  - 註4:若額定電壓是一個範圍，在電壓上限及下限實測到的W值若大於W中值20%，則須分開標示W值。

Marking

- **量測端子須標示其CAT值、電壓值及交直流符號。**
  - 註1: CAT為Measurement (Installation) Category的縮寫，請參照附圖
  - 註2: 若量測對象是限在50Vac或120Vdc以下或量測對象是不能在活電狀況下，則不必標示CAT值，亦不鼓勵
  - 註3: 對於勾表，其勾部亦須加標CAT值、電壓值及交直流符號。
- **量測端子須標示符號Symbol 14  。(From:-2-030)**
- **其他安全警語，如將所有Test Leads移除再進行保養、清潔或更換Fuse及Battery。若空間不夠，可只標Symbol 14  而另在manual 警示.**

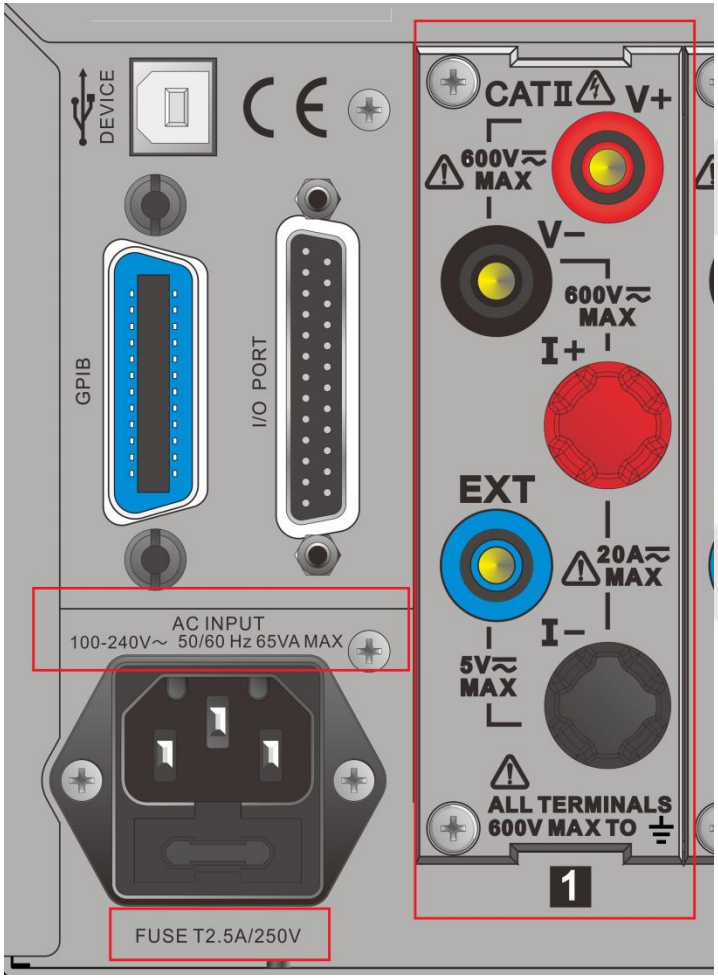
Marking

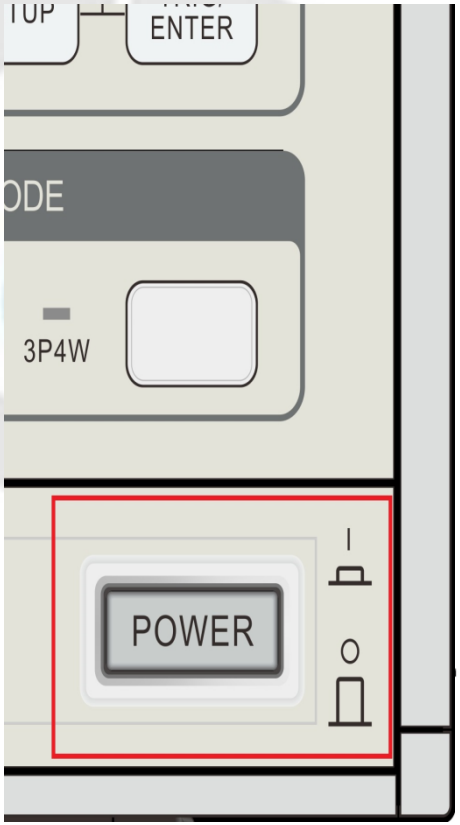
- **紅鈕只能用於急停或危險的開關 (From:-1:2010)**
- **適用的標示Symbol，請見附表**
  - 註1: 若有Inlet，Symbol 6  可以不標
  - 註2: Symbol 7  適用於示波器或耐電壓測試儀等負端可能接大地的儀器
  - 註3: 若輸出電壓大於1kVrms或1.5kVdc，則要標示Symbol 12 
  - 註4: Symbol 9 及10  僅能用在電源開關，而Push-Push Switch則用Symbols 9/15  及10/16  來表示

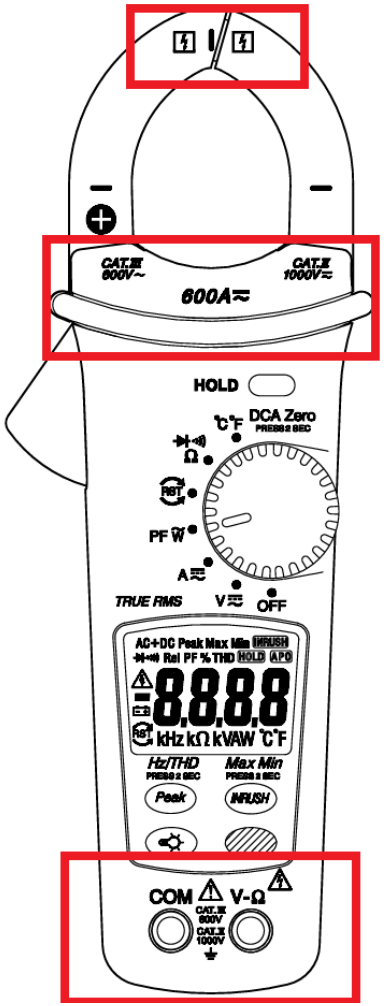
Marking

- 註5: Symbol高度須為2.75mm以上，警告文字須為1.5mm以上
- 註6: Symbol及警告文字若用刻模時，均須2mm以上；若無色差，則須凸出或凹入0.5mm以上
- 註7: 對於勾表，其勾部須加標 
- 註8:電源開關不能只以指示燈標示開關狀態
- 註9: symbol 17, 增加輻射符號  (Ionizing radiation)
  (From:-1:2010)

Marking Example







Manual Requirement

- **在手冊上須標示：**
  - 產品用途
  - 技術規格 (含所有輸入及輸出的規格)
  - 操作方法
  - 清潔方式
  - 耗材(如電池或保險絲等)的規格及其更換方法
  - 維修中心或銷售商的名字及地址

Manual Requirement

- 安全注意事項
- 產品的環境規格，如下:
  - Indoor Use
  - Altitude: 2000 m
  - Temperature: 5℃ to 40℃
  - Humidity: Maximum 80%RH at 31℃ decreasing to 50%RH at 40℃
  - Transient overvoltage at Mains Supply: 2500V
  - Pollution Degree: 2
- **Manual可只用電子方式(如光碟)提供，但安全注意事項一定要有紙本 (From -1:2010)**
- 所有產品上的標示

Manual Requirement

- **CAT 的相關解釋 (當產品有標CAT值時)， 如：**
  - CAT IV – Is for measurements performed at the source of the low-voltage installation.
  - CAT III – Is for measurements performed in the building installation.
  - CAT II – Is for measurement performed on circuits directly connected to the low voltage installation.
  - ~~CAT I – Is for measurement performed on circuits not directly connected to mains.~~ (Changed by -2-030:2010)
- **Symbol的解釋，如Symbol的附表。**
- **Manual shall indicate the CAT and V of the probe assemblies to be used for MAINS measurements. (From -2-033)**

Manual Requirement

■ 對於勾表，須加入以下文字：

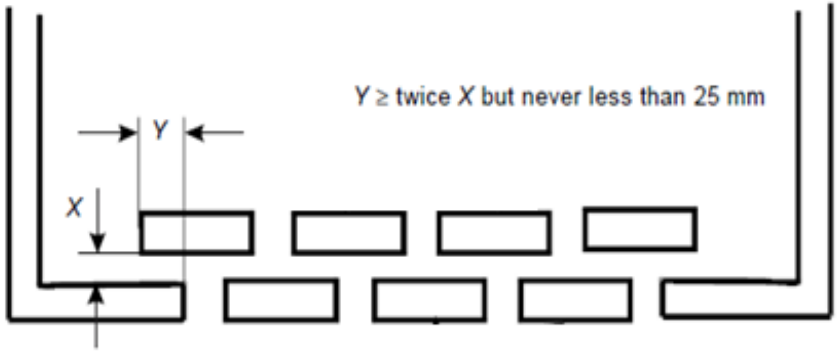
- Individual protective equipment must be used if hazardous live parts in the installation where measurement is to be carried out could be accessible.
- The barrier on the JAW is indicating the limit of safe access of the hand-held part, do not over the barrier when in normal use.
- Do not use a flexible current sensor if the inner contrasting color of the insulation of the flexible cord is visible.
- If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

Protection against electric shock

- **HAZARDOUS LIVE(活電部位): (Normal condition)**
  - Above the a.c. voltage levels are
    33 V r.m.s, 46,7 V peak and the d.c voltage level is 70 V.
  - for equipment intended for use in WET LOCATIONS,
    the a.c. voltage levels are 16 V r.m.s, 22,6 V peak and the d.c voltage level is 35 V.
  - 若某線路電壓的小於安全電壓 (33Vrms、46.7Vp或70Vdc)，但和 Mains circuit沒有足夠的絕緣，該線路亦視為危險線路，不得觸及。
  - 即便和 Mains circuit 有足夠的絕緣，若電壓大於 33Vrms、46.7Vp 或 70Vdc，該線路亦視為危險線路，不得觸及。

Enclosure Requirement

- **外殼的開孔不能使Test Finger 可以觸及活電部位。**
  - 註 1: Locking Type 及 Screw-Held Type 的量測端子不在此限
  - 註 2: 須由使用者更換的耗材，其外蓋須有警語且須用工具方能打開
- **上蓋的開孔，其寬度不能大於4mm。**
- **下蓋最好不要有開孔。**
- **若下蓋要開孔，須符合以下其一:**



Acceptable perforation of the bottom of an ENCLOSURE

Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm²)
0,66	1,19	2,36
0,76	1.15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm²)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

Enclosure Requirement

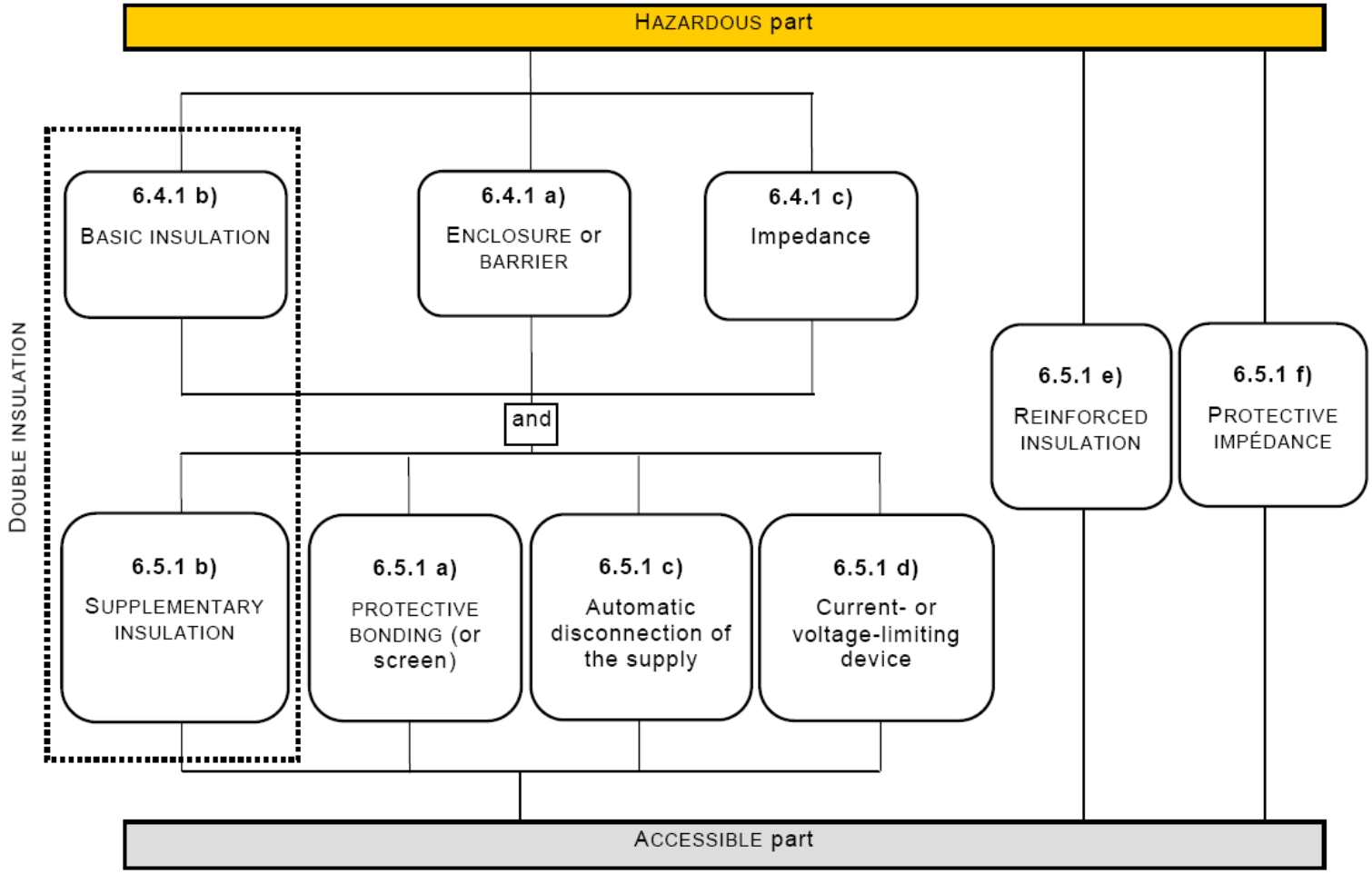
- 桌上式產品，其外殼須承受三次5 J的撞擊 (用500g的鋼球由1m高度落下)，勾部亦同。
- 手持式產品，須進行1m的落下測試。
- 塑膠外殼須為V-1等級或以上。
- 把手須能承受產品4倍的重量達1分鐘。
- 超過18kg的產品須提供把手，或在說明書內說明搬移方式。

Grounding Requirement

- Class I 產品的金屬外殼均須接大地
- 接地線的線徑不能小於電源線
- 接地線須為黃綠線
- 電氣螺絲須有spring washer 或 star washer

- 接地端子不可由外部鬆開，亦不可用來固定其他元件
- 和外部電源線相接的接地端須標上symbol 6 ⏚

Insulation Requirement



Clearance and Creepage

TABLE 4 – CLEARANCES and CREEPAGE DISTANCES for MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V

Voltage line-to-neutral a.c. r.m.s. or d.c.	Values for CLEARANCE	Values for CREEPAGE DISTANCE								
		Printed wiring board material		Other insulating material						
		POLLUTION DEGREE 1	POLLUTION DEGREE 2	POLLUTION DEGREE 1	POLLUTION DEGREE 2			POLLUTION DEGREE 3		
		All material groups	Material groups I, II, IIIa	All material groups	Material group I	Material group II	Material group III	Material group I	Material group II	Material group III
V	mm	mm	mm	mm	mm	mm	mm	mm	mm	mm
≤150	0,5	0,5	0,5	0,5	0,8	1,1	1,6	2,0	2,2	2,5
>150 ≤ 300	1,5	1,5	1,5	1,5	1,5	2,1	3,0	3,8	4,1	4,7

- **From -1:2010**

Clearance

- Material Group 和 UL 的CTI比對如下:

Material Group	I	II	IIIa	IIIb
CTI	0	1	2-3	4

Plastics - Component

See General Information for Plastics - Component

CHI MEI CORPORATION E56070

59-1 SAN CHIA

									H	D	
		Min.		H	H	R T I			V	4	C
		Thk	Flame	W	A	Elec	Mech		T	9	T
Material Dsg	Color	mm	Class	I	I		Imp	Str	R	5	I
PA-765B(+)	ALL	1.5	V-2	4	0	80	65	80	2	7	0
		2.1	V-2	2	0	80	65	80			
		2.5	V-0, 5VB	2	0	80	65	80			
		3.0	V-0, 5VA	2	0	80	75	80			

Clearance

Component - Plastics E56070

CHI MEI CORPORATION

59-1 SAN CHIA, JEN TE, TAINAN HSIEN 717 TW

PA-765B(+)

Acrylonitrile Butadiene Styrene (ABS), "Polylac", furnished as pellets

Color	Min Thk (mm)	Flame Class	HWI	HAI	RTI Elec	RTI Imp	RTI Str
ALL	1.5	V-2	4	0	80	65	80
	2.1	V-2	2	0	80	65	80
	2.5	V-0, 5VB	2	0	80	65	80
	3.0	V-0, 5VA	2	0	80	75	80

Comparative Tracking Index (CTI): 0

Inclined Plane Tracking (IPT): -

Dielectric Strength (kV/mm): -

Volume Resistivity (10^x ohm-cm) : -

High-Voltage Arc Tracking Rate (HVTR): 2

High Volt, Low Current Arc Resis (D495): 7

Dimensional Stability (%): -

Creepage of secondary

Table 7 – CREEPAGE DISTANCES for secondary circuits

Secondary WORKING VOLTAGE a.c. r.m.s. or d.c.	Printed wiring board material		Other insulating material						
	POLLUTION DEGREE 1	POLLUTION DEGREE 2	POLLUTION DEGREE 1	POLLUTION DEGREE 2			POLLUTION DEGREE 3		
	All material groups	Material groups I, II or IIIa	All material groups	Material group I	Material group II	Material group III	Material group I	Material group II	Material group IIIb
V	mm	mm	mm	mm	mm	mm	mm	mm	mm
250	0,56	1,0	0,56	1,25	1,8	2,5	3,2	3,6	4,0
320	0,75	1,6	0,75	1,60	2,2	3,2	4,0	4,5	5,0
400	1,0	2,0	1,0	2,0	2,8	4,0	5,0	5,6	6,3
500	1,3	2,5	1,3	2,5	3,6	5,0	6,3	7,1	8,0
630	1,8	3,2	1,8	3,2	4,5	6,3	8,0	9,0	10,0
800	2,4	4,0	2,4	4,0	5,6	8,0	10,0	11	12,5
1 000	3,2 a	5,0 a	3,2	5,0	7,1	10,0	12,5	14	16
1 250			4,2	6,3	9,0	12,5	16	18	20
1 600			5,6	8,0	11	16	20	22	25
2 000			7,5	10,0	14	20	25	28	32
2 500			10,0	12,5	18	25	32	36	40
3 200			12,5	16	22	32	40	45	50
4 000			16	20	28	40	50	56	63
5 000			20	25	36	50	63	71	80
6 300			25	32	45	63	80	90	100
8 000			32	40	56	80	100	110	125
10 000			40	50	71	100	125	140	160

- **From -1:2010**
- **Creepage for measuring circuit is same as this table.**

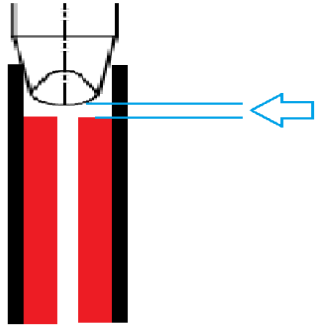
Clearance of secondary

Table 6 – CLEARANCES and test voltages for secondary circuits derived from MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V

Secondary WORKING VOLTAGE		MAINS voltage, line-to-neutral, OVERVOLTAGE CATEGORY II			
		≤ 150 V a.c. r.m.s.		> 150 V ≤ 300 V a.c. r.m.s.	
a.c. r.m.s. V	d.c. or a.c. peak V	CLEARANCE mm	Test voltage V a.c. r.m.s.	CLEARANCE mm	Test voltage V a.c. r.m.s.
16	22,6	0,10	500	0,50	840
33	46,7	0,11	510	0,52	850
50	70	0,12	520	0,53	860
100	140	0,13	540	0,61	900
150	210	0,16	580	0,69	940
300	420	0,39	770	0,94	1 040
600	840	1,01	1 070	1,61	1 450
1 000	1 400	1,92	1 630	2,52	1 970
1 250	1 750	2,50	1 960	3,16	2 280
1 600	2 240	3,39	2 390	4,11	2 730
2 000	2 800	4,49	2 890	5,30	3 230
2 500	3 500	6,02	3 520	6,91	3 850
3 200	4 480	8,37	4 390	9,16	4 660
4 000	5 600	10,9	5 320	11,6	5 610
5 000	7 000	14,0	6 590	14,9	6 960
6 300	8 820	18,2	8 270	19,1	8 620
8 000	11 200	23,9	10 400	24,7	10 700
10 000	14 000	30,7	12 900	31,6	13 300

Clearance and Creepage of Measuring Terminal

- **Spacing for terminals:**
  - Unmated position and test by test finger (From -2-030 , -2-032 and -2-033)



  - Components, sensors, and devices intended to be connected to specialized measuring circuit TERMINALS shall not be ACCESSIBLE. Examples of specialized TERMINALS are semiconductor measuring terminal, capacitance measurements terminal, or thermocouple sockets. (From -2-033)

Clearance and Creepage of Measuring Terminal

Voltage on conductive parts of TERMINAL		CLEARANCE and CREEPAGE DISTANCE
V a.c. r.m.s.	V d.c.	mm
≥33 ≤ 300	≥70 ≤ 414	0,8
>300 ≤ 600	>414 ≤ 848	1,0
>600 ≤ 1 000	>848 ≤ 1 414	2,6
NOTE Values are determined by calculation for REINFORCED INSULATION. Transients are not taken into account.		

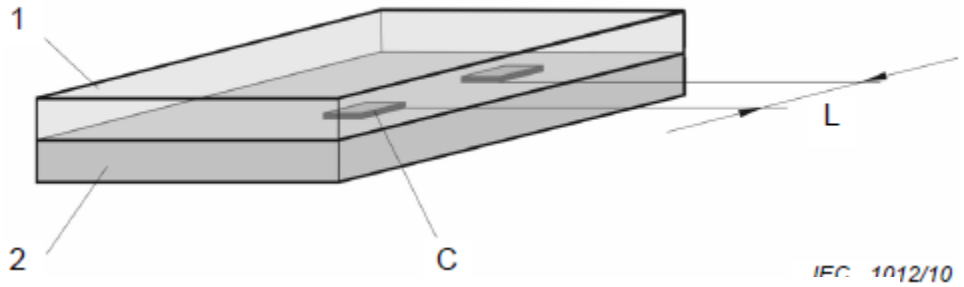
Clearance for Measuring circuit

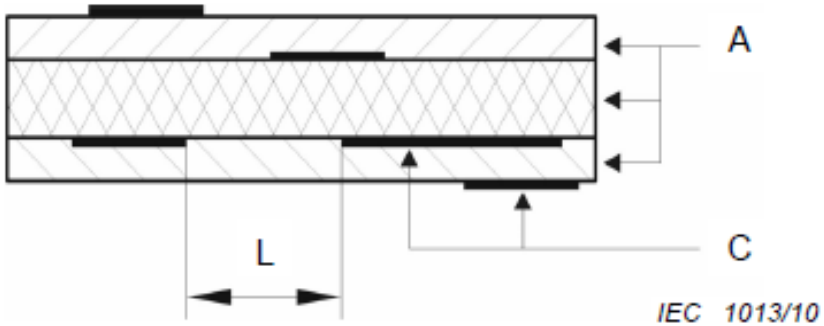
For CAT II, III and IV Measuring Circuits

Table 8 – CLEARANCES for measurement categories II, III and IV

Nominal a.c. or d.c. line-to-neutral voltage of MAINS supply	BASIC INSULATION or SUPPLEMENTARY INSULATION			DOUBLE INSULATION or REINFORCED INSULATION		
	Measurement category			Measurement category		
	II	III	IV	II	III	IV
V	mm	mm	mm	mm	mm	mm
≤50	0,04	0,1	0,5	0,1	0,3	1,5
>50 ≤100	0,1	0,5	1,5	0,3	1,5	3,0
>100 ≤150	0,5	1,5	3,0	1,5	3,0	6,0
>150 ≤300	1,5	3,0	5,5	3,0	5,9	10,5
>300 ≤600	3,0	5,5	8	5,9	10,5	14,3
>600 ≤1 000	5,5	8	14	10,5	14,3	24,3

Solid Insulation Requirement



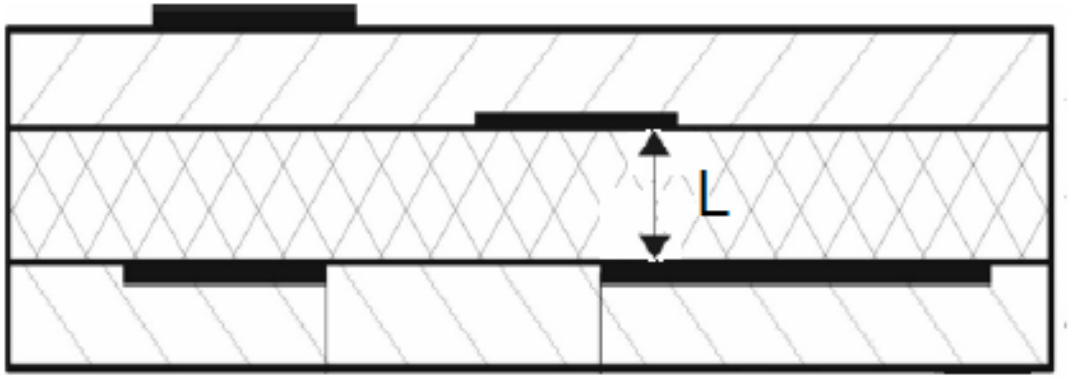


L is 0.4mm min. (for B/I, S/I and R/I)

(for both potted parts or multi-layer PCB)

- **From -1: 2010**

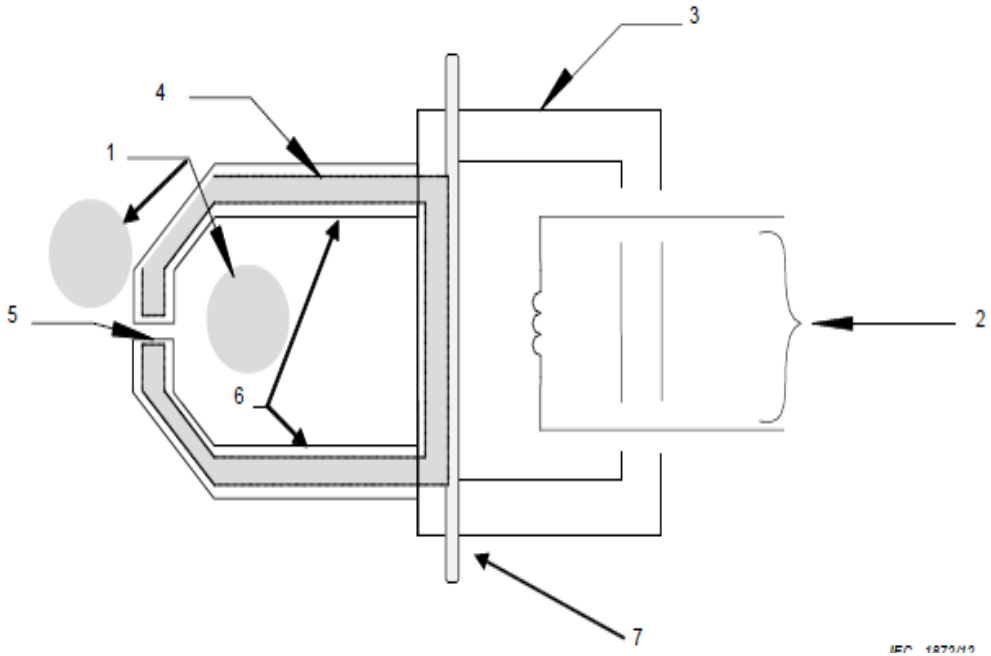
Solid Insulation Requirement



L is 0.4mm min. if only single layer is used for R/I.

If two layers are used for R/I, no thickness requirement.

Clamp Meter Insulation Requirement



Key

1	HAZARDOUS LIVE UNINSULATED conductor within the JAWS or near the JAWS		
2	Input/output circuit	3	HAND-HELD or hand-manipulated parts
4	Magnetic circuit	5	JAW END
6	JAW ENCLOSURE	7	PROTECTIVE BARRIER

Current sensor	Insulation between							
	1 and 2	1 and 3	1 and 4 [a]	2 and 3 [b]	2 and 5	2 and 6 [b]	3 and 5	4 and 6
Type A	D	D	B	D	D	D	D	B
Type B	D	-	B	D	D	D	-	B
Type C	D	-	B	D	-	D	-	B
Type D	NA	NA	NA	D	B	D	-	-

Over current Protection

- Fuse or other OCP should be located at **Line side.**
  (Include three phase equipment)
- Fuse should be provided in **portable appliances**.
- If certified OCP is used as the protective device for the measuring terminal, only hipot test (**2xUn**) is required. **(From -2-030)** (*Also apply to the traces under the fuse*)
- If uncertified OCP is used as the protective device for the measuring terminal, reinforced insulation between its terminals is required. **(From -2-030)**

Over current Protection

- The a.c. and d.c. RATED voltages of the OCP device shall be at least as high as, respectively, the highest a.c. and d.c. RATED voltages of any measuring TERMINAL on the equipment. (From -2-030)

- The a.c. and d.c. rated breaking capacities of the OCP need not exceed the table below:

MEASUREMENT CATEGORY	Short-circuit current (typical) kA
II	10
III	50
IV	50

Other Requirement

- **MAINS voltage measurement shall be rated > 300 V a.c. r.m.s. to earth, and minimum CAT III. (From -2-033)**
  - *(we accept to mark with CAT III 300V and CAT II 600V at the same time)*

- **The output leads of current clamp should be Reinforced insulated and having the CAT and V not less than the ratings of the current clamp, or CAT II/300V, whichever is higher. (From -2-032)**

Grounding Test

- Test with twice the rated current but not less than 25A.
- Test for 1 minute.
- Max. 0.2 Ω for equipment has a non-detachable power cord. (From -1:2010)
- Max. 0.1 Ω for other equipment.
- For permanently connected equipment, test with twice the rated current of protective device and the limit is 10V.

Temperature test

- The supply voltage shall be between 90 % and 110 % of any RATED supply voltage

Table 19 – Surface temperature limits in NORMAL CONDITION

Part	Limit °C
1 Outer surface of ENCLOSURE (unintentional contact)	
a) metal, uncoated or anodized	65
b) metal, coated (paint, non metallic)	80
c) plastics	85
d) glass and ceramics	80
e) small areas (<2 cm^2) that are not likely to be touched in NORMAL USE	100
2 Knobs and handles (NORMAL USE contact)	
a) metal	55
b) plastics	70
c) glass and ceramics	65
d) non-metallic parts that in NORMAL USE are held only for short periods (1 s – 4 s)	70
NOTE EN 563 gives information about the effect of the duration of contact.	

Temperature test

Table 20 – Maximum temperatures for insulation material of windings

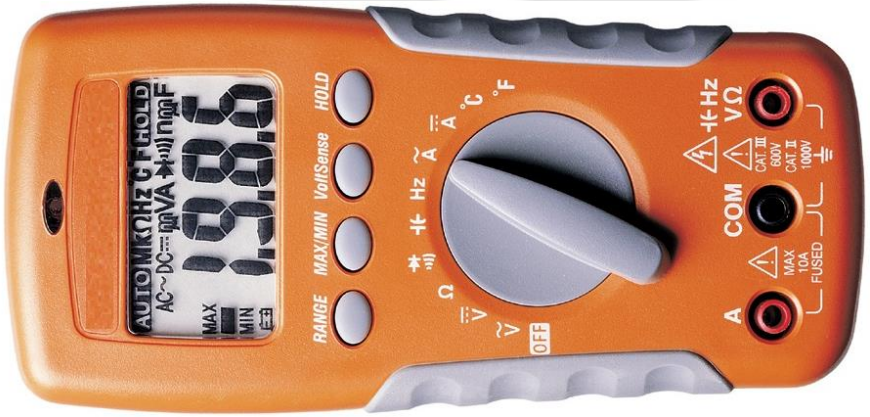
Class of insulation (see IEC 60085)	NORMAL CONDITION °C	SINGLE FAULT CONDITION °C
Class A	105	150
Class B	130	175
Class E	120	165
Class F	155	190
Class H	180	210

Abnormal Test

- Block opening if filter is provided.
- Lock fan or motor.
- Continuous operating for short time equipment
- Single component fault
- Short output
- Incorrect voltage selection (From -2-081 & -2-101)
- Spillage Test (From -2-101)
  - 0,2 l of water over a period of 15 Sec,
  - Pass the voltage tests of 6.8,
  - ACCESSIBLE parts shall not exceed the limits of 6.3.1.

Abnormal Test

- **Abnormal (Over) Input voltages (From -2-033):**
  - < 600 V a.c. r.m.s., multiplied by 1.90 but < 920 V a.c. r.m.s.;
  - 600 to 1, 000 V a.c. r.m.s., the voltage applied is 1 ,100 V a.c. r.m.s.;
  - > 1 ,000 V a.c. r.m.s., multiplied by 1.1;
  - for d.c. voltage, multiplied by 1.1
  - METER shall continue to be able to indicate the presence of HAZARDOUS LIVE voltages



Impulse Test

- Modified at From -1:2010 and -2-030.
- Test at measuring terminals with voltage limiting devices
- Also test at each pair of MAINS supply TERMINALS of the equipment where voltage limiting devices are present.
- 5 positive and 5 negative impulses, spaced up to 1 min apart
- Open-circuit voltage of 1,2/50 μs, a short-circuit current of 8/20 μs.
- The output impedance is 12 Ω for CAT II and 2 Ω for CAT III to IV.

Impulse Test

For measuring terminals:

Nominal a.c. or d.c. line-to-neutral voltage of MAINS being measured V	Impulse withstand voltage V		
	MEASUREMENT CATEGORY II	MEASUREMENT CATEGORY III	MEASUREMENT CATEGORY IV
≤50	500	800	1 500
>50 ≤ 100	800	1 500	2 500
>100 ≤ 150	1 500	2 500	4 000
>150 ≤ 300	2 500	4 000	6 000
>300 ≤ 600	4 000	6 000	8 000
>600 ≤ 1 000	6 000	8 000	12 000

Impulse Test

- If a rupture occurs, no part of the component shall bridge safety-relevant insulation.
- If the component overheats, it shall not heat other materials to their self-ignition points.
- Tripping the circuit breaker of the MAINS supply is an indication of failure
- EMC: L-N: 1KV (2Ω)
  L-G: 2KV (12Ω)
  N-G: 2KV (12Ω)

For mains terminals

Line-to-neutral MAINS voltage V r.m.s. or d.c.	Impulse withstand voltage V
≤50	500
>50 ≤ 100	800
>100 ≤ 150	1 500
>150 ≤ 300	2 500
>300 ≤ 600	4 000
>600 ≤ 1 000	6 000

Impact Test

- Test with 5J (500g steel ball drop from 1m high)
- Unless higher IK code (IEC 62262) is marked (From -1:2010)
  - IK08: 5J
  - IK09: 10J
  - IK10: 20J

- Not for Hand-Held or Direct Plug-In Equipment

Drop Test

- Drop once through a distance of 1 m onto a 50 mm thick hardwood board.
- Non-metallic ENCLOSURES of equipment with a minimum RATED ambient temperature below 2˚C are cooled to the minimum RATED ambient temperature, then tested within 10 min.

➢ For Hand-Held or Direct Plug-In equipment

Resistance to heat

Enclosure:

- The equipment not energized, is stored for 7 h at 70˚C ± 2˚C, or at 10˚C ± 2˚C above the temperature measured during the normal heating test, whichever is higher

Insulating material:

- Supporting the Mains supply, or
- Insulating material carry current > 0.5A.
  - Ball pressure test with 125˚C for 1Hr (test result: < 2mm)
- The Insulating material of JAWS surrounding a magnetic material shall complied with ball pressure test of at least 105 ˚C . (From -2-032)

Discharge Test

- If plug pins of cord-connected equipment receive a charge from an internal capacitor, the pins shall not be HAZARDOUS LIVE 5 s after disconnection of the supply.

Solid insulation (Hipot)

- **For Mains (Primary) circuit, test with:**
  - AC voltage test for 60s for AC mains circuit
  - DC voltage test for 60s for DC mains circuit
- **For Secondary circuit, test with:**
  - AC voltage for 5s, or
  - DC voltage for 60s
  - Times 1.6 for DI/RI

  (From -1:2010)

Solid insulation (Hipot)

Table 5 – Test voltages for solid insulation in MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V

Voltage line-to-neutral a.c. r.m.s. or d.c.	1 min a.c. test voltage		1 min d.c. test voltage	
	BASIC INSULATION and SUPPLEMENTARY INSULATION	REINFORCED INSULATION	BASIC INSULATION and SUPPLEMENTARY INSULATION	REINFORCED INSULATION
V	V	V	V	V
≤ 150	1 350	2 700	1 900	3 800
>150 ≤ 300	1 500	3 000	2 100	4 200

Solid insulation (Hipot)

Table 6 – CLEARANCES and test voltages for secondary circuits derived from MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V

Secondary WORKING VOLTAGE		MAINS voltage, line-to-neutral, OVERVOLTAGE CATEGORY II			
		≤ 150 V a.c. r.m.s.		> 150 V ≤ 300 V a.c. r.m.s.	
a.c. r.m.s. V	d.c. or a.c. peak V	CLEARANCE mm	Test voltage V a.c. r.m.s.	CLEARANCE mm	Test voltage V a.c. r.m.s.
16	22,6	0,10	500	0,50	840
33	46,7	0,11	510	0,52	850
50	70	0,12	520	0,53	860
100	140	0,13	540	0,61	900
150	210	0,16	580	0,69	940
300	420	0,39	770	0,94	1 040
600	840	1,01	1 070	1,61	1 450
1 000	1 400	1,92	1 630	2,52	1 970
1 250	1 750	2,50	1 960	3,16	2 280
1 600	2 240	3,39	2 390	4,11	2 730
2 000	2 800	4,49	2 890	5,30	3 230
2 500	3 500	6,02	3 520	6,91	3 850
3 200	4 480	8,37	4 390	9,16	4 660
4 000	5 600	10,9	5 320	11,6	5 610
5 000	7 000	14,0	6 590	14,9	6 960
6 300	8 820	18,2	8 270	19,1	8 620
8 000	11 200	23,9	10 400	24,7	10 700
10 000	14 000	30,7	12 900	31,6	13 300

Solid insulation (Hipot)

- **For CAT II, III and IV Measuring Circuit (-2-030)**

Nominal voltage line-to-neutral a.c. r.m.s. or d.c. of MAINS being measured V	Test voltage 5 s a.c. test					
	CAT II V a.c. r.m.s.		CAT III V a.c. r.m.s.		CAT IV V a.c. r.m.s.	
	BASIC INSULATION and SUPPLEMENTARY INSULATION	REINFORCED INSULATION	BASIC INSULATION and SUPPLEMENTARY INSULATION	REINFORCED INSULATION	BASIC INSULATION and SUPPLEMENTARY INSULATION	REINFORCED INSULATION
≤150	1 350	2 700	1 390	2 210	2 210	3 510
>150 ≤ 300	1 500	3 000	2 210	3 510	3 310	5 400
>300 ≤ 600	2 210	3 510	3 310	5 400	4 260	7 400
>600 ≤ 1 000	3 310	5 400	4 260	7 400	6 600	11 940

Solid insulation (Hipot)

Correction factor to test site altitude

Table 10 – Correction factors according to test site altitude for test voltages for CLEARANCES

	Correction factors			
Test voltage peak	≥327 V < 600 V	≥600 V < 3 500 V	≥3 500 V < 25 kV	≥25 kV
Test voltage r.m.s.	≥231 V < 424 V	≥424 V < 2 475 V	≥2 475 V < 17,7 kV	≥17,7 kV
Test site altitude m				
0	1,08	1,16	1,22	1,24
500	1,06	1,12	1,16	1,17
1 000	1,04	1,08	1,11	1,12
2 000	1,00	1,00	1,00	1,00
3 000	0,96	0,92	0,89	0,88
4 000	0,92	0,85	0,80	0,79
5 000	0,88	0,78	0,71	0,70
Linear interpolation is allowed.				

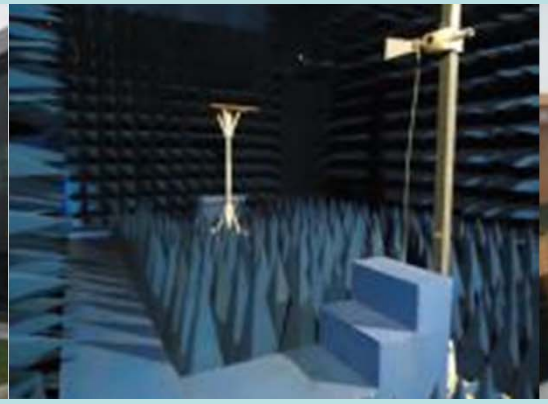
Thanks

世 騰 認 證 集 團

Cerpass Group

量測儀器產品
EMC標準 (EN 61326-1) 簡介






EN 61326-1: 2013

Electrical equipment for measurement, control and laboratory use — EMC requirements

Part 1: General requirements

產品涵蓋範圍

電子產品設備含電腦裝置,工作電壓低於AC 1000V或 DC 1500V.
用於專業,工業程式,工業製造,教育用途等,應用於

- *measurement and test*
- control
- laboratory use
- accessories intended for use with the above（如手持設備）

EN 61326-1

Emission Testing:

CISPR 11

RF Radiated Emissions

RF Conducted Emissions

Note: class B equipment will require Harmonics & Flicker Emissions measurements

Immunity Testing:

IEC 61000-4-2 ESD Electrostatic Discharge
IEC 61000-4-3 RS RF Radiated Immunity
IEC 61000-4-4 EFT Electrical Fast Transients/Burst Surge Immunity
IEC 61000-4-5 Surge Surge Immunity
IEC 61000-4-6 CS Conducted RF Immunity
IEC 61000-4-8 PFMF Power Frequency Magnetic Field Immunity
IEC 61000-4-11 Dips Voltage Dips & Interruptions on Supply Line

引用相關法規版本

IEC/CISPR Document	EN Document
IEC 61000-3-2 (2005) + A1 (2008) + A2 (2009)	EN 61000-3-2 (2006) + A1 (2009) + A2 (2009)
IEC 61000-3-3 (2008)	EN 61000-3-3 (2008)
IEC 61000-4-2 (2008)	EN 61000-4-2 (2009)
IEC 61000-4-3 (2006) + A1 (2007) + A2 (2010)	EN 61000-4-3 (2006) + A1 (2008) + A2 (2010)
IEC 61000-4-4 (2004) + Corr (2007) + A1 (2010)	EN 61000-4-4 (2004) + A1 (2010)
IEC 61000-4-5 (2005) + Corr (2009)	EN 61000-4-5 (2006)
IEC 61000-4-6 (2008)	EN 61000-4-6 (2009)
IEC 61000-4-8 (2009)	EN 61000-4-8 (2010)
IEC 61000-4-11 (2004)	EN 61000-4-11 (2004)
CISPR 11 2009 + A1 (2010)	EN 55011 (2009) + A1 (2010)

Immunity for "Basic" Environments

Changes for "basic" electromagnetic environments are summarized in Table 2.

Test	2013 Version	2006 Version
61000-4-2	The ESD requirement for air discharge is now ±8 kV. Performance criterion B is specified for both contact and air discharge.	The air discharge requirement was ±4 kV in the 2006 version.
61000-4-3	No change.	N/A
61000-4-4	No change.	N/A
61000-4-5	No change.	N/A
61000-4-6	No change.	N/A
61000-4-8	A power frequency H-field requirement of 3 A/m for both 50 and 60 Hz has been added. This standard has the standard caveat that this test is only for "magnetically sensitive equipment". It also allows for CRT display interference above 1 A/m.	There was no requirement for H-field immunity for basic environments.
61000-4-11	No change.	N/A

Table 2. Summary of Changes Required for Basic Immunity.

Immunity for "Portable Test and Measurement Equipment" (Annex A)

Changes for "basic" electromagnetic environments are summarized in Table 3.

Test	2013 Version	2006 Version
61000-4-2	No change.	N/A
61000-4-3	No change.	N/A
61000-4-8	A power frequency H-field requirement of 3 A/m for both 50 and 60 Hz has been added. This standard has the standard caveat that this test is only for "magnetically sensitive equipment". It also allows for CRT display interference above 1 A/m.	There was no requirement for H-field immunity for basic environments.

Table 3. Summary of Changes Required for Immunity of Portable Test and Measurement Equipment.

Immunity Performance criteria

- Performance criterion A: During testing, normal performance within the specification limits.
- Performance criterion B: During testing, temporary degradation, or loss of function or performance which is self-recovering.
- Performance criterion C: During testing, temporary degradation, or loss of function or performance which requires operator intervention or system reset occurs.

Table 1 – Immunity test requirements for equipment intended to be used in a basic electromagnetic environment

Port	Phenomenon	Basic standard	Test value	Perform-ance criterion
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	4 kV contact discharge 8 kV air discharge	B B
	Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 1 GHz) 3 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)	A A A
	Power frequency magnetic field	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz) [f]	A
AC power (including protective earth)	Voltage dip	IEC 61000-4-11	0 % during half cycle 0 % during 1 cycle 70 % during 25/30[e] cycles	B B C
	Short interruptions	IEC 61000-4-11	0 % during 250/300[e] cycles	C
	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	0,5 kV[a]/1 kV[b]	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
DC power[d, g] (including protective earth)	Burst	IEC 61000-4-4	1 kV(5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	0,5 kV[a]/1 kV[b]	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
I/O signal/control (including functional earth)	Burst	IEC 61000-4-4	0,5 kV[d](5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	1 kV[b, c]	B
	Conducted RF	IEC 61000-4-6	3 V[d] (150 kHz to 80 MHz)	A
I/O signal/control connected directly to mains supply	Burst	IEC 61000-4-4	1 kV(5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	0,5 kV[a]/1 kV[b]	B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A

[a] Line to line.

[b] Line to ground.

[c] Only in the case of long-distance lines (see 3.10).

[d] Only in the case of lines >3 m.

[e] For example “25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test”.

[f] Only to magnetically sensitive equipment. CRT display interference is allowed above 1 A/m.

[g] DC connections between parts of equipment/system which are not connected to a d.c. distribution network are treated as I/O signal/control ports.

Table 2 – Immunity test requirements for equipment intended to be used in an industrial electromagnetic environment

Port	Phenomenon	Basic standard	Test value	Perform-ance criterion
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	4 kV contact discharge 8 kV air discharge	B B
	Electromagnetic field	IEC 61000-4-3	10 V/m (80 MHz to 1 GHz) 3 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)	A A A
	Power frequency magnetic field	IEC 61000-4-8	30 A/m (50 Hz, 60 Hz) [e]	A
AC power (including protective earth)	Voltage dip	IEC 61000-4-11	0 % during 1 cycle 40 % during 10/12 [g] cycles 70 % during 25/30 [g] cycles	B C C
	Short interruptions	IEC 61000-4-11	0 % during 250/300 [g] cycles	C
	Burst	IEC 61000-4-4	2 kV(5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	1 kV[a]/2 kV[b]	B
	Conducted RF	IEC 61000-4-6	3 V[f] (150 kHz to 80 MHz)	A
DC power[f] (including protective earth)	Burst	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	1 kV[a]/2 kV[b]	B
	Conducted RF	IEC 61000-4-6	3 V[f] (150 kHz to 80 MHz)	A
I/O signal/ control (including functional earth)	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)[d]	B
	Surge	IEC 61000-4-5	1 kV[b, c]	B
	Conducted RF	IEC 61000-4-6	3 V[d, f] (150 kHz to 80 MHz)	A
I/O signal/ control connected directly to mains supply	Burst	IEC 61000-4-4	2 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	1 kV[a]/2 kV[b]	B
	Conducted RF	IEC 61000-4-6	3 V[f] (150 kHz to 80 MHz)	A

[a] Line to line.

[b] Line to ground.

[c] Only in the case of long-distance lines (see 3.10).

[d] Only in the case of lines > 3 m.

[e] Only to magnetically sensitive equipment. CRT display interference is allowed above 1 A/m.

[f] DC connections between parts of equipment/system which are not connected to a d.c. distribution network are treated as I/O signal/control ports.

[g] For example “25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test".

Table 3 – Immunity test requirements for equipment intended to be used in a controlled electromagnetic environment

Port	Phenomenon	Basic standard	Test value	Performance criterion
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	4 kV contact discharge 8 kV air discharge	B B
	Electromagnetic field	IEC 61000-4-3	1 V/m (80 MHz to 1 GHz) 1 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)	A A A
AC power (including protective earth)	Voltage dip	IEC 61000-4-11	0 % during half cycle	B
	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	0,5 kV[a]/1 kV[b]	B
	Conducted RF	IEC 61000-4-6	1 V (150 kHz to 80 MHz)	A
DC power[c, d] (including protective earth)	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	Not required	-
	Conducted RF	IEC 61000-4-6	1 V (150 kHz to 80 MHz)	A
I/O signal/ control (including functional earth)	Burst	IEC 61000-4-4	0,5 kV[c] (5/50 ns, 5 kHz)	B
	Surge	IEC 61000-4-5	Not required	-
	Conducted RF	IEC 61000-4-6	1 V[c] (150 kHz to 80 MHz)	A

[a] Line to line.

[b] Line to ground.

[c] Only in the case of lines >3 m.

[d] DC connections between parts of equipment/system which are not connected to a d.c. distribution network are treated as I/O signal/control ports.

Table A.1 – Immunity test requirements for portable test and measurement equipment

Port	Phenomenon	Basic standard	Test value	Performance criterion
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	4 kV contact discharge 8 kV air discharge	B B
	Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 1 GHz) 3 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)	A A A
	Power-frequency magnetic field [a]	IEC 61000-4-8	3 A/m at 50 Hz, 60 Hz [b]	A

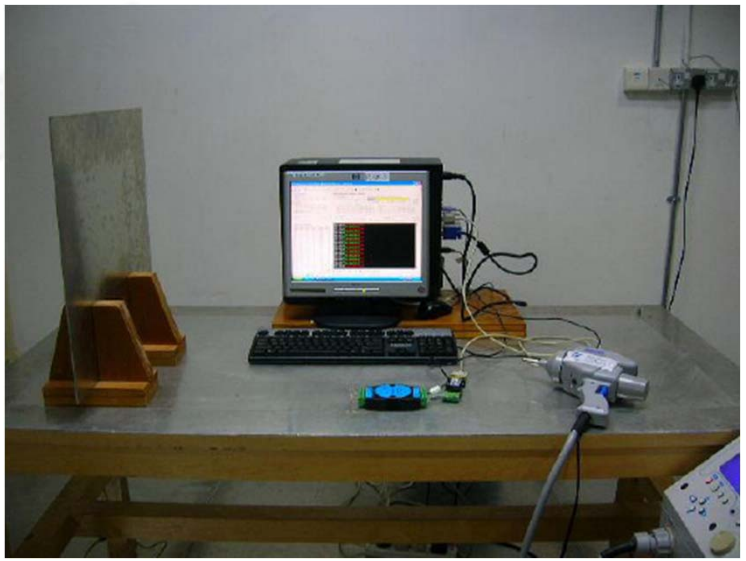
[a] Only to magnetically sensitive equipment. CRT display interference is allowed above 1 A/m.

[b] The test shall be carried out at the frequencies appropriate to the power supply frequency. Equipment intended for use in areas supplied only at one of these frequencies need only be tested at that frequency

Immunity

Electrostatic Discharge

- IEC 61000-4-2
  - 4 kV contact discharge
  - 8 kV air discharge



Immunity

Radiated Immunity

- IEC 61000-4-3
- Test at 3 meters
- Four sides of test item

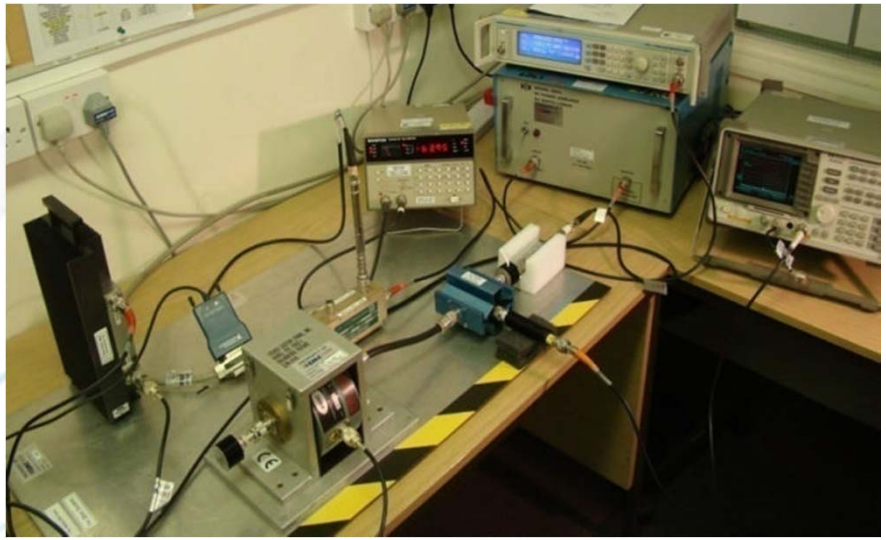
Frequency (MHz)	Modulation	Level (V/m)
80 to 1000	1 kHz AM @ 80%	3
1400 to 2000	1 kHz AM @ 80%	3
2000 to 2700	1kHz AM @ 80%	1

Immunity

Conducted RF Immunity

IEC 61000-4-6

3Vpp 150 kHz to 80 MHz



Power frequency magnetic field

IEC 61000-4-8

3 A/m (50 Hz, 60 Hz)

Immunity

Electrical Fast Transients

- IEC 61000-4-4
- 1 kV (5/50 ns, 5 kHz)

Surge

- IEC 61000-4-5
- 0.5 kV L-L 1.0 kV L-E

Voltage Dips

- IEC 61000-4-11
- 0 % during half cycle
- 0 % during 1 cycle
- 70 % during 25/30e) cycles

Short Interruptions

- IEC 61000-4-11
- 0 % during 250/300 cycles

Conducted Emissions

Conducted Emissions

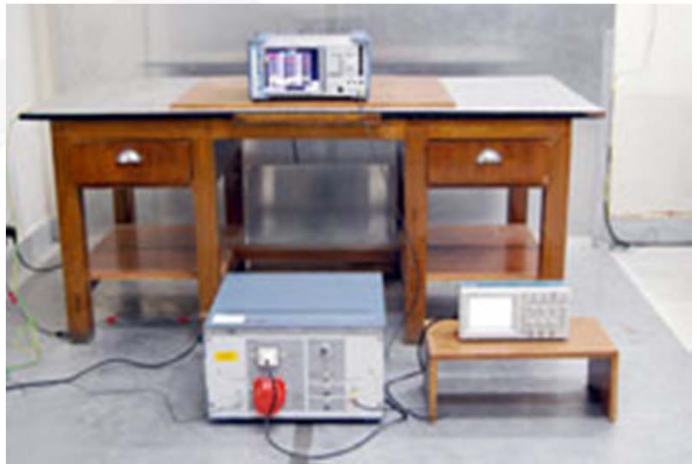
- CISPR 11

Frequency Range MHz	Limits dB(μV)	Limits dB(μV)
	Quasi-Peak	Average
0.15 to 0.5	79	66
0.5 to 30	73	60

Class A Limits

Frequency Range MHz	Limits dB(μV)	Limits dB(μV)
	Quasi-Peak	Average
0.15 to 0.5	56 to 46	66 to 56
0.5 to 5	46	56
5 to 30	50	60

Class B Limits



Radiated Emissions

Radiated Emissions

- CISPR 11

Frequency MHz	Measuring Distance (meters)	Quasi-peak limits (dBμV/m)
30 to 230	10	40
230 to 1000	10	47

Class A Limits

Frequency MHz	Measuring Distance (meters)	Quasi-peak limits (dBμV/m)
30 to 230	10	30
230 to 1000	10	37

Class B Limits


Thanks!

Safety Requirement for Medical Equipment

IEC 60601-1之安規簡介

Cerpass Group
世騰認證集團

601 Safety Standards Worldwide

- International Electrotechnical Commission:
  - IEC 60601-1:2005 (Edition 3.0)
  - IEC 60601-1/A1:2012 (Edition 3.1)

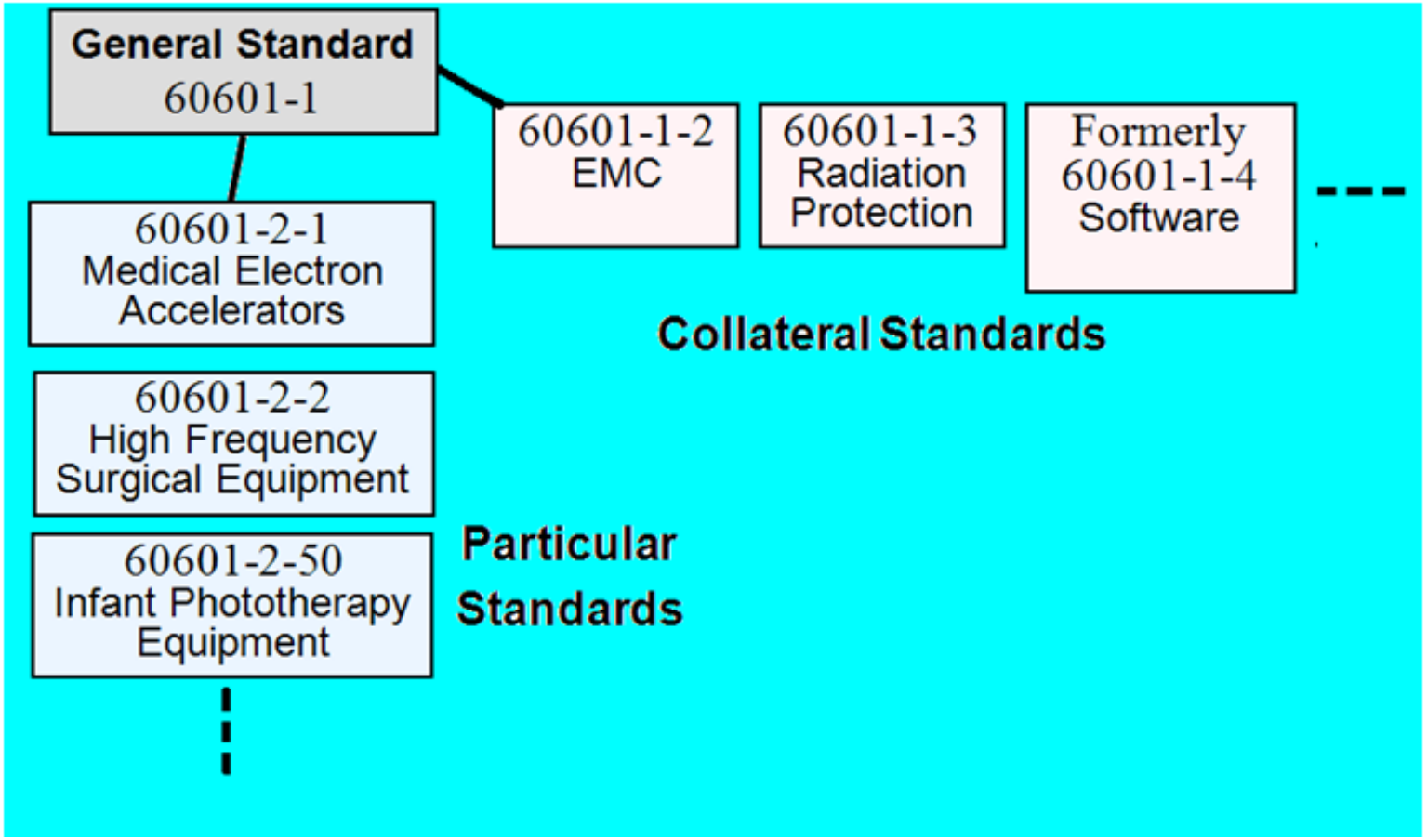
- Taiwan: CNS 14509, IEC 60601-1:1998 or IEC 60601-1:2005
  - Transition date: TBD

- China: GB 9706.15-1999
  - Transition date: TBD

601 Safety Standards Worldwide

- EU Community: EN 60601-1:2006
  - Effective date: June 1, 2012
  - DOA of A1: December 24, 2013
  - DOW of A1: December 31, 2018
- USA: ANSI/AAMI ES 60601-1:2005
  - Effective date: June 30, 2013 by FDA
  - Effective date: January 1, 2014 by FDA for Edition 3.1
- Canada: CAN/CSA C22.2 No. 60601-1:08
  - Effective date: June 1, 2012
- Japan: JIS T 0601-1:2012
  - Transition date: To 2017

Structure of 60601 Standards



Structure of 60601 Standards

- 60601-1: General Requirement
- 60601-1-XX: Collateral Standards
  - 60601-1-2: Electromagnetic compatibility
  - 60601-1-3: Radiation protection in diagnostic X-ray equipment
  - 60601-1-11: For used in the home healthcare environment
- 60601-2-XX: Particular Standards
  - 60601-2-2: For high frequency surgical equipment
  - 60601-2-5: For ultrasonic physiotherapy equipment
  - 60601-2-18: For endoscopic equipment

What's New in Edition 3.0?

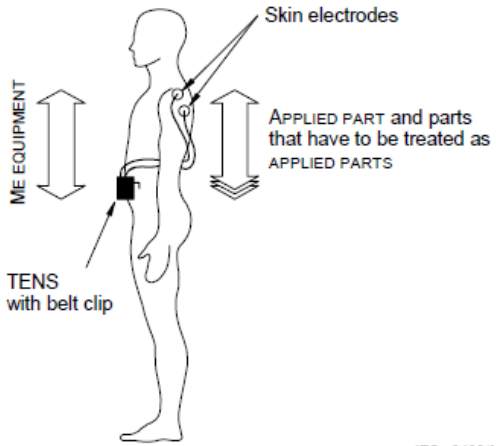
- Essential Performance 的導入
  - Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

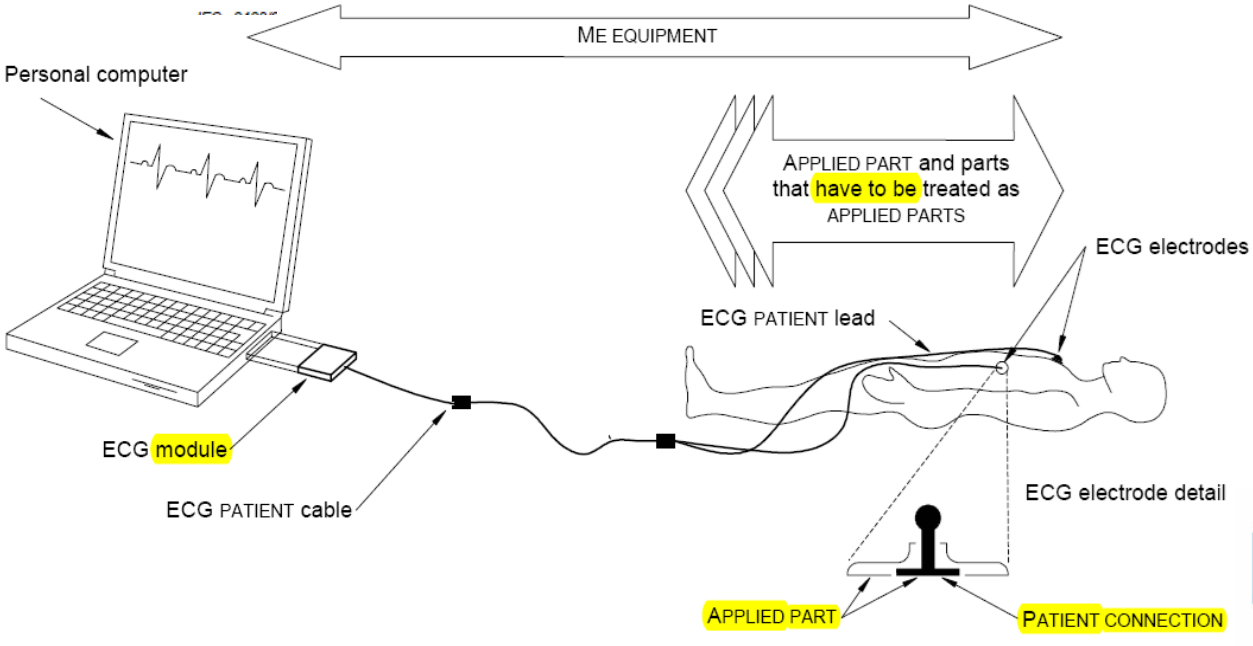
Part 1:
General requirements for basic safety and essential performance

  - 導入可用性確效要求 (原IEC 60601-1-6)
  - 導入軟體確效要求 (原IEC 60601-1-4)
- 風險管理的導入 (ISO 14971)
- IEC 60950-1 的大量引用
- MOOP及MOPP的分等要求
  - MOOP: Means Of Operator Protection
  - MOPP: Means Of Patient Protection

Terminology and Definitions

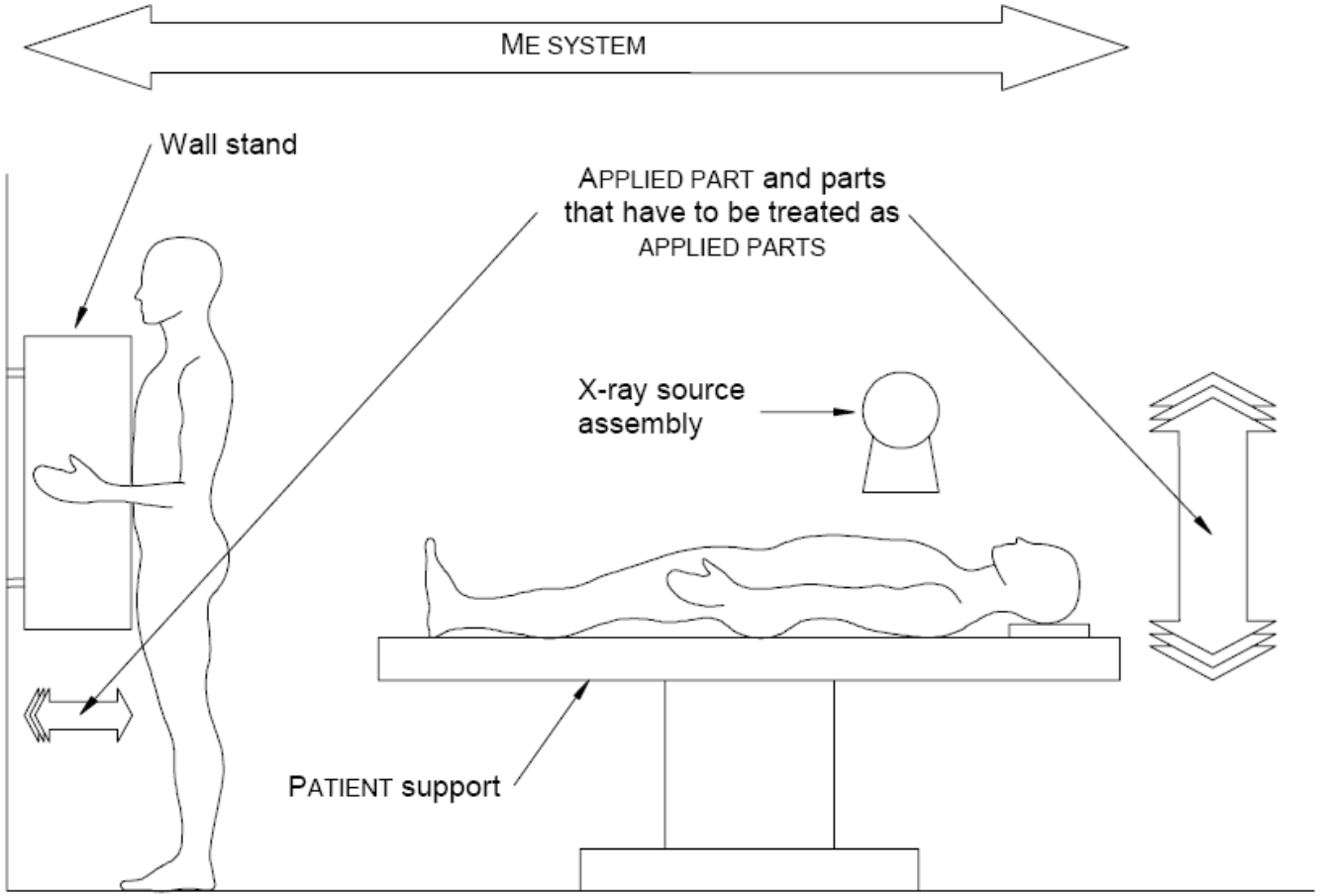
- ACCESSIBLE PART, APPLIED PART, PATIENT CONNECTION





Terminology and Definitions

- APPLIED PART



Terminology and Definitions

- Type B APPLIED PART
  - APPLIED PART that has no PATIENT CONNECTION

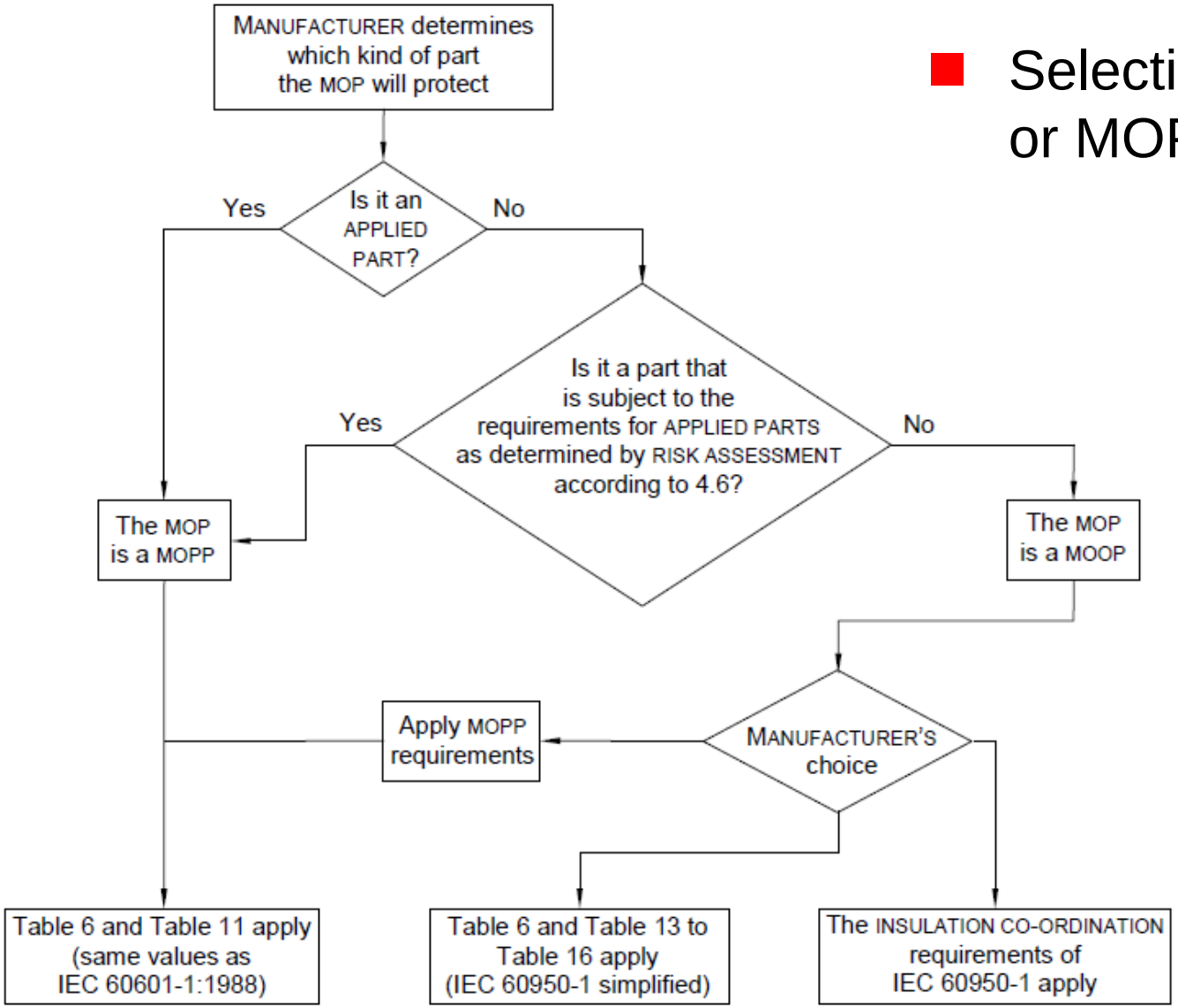
- Type BF APPLIED PART
  - APPLIED PART with PATIENT CONNECTION

- Type CF APPLIED PART
  - APPLIED PART with PATIENT CONNECTION and suitable for cardiac use.

- 2 MOOP/MOPP = Double/Reinforced Insulation
- 1 MOOP/MOPP = Basic Insulation

Terminology and Definitions

- Selection of MOOP or MOPP



Terminology and Definitions

- LEAKAGE CURRENT
  - current that is not function
- EARTH LEAKAGE CURRENT
  - leakage current flowing from the mains supply through or across the insulation into the protective earth conductor
- TOUCH CURRENT
  - leakage current flowing from the enclosure (case) or from parts thereof, excluding PATIENT CONNECTIONS, accessible to any operator or patient in normal use, through an external path other than the protective earth conductor, to earth or to another part of the enclosure.

Terminology and Definitions

- PATIENT LEAKAGE CURRENT
  - leakage current flowing from the PATIENT CONNECTIONS via the PATIENT to earth

- PATIENT AUXILIARY CURRENT
  - current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other PATIENT CONNECTIONS.
  - 60601-1 does not specify any limits for currents that are intended to produce a physiological effect in the PATIENT, but particular standards can do so.

Leakage Currents in 60601-1

- Legends of Symbols for the Leakage Current Testing:

(1)	ME EQUIPMENT ENCLOSURE
(2)	Separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see 5.5 g) and Annex F)
(3)	SIGNAL INPUT/OUTPUT PART short circuited or loaded
(4)	PATIENT CONNECTIONS
(5)	Metal ACCESSIBLE PART not PROTECTIVELY EARTHED
(6)	PATIENT circuit
MD	Measuring device
FE	FUNCTIONAL EARTH TERMINAL
PE	PROTECTIVE EARTH TERMINAL

NC NORMAL CONDITION

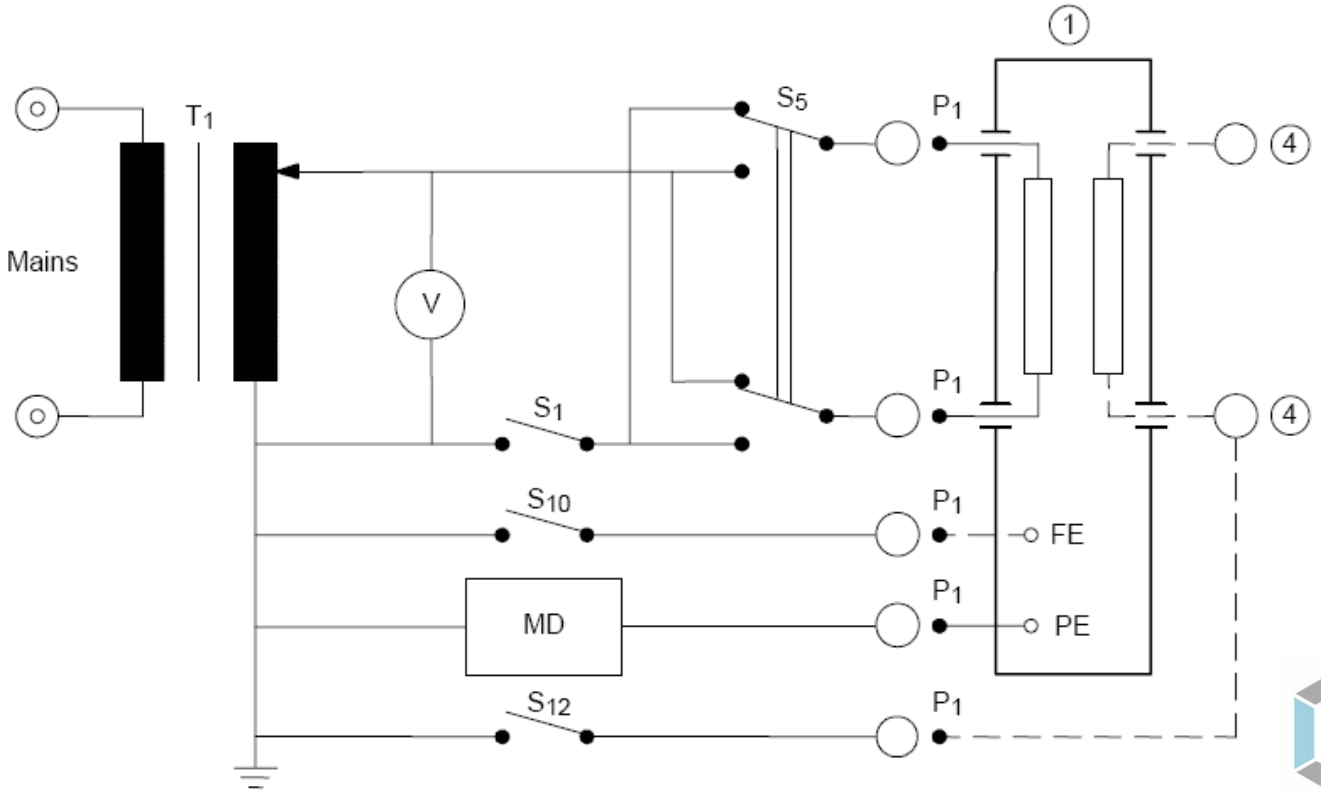
- Short any parts of less than 1MOP is a NC.

SCF SINGLE FAULT CONDITION

- Short 1 MOP is also a SFC except the 1MOP which is in conjunction to PE for other than Type BF or CF .

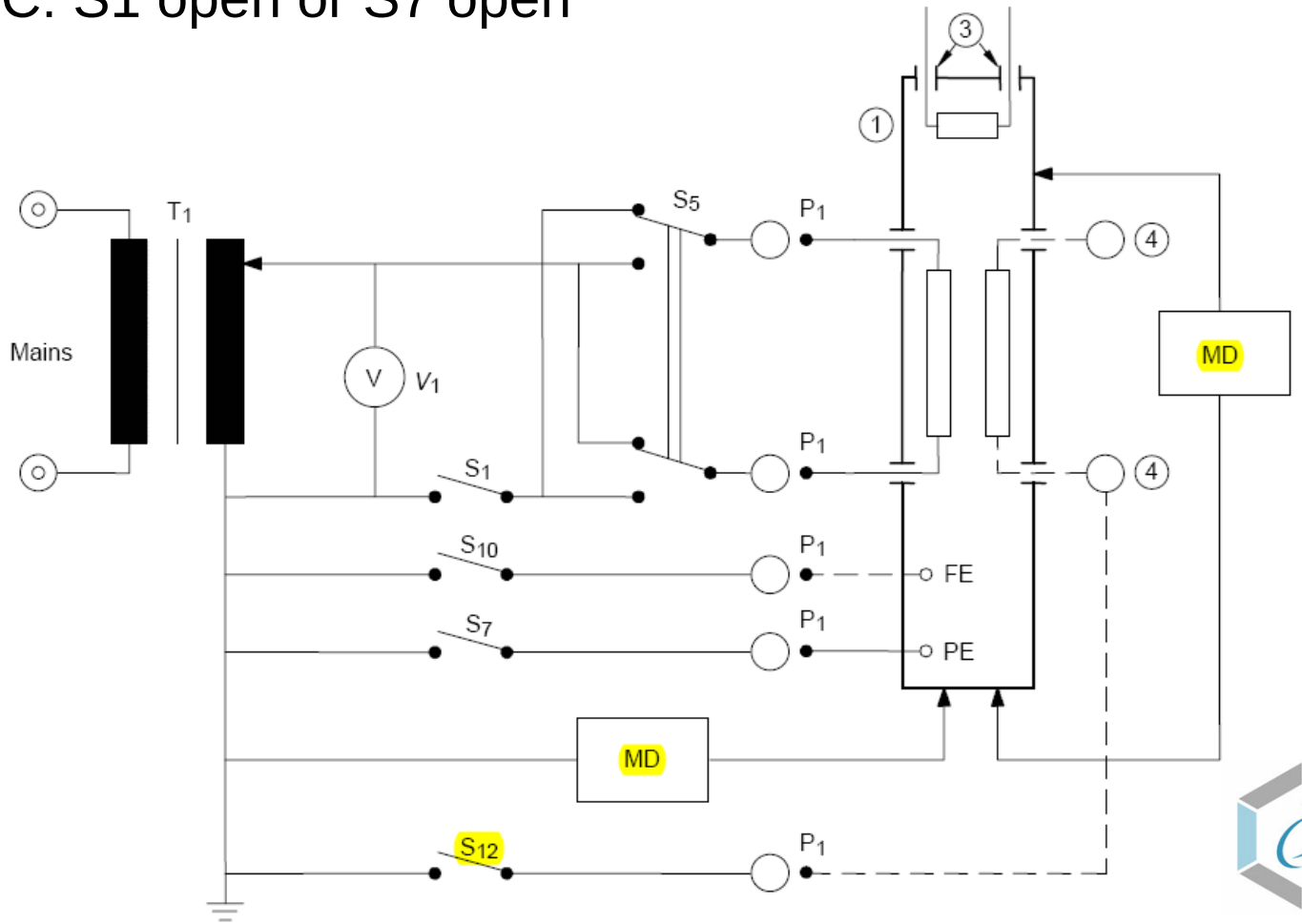
Leakage Currents in 60601-1

- Earth Leakage Current Testing:
  - For Class I equipment only
  - Limit: NC: 5mA; SFC:10mA
  - SFC: S1 open



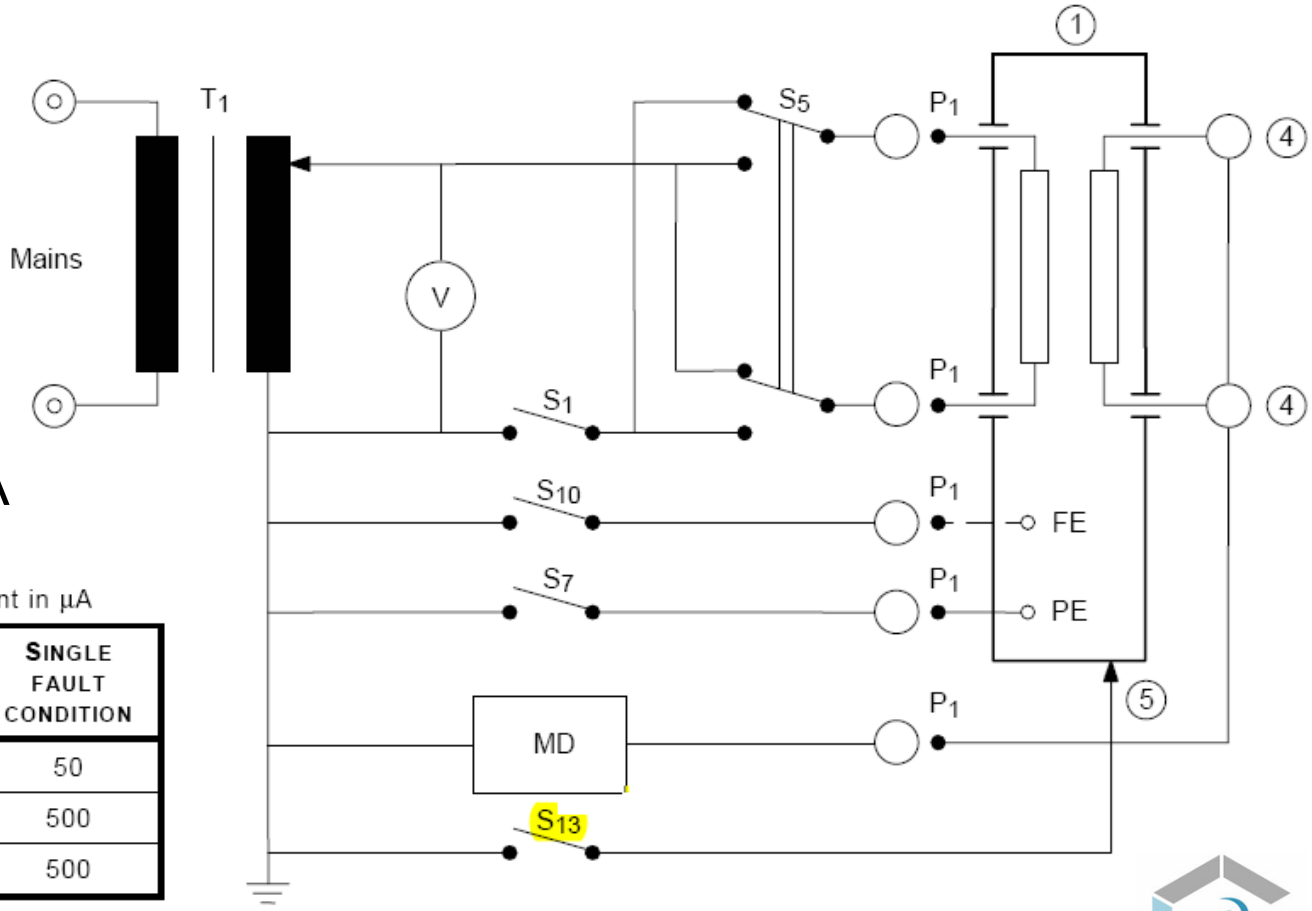
Leakage Currents in 60601-1

- Touch Leakage Current Testing:
  - Limit: NC: 0.1mA; SFC:0.5mA
  - SFC: S1 open or S7 open



Leakage Currents in 60601-1

- Patient Leakage Current Testing (Type B, BF, CF):
  - SFC: S1 open or S7 open (see also page 25)
  - Limit: uA

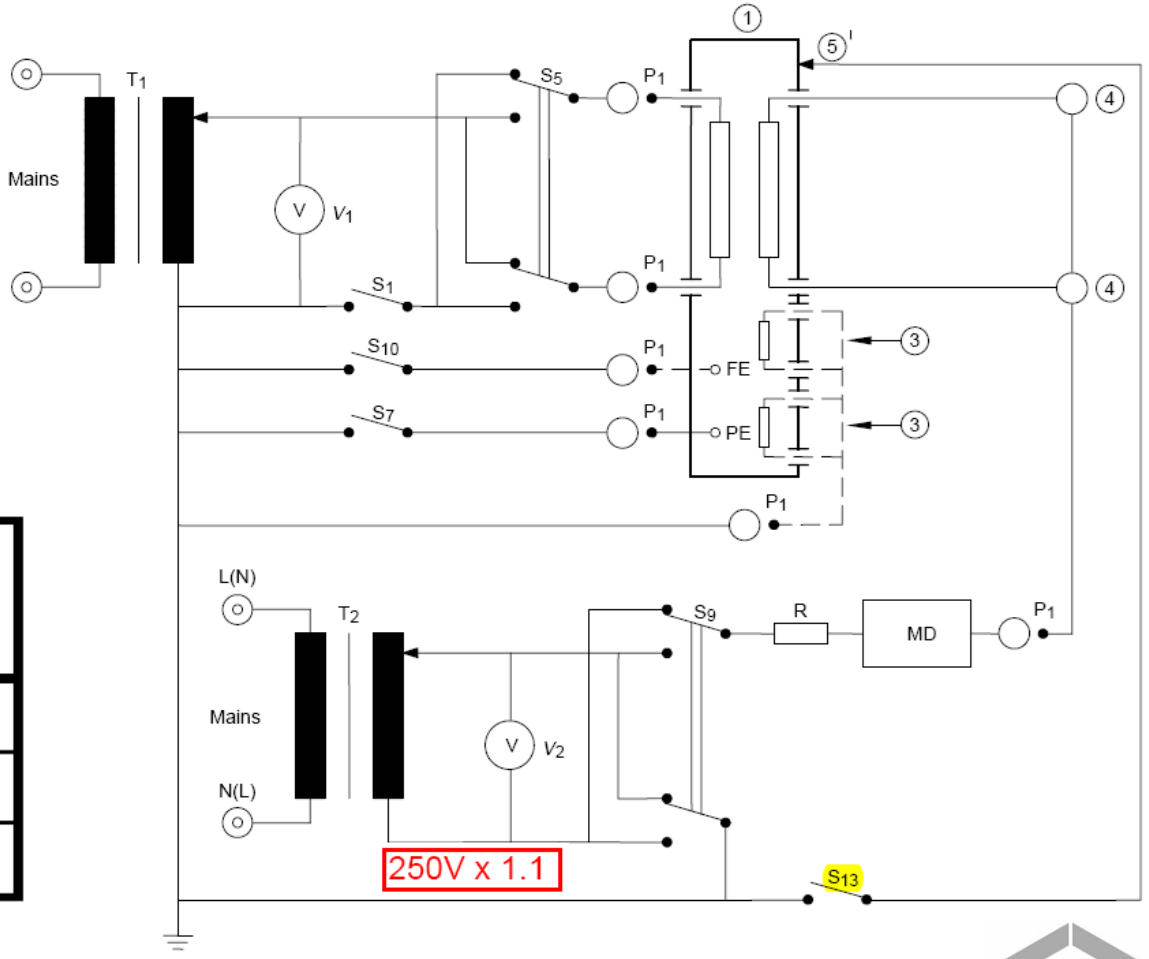


Current in µA

Applied part type	Normal condition	Single fault condition
CF	10	50
BF	100	500
B	100	500

Leakage Currents in 60601-1

- Patient Leakage Current Testing (Type BF and CF):



- Limit: (uA)

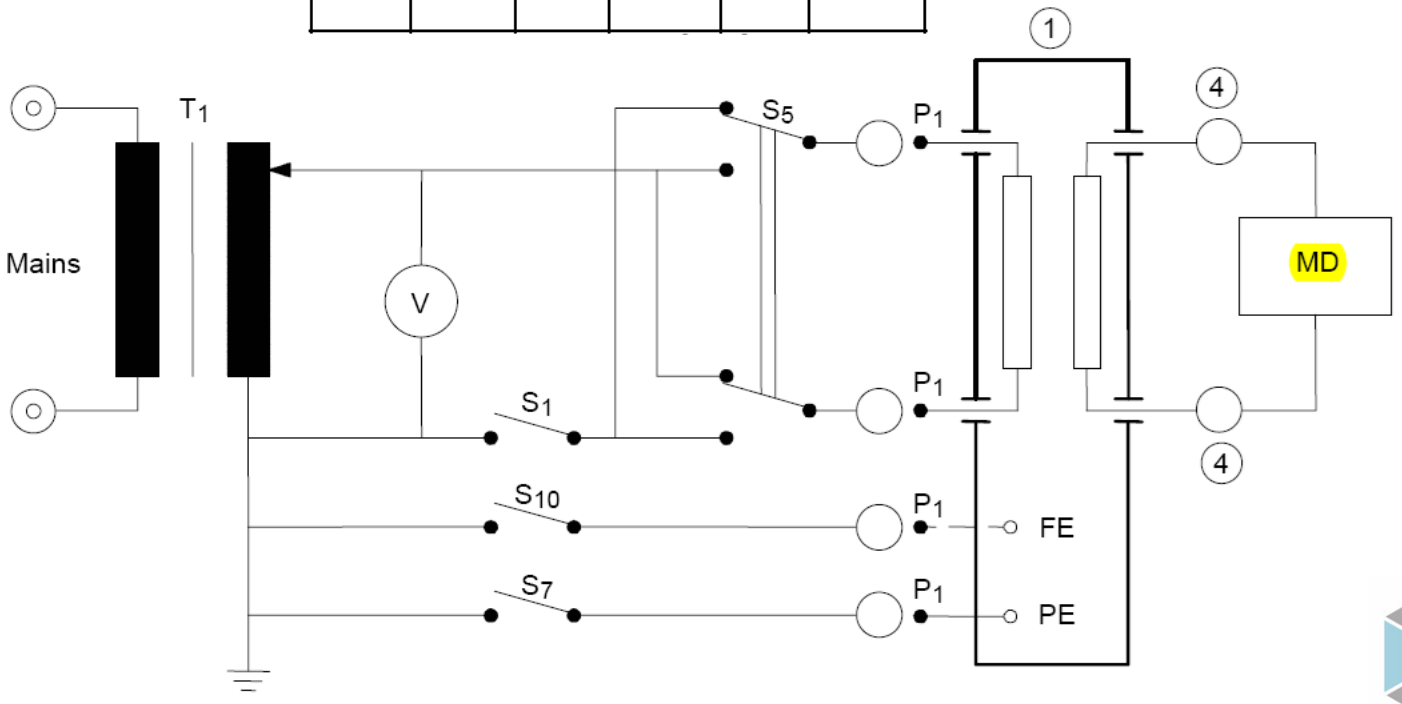
Current in µA

APPLIED PART TYPE	Special test condition
CF	50
BF	5 000
B	—

Leakage Currents in 60601-1

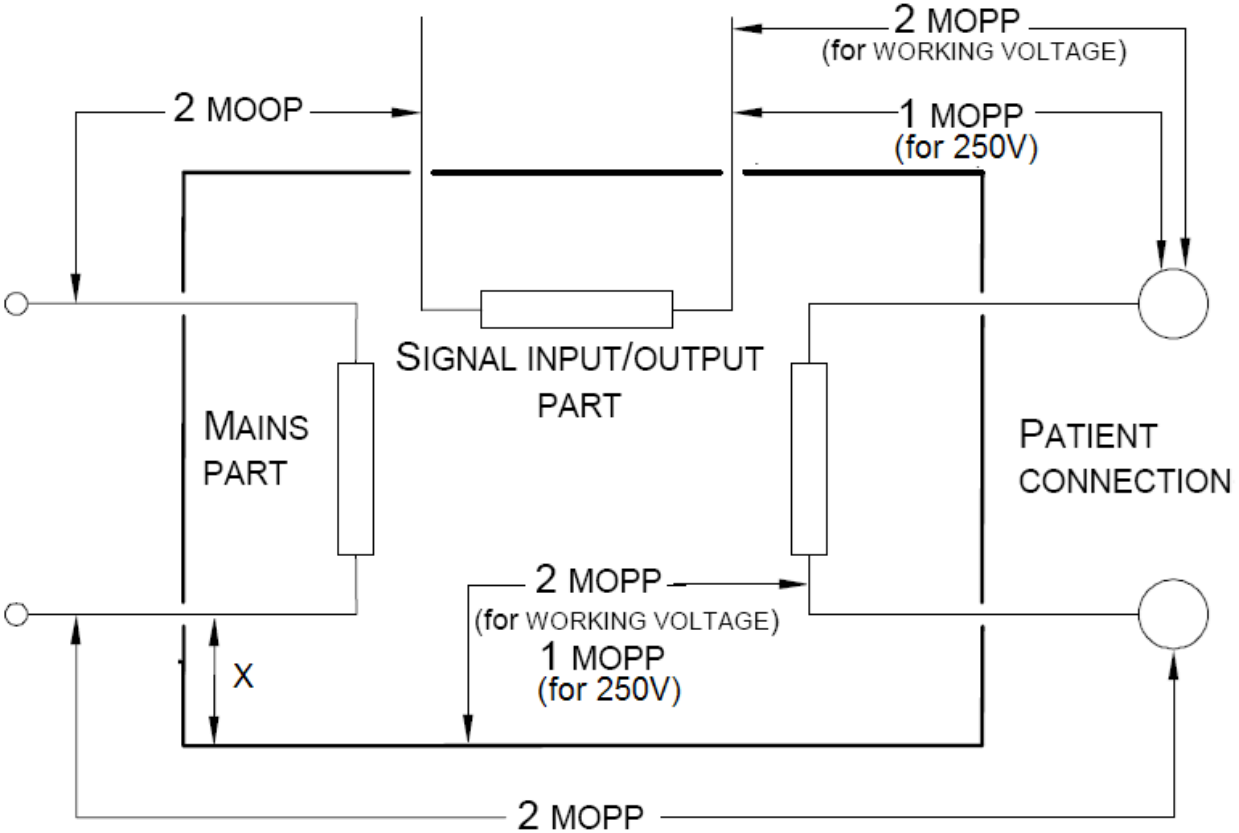
- Patient Auxiliary Current Testing:
  - SFC: S1 open or S7 open
  - Limit: uA

TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
NC	SFC	NC	SFC	NC	SFC
100	500	100	500	10	50



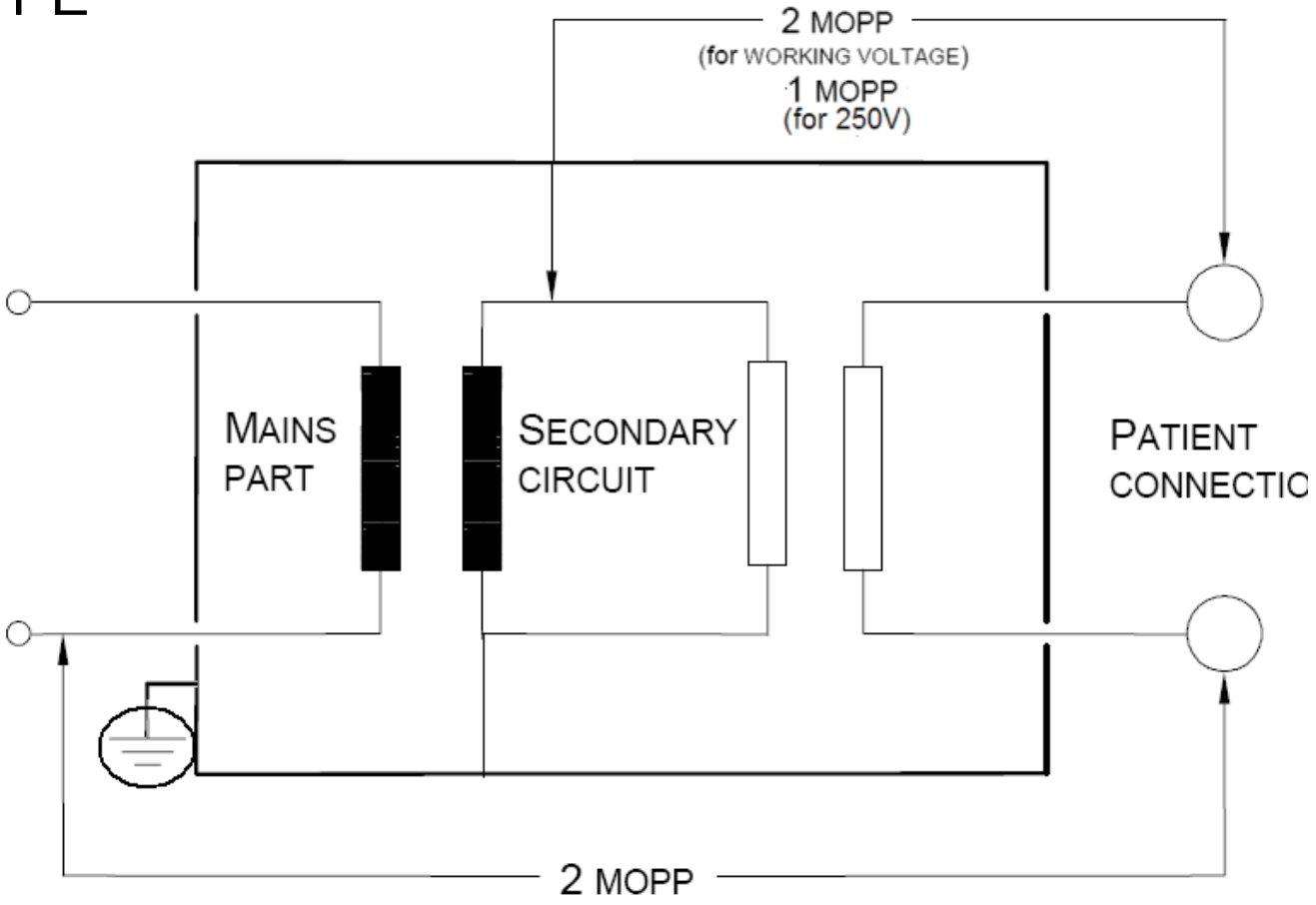
Isolation in 60601-1

- Isolation Diagram (Type BF or CF):
  - X: 1MOOP or 1MOPP if enclosure is connected to PE
  - X: 2MOOP or 2MOPP if enclosure not connect to PE



Isolation in 60601-1

- Isolation Diagram (Type BF or CF):
  - Need 2MOPP even the secondary circuit is connected to PE



Isolation in 60601-1

- Spacing Requirement for MOPP:

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 two MEANS OF PATIENT PROTECTION	
		CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5
566	400	6	3,5	12	7
707	500	8	4,5	16	9
934	660	10,5	6	21	12
1 061	750	12	6,5	24	13
1 414	1 000	16	9	32	18
1 768	1 250	20	11,4	40	22,8
2 263	1 600	25	14,3	50	28,6
2 828	2 000	32	18,3	64	36,6
3 535	2 500	40	22,9	80	45,8
4 525	3 200	50	28,6	100	57,2
5 656	4 000	63	36,0	126	72,0
7 070	5 000	80	45,7	160	91,4

Isolation in 60601-1

Safety of Medical Equipment

- Clearance Requirement for MOOP:

AIR CLEARANCE in mm

WORKING VOLTAGE up to and including		NOMINAL MAINS VOLTAGE ≤ 150 V (MAINS TRANSIENT VOLTAGE 1 500 V)				150 V < NOMINAL MAINS VOLTAGE ≤ 300 V (MAINS TRANSIENT VOLTAGE 2 500 V)		300 V < NOMINAL MAINS VOLTAGE ≤ 600 V (MAINS TRANSIENT VOLTAGE 4 000V)	
Voltage peak or d.c.	Voltage r.m.s (sinusoidal)	Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1, 2 and 3		Pollution degrees 1, 2 and 3	
V	V	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
210	150	1,0	2,0	1,3	2,6	2,0	4,0	3,2	6,4
420	300	1 MOOP 2,0 2 MOOP 4,0						3,2	6,4
840	600	1 MOOP 3,2 2 MOOP 6,4							
1 400	1 000	1 MOOP 4,2 2 MOOP 6,4							
2 800	2 000	1 or 2 MOOP 8,4							
7 000	5 000	1 or 2 MOOP 17,5							
9 800	7 000	1 or 2 MOOP 25							
14 000	10 000	1 or 2 MOOP 37							
28 000	20 000	1 or 2 MOOP 80							

Isolation in 60601-1

- Creepage Distance Requirement for 1 MOOP:

CREEPAGE DISTANCE in mm

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
50	Use the AIR CLEARANCE from the appropriate table	0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4.0	5,6	8,0	10,0	11,0	12,5
1 000		5,0	7,1	10,0	12,5	14,0	16,0

NOTE Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

Isolation in 60601-1

- Dielectric Strength Requirement
  - Test duration: 60s

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
$42{,}4 < U \leq 71$	$60 < U \leq 71$	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
$71 < U \leq 184$	$71 < U \leq 184$	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
$184 < U \leq 212$	$184 < U \leq 212$	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
$212 < U \leq 354$	$212 < U \leq 354$	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
$354 < U \leq 848$	$354 < U \leq 848$	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
$848 < U \leq 1\,414$	$848 < U \leq 1\,414$	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
$1\,414 < U \leq 10\,000$	$1\,414 < U \leq 10\,000$	See Table 7	See Table 7	See Table 7	See Table 7	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
$10\,000 < U \leq 14\,140$	$10\,000 < U \leq 14\,140$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000

Isolation in 60601-1

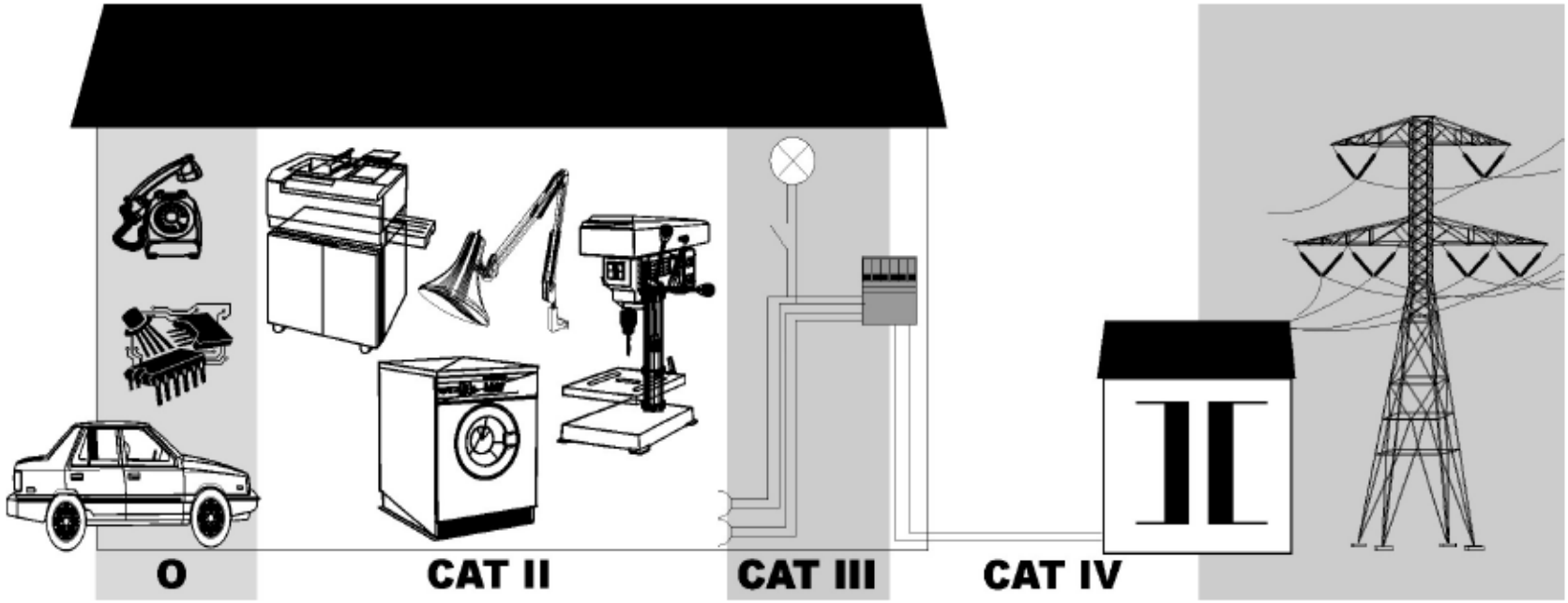
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION

Test voltage in V r.m.s.

PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP	PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP
105	844	1 350	250	1 261	2 018
110	862	1 379	260	1 285	2 055
115	880	1 408	270	1 307	2 092
120	897	1 436	280	1 330	2 127
125	915	1 463	290	1 351	2 162
130	931	1 490	300	1 373	2 196
135	948	1 517	310	1 394	2 230
140	964	1 542	320	1 414	2 263
145	980	1 568	330	1 435	2 296
150	995	1 593	340	1 455	2 328
152	1 000	1 600	350	1 474	2 359
155	1 000	1 617	360	1 494	2 390
160	1 000	1 641	380	1 532	2 451
165	1 000	1 664	400	1 569	2 510
170	1 000	1 688	420	1 605	2 567
175	1 000	1 711	440	1 640	2 623
180	1 000	1 733	460	1 674	2 678
184	1 000	1 751	480	1 707	2 731
185	1 097	1 755	500	1 740	2 784
190	1 111	1 777	520	1 772	2 835
200	1 137	1 820	540	1 803	2 885
210	1 163	1 861	560	1 834	2 934
220	1 189	1 902	580	1 864	2 982
230	1 214	1 942	588	1 875	3 000
240	1 238	1 980	600	1 893	3 000

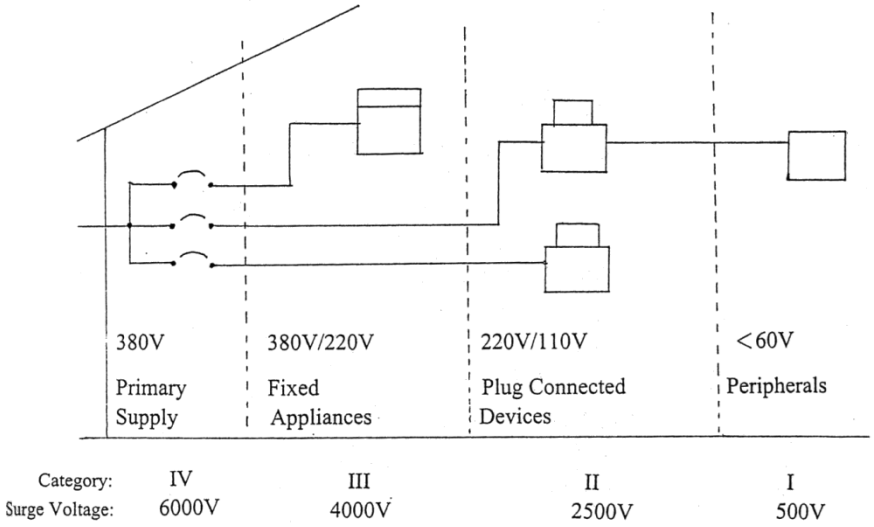
Isolation in 60601-1

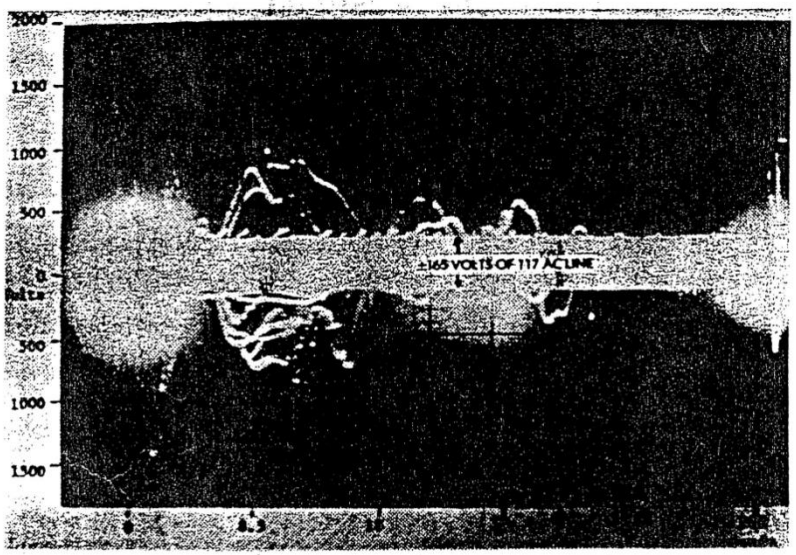
- Installation Category (CAT)



Isolation in 60601-1

- Installation Category (CAT)

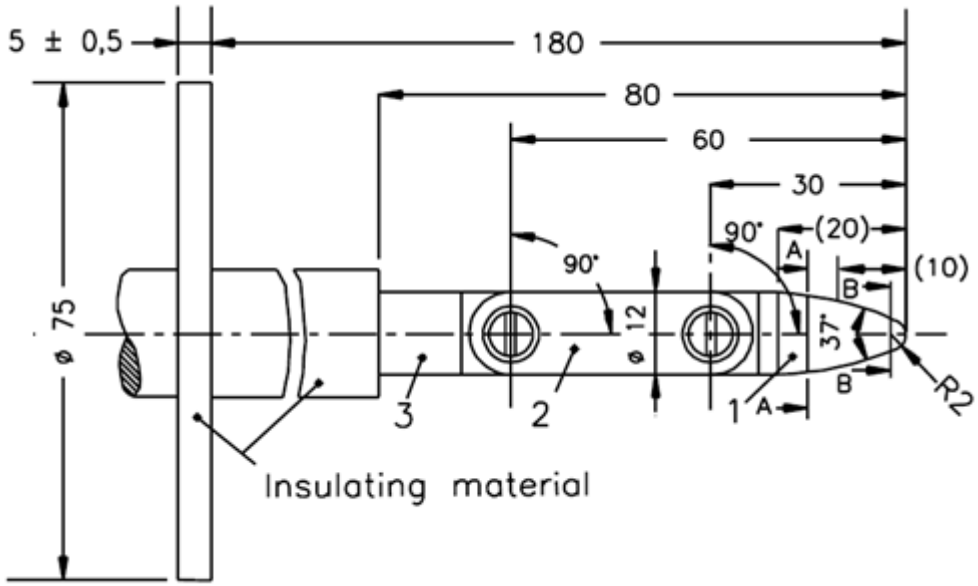


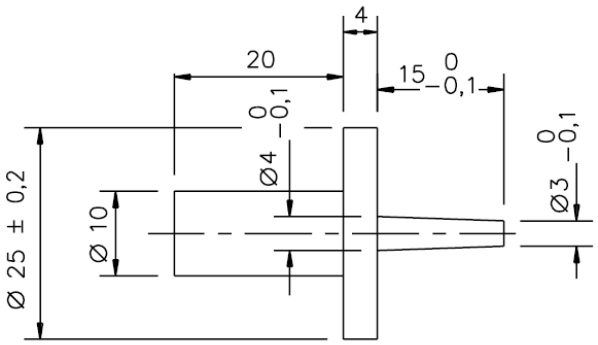


Typical surge voltages on residential power line; recordings taken over 24-hour period *(Photography courtesy F. Martzloff, General Electric Company)*

Requirement on Enclosure

- Accessibility of Live Parts (Electrical Parts)
  - By test rod of 4mm∅ to top opening and opening for pre-set control.
  - By test finger and test pin to any part of enclosure:





Requirement on Enclosure

- Opening on Bottom Enclosure
  - By baffle or perforation specified below

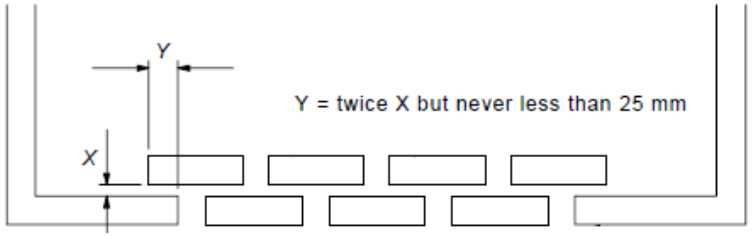


Table 25 – Acceptable perforation of the bottom of an ENCLOSURE

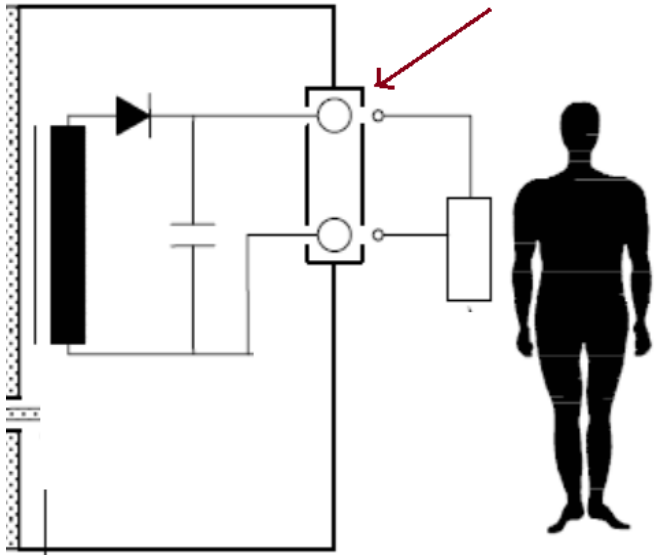
Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm^2)
0,66	1,19	2,36
0,76	1.15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm^2)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

Requirement on Enclosure

- Flammability of Enclosure:
  - 外殼(移動式產品) : V-2 or better
  - 外殼(固定式產品) : V-1 or better
  - 端子: V-2 or better
  - 線路板(及絕緣材料): V-2 or better
  - 5V-A 優於5V-B 優於V-0 優於 V-1 優於 V-2 優於 HB

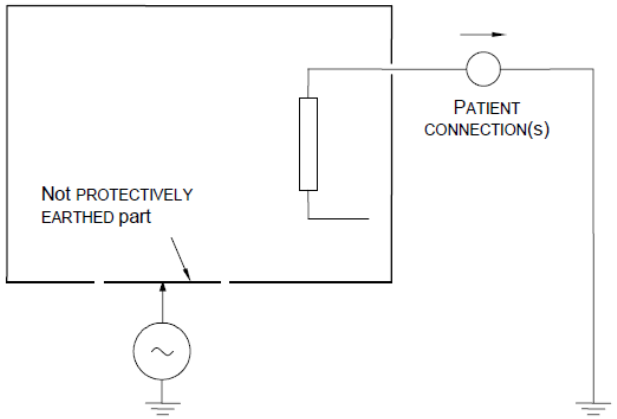
Requirement on Enclosure

- Any connector pins for electrical connections on a PATIENT lead shall:
  - not come into contact with a flat conductive plate
  - not to be touched by the test finger
  - have an AIR CLEARANCE of >0.5mm to the flat plate



Earthing Requirement

- Class I產品的金屬外殼均須接大地
  否則在漏電流試驗時，未接大地的
  金屬外殼須另加250Vac的電壓



- 接地線的線徑不能小於電源線
- 接地線須為黃滾綠線
- 電氣螺絲須有spring washer 或 star washer
- 接地端子不可由外部鬆開，亦不可用來固定其他元件
- 和外部電源線相接的接地端須標上:

Earthing Requirement

- Earthing Impedance Test
  - Test current: 25A or 1.5 times rated input current (whichever the bigger)
  - Test voltage: <6V
  - Test duration: 5s to 10s
  - Limit: Max. 0.1Ω (0.2 Ω if Non-detachable Power Supply Cord is used)

Cord-Connected Hand-Held or Foot-operated Control

- Cord-Connected Hand-Held or Foot-operated control shall:
  - operated at voltage not exceeding 42.4Vp or 60Vdc
  - foot-operated control device shall withstand an actuating force of 1350 N for 1 min over an area of 30 mm diameter
  - foot-operated control device shall be rated at least IPX2. IPX6 is needed if they are intended use in areas where liquids are likely to be found (such as emergency rooms and operating theatres)

Cord-Connected Hand-Held or Foot-operated Control

INGRESS PROTECTION (IP) CODES			
First Number[1]		Second Number[1]	
0	No Protection	0	No Protection
1	Objects Greater than 50mm	1	Vertically Dripping Water
2	Objects Greater than 12mm	2	75° to 90° F Dripping Water
3	Objects Greater than 2.5mm	3	Sprayed Water
4	Objects Greater than 1mm	4	Splashed Water
5	Dust Protected	5	Water Jets
6	Dust Tight	6	Powerful Water Jets
		7	Effects of Immersion
		8	Indefinite Immersion

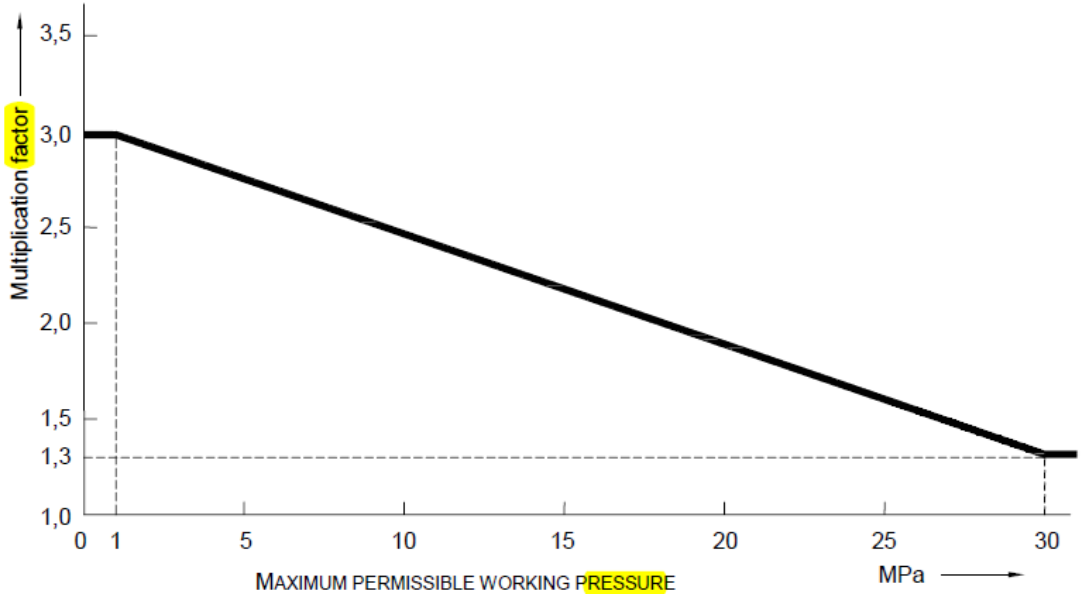
Mechanical Hazards

- Type of Mechanical Hazards

MECHANICAL HAZARD	Covered by subclause
Crushing HAZARD	9.2, 9.4 and 9.8
Shearing HAZARD	9.2 and 9.8
Cutting or severing HAZARD	9.2, 9.3 and 9.8
Entanglement HAZARD	9.2
Trapping HAZARD	9.2
Stabbing or puncturing HAZARD	9.2, 9.3 and 9.8
Friction or abrasion HAZARD	9.2 and 9.3
Expelled parts HAZARD	9.5
High pressure fluid ejection HAZARD	9.7
Falling HAZARD	9.8
Instability HAZARD	9.4
Impact HAZARD	9.2 and 9.8
Moving and positioning of PATIENT	9.2 and 9.4
Vibration and noise	9.6

Mechanical Hazards

- High Pressure Hydraulic Test
  - a pressure vessel shall withstand a hydraulic test pressure if both the following conditions are met:
    - the pressure is greater than 50 kPa; and
    - the product of pressure and volume is greater than 200kPa·l
  - ratio of test pressure and working pressure (test for 60s)



Mechanical Hazards

- Safety Factor of Support or Suspend System

Situation			Minimum TENSILE SAFETY FACTOR [a]	
No.	System Part	Elongation	A [b]	B [c]
1	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
2	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
3	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	5	8
4	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break of less than 5 %	8	12
5	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
6	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
7	MECHANICAL PROTECTIVE DEVICE (or back-up system of multiple support system)		2,5	4

A:材料張力及外部應力可量化者。

B:非A者

Test for 60s

Mechanical Hazards

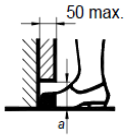
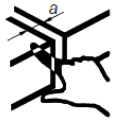
- Medical equipment shall comply with the strength tests

ME EQUIPMENT type	Test
HAND-HELD	Push (15.3.2)
	Drop (15.3.4.1)
	Moulding stress relief (15.3.6)
PORTABLE	Push (15.3.2)
	Impact (15.3.3)
	Drop (15.3.4.2)
	Moulding stress relief (15.3.6)
MOBILE	Push (15.3.2)
	Impact (15.3.3)
	Rough handling (15.3.5)
	Moulding stress relief (15.3.6)
FIXED or STATIONARY	Push (15.3.2)
	Impact (15.3.3)
	Moulding stress relief (15.3.6)

Mechanical Hazards

Safety of Medical Equipment

Table 20 – Acceptable gaps [a]

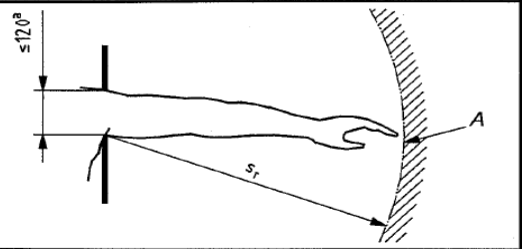
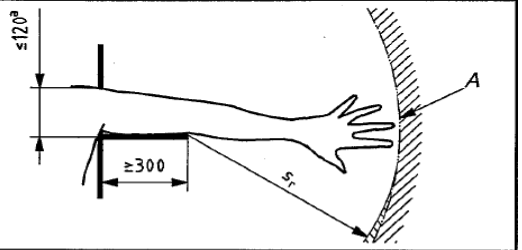
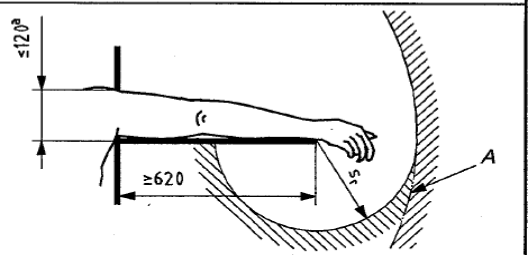
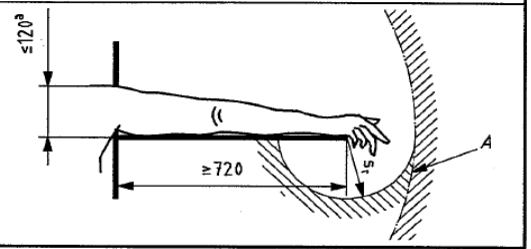
Part of body	Adult gap *a* mm	Children gap *a* mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, wrist, fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	

[a] The values in this table are taken from ISO 13852:1996.

Mechanical Hazards

Table 3 — Reaching around with limitation of movement

Dimensions in millimetres

Limitation of movement	Safety distance, s_r	Illustration
Limitation of movement only at shoulder and armpit	⩾ 850	
Arm supported up to elbow	⩾ 550	
Arm supported up to wrist	⩾ 230	
Arm and hand supported up to knuckle joint	⩾ 130	

A range of movement of arm

s_r radial safety distance

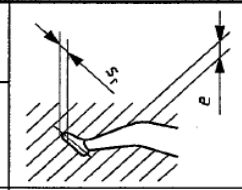
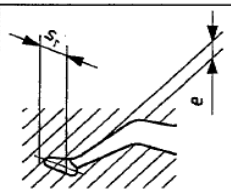
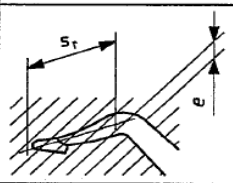
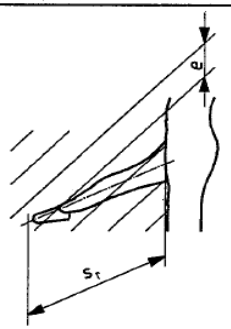
[a] This is either the diameter of a round opening, or the side of a square opening, or the width of a slot opening.

Mechanical Hazards

Safety of Medical Equipment

Table 7 — Reaching through openings of regular shape by lower limbs

Dimensions in millimetres

Part of lower limb	Illustration	Opening	Safety distance, s_r	
			Slot	Square or round
Toe tip		$e \leqslant 5$	0	0
		$5 < e \leqslant 15$	$\geqslant 10$	0
Toe		$15 < e \leqslant 35$	$\geqslant 80$ [a]	$\geqslant 25$
Foot		$35 < e \leqslant 60$	$\geqslant 180$	$\geqslant 80$
		$60 < e \leqslant 80$	$\geqslant 650$ [b]	$\geqslant 180$
Leg (toe tip to knee)		$80 < e \leqslant 95$	$\geqslant 1\,100$ [c]	$\geqslant 650$ [b]
Leg (toe tip to crotch)		$95 < e \leqslant 180$	$\geqslant 1\,100$ [c]	$\geqslant 1\,100$ [c]
		$180 < e \leqslant 240$	Not admissible	$\geqslant 1\,100$ [c]

[a] If the length of the slot opening is $\leqslant 75$ mm, the distance can be reduced to $\geqslant 50$ mm.

[b] The value corresponds to leg (toe tip to knee).

[c] The value corresponds to leg (toe tip to crotch).

NOTE Slot openings with $e > 180$ mm and square or round openings with $e > 240$ mm will allow access for the whole body (see also Clause 1, final paragraph).

Radiation Hazards

- Unwanted X-Radiation
  - the dose-rate shall not exceed 36 pA/kg (5 μSv/h) (0.5 mR/h) at a distance of 5 cm from a surface of the product.
  - EU requires that at any point 10 cm from the surface of the equipment, the dose-rate shall not exceed 1 μSv/h (0.1 mR/h)
- Intended X-Radiation shall comply with IEC 60601-1-3
- Alpha, beta, gamma, neutron and other particle radiation hazards are checked by the Risk Management File.
- Microwave radiation, Infrared radiation and ultraviolet radiation hazards are checked the Risk Management File.

Temperature Test

- 樣品貼住試驗角落(Test Corner)的2面牆
- 電熱類產品的輸入電壓為額定的+10%
- 電動類和綜合類產品的輸入電壓為額定的±10%
- 可在一般室溫下測，再加值到額定室溫
- 若Applied Part大於41˚C ，則須於手冊作相關警告說明
  - radiating surface of ultrasonic physiotherapy equipment shall not exceed 41 ˚C
- 用熱偶線量測者，winding限制須降10˚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

Temperature Test

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

Table 22 – Allowable maximum temperatures of parts

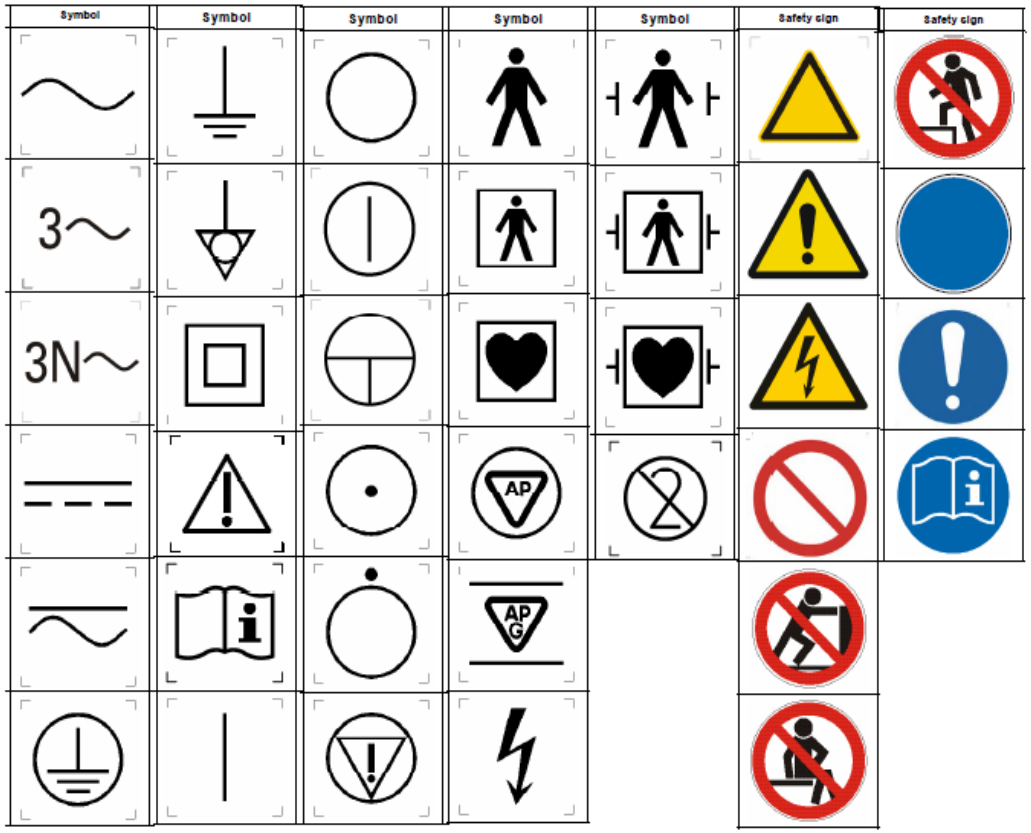
Parts	Maximum Temperature °C
Insulation, including winding insulation [a]	
- of Class A Material	105
- of Class E Material	120
- of Class B Material	130
- of Class F Material	155
- of Class H Material	180
Parts with T marking	T [b]
Other components and materials	[c]
Parts in contact with flammable liquid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

Marking Requirement

- Colour coding on control, marking, signaling and display

Colour	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 colour	Meaning other than that of red, yellow or green

- Symbols:



Changing on IEC 60601-1/A1

- Marking shall include:
  - serial number or lot or batch identifier, and
  - the date of manufacture or use by (if any)

CE mark (made in compliance with 93/42EEC Directive on class IIA or IIB medical devices)	CE 0120 (*)	expiry date, if the product is perishable (year/month)	2020-12 (*)	storage temperature	(*)
lot number (indicated by LOT mark)	LOT (*)	for professional use only	P (**)	for single use only	(*)
keep dry	(*)	this product contains Nickel-Chromium: possible allergic reactions	Cr Ni (**)	keep away from sunlight	(*)
CE mark (made in compliance with 93/42EEC Directive on class I medical devices)	CE (*)	see instructions for use	(*)	gamma-ray sterilized	STERILE R (*)
titanium	Ti (*)	surgical steel	SS (*)	this product contains Chromium: possible allergic reactions	Cr (**)
autoclavable at temperature indicated	135°C (*)	non-sterile	NON STERILE (*)	date of manufacture	

- PEMS shall comply with Clause 4.3, 5, 7, 8 and 9 of IEC 62304:2006

Changing on IEC 60601-1/A1

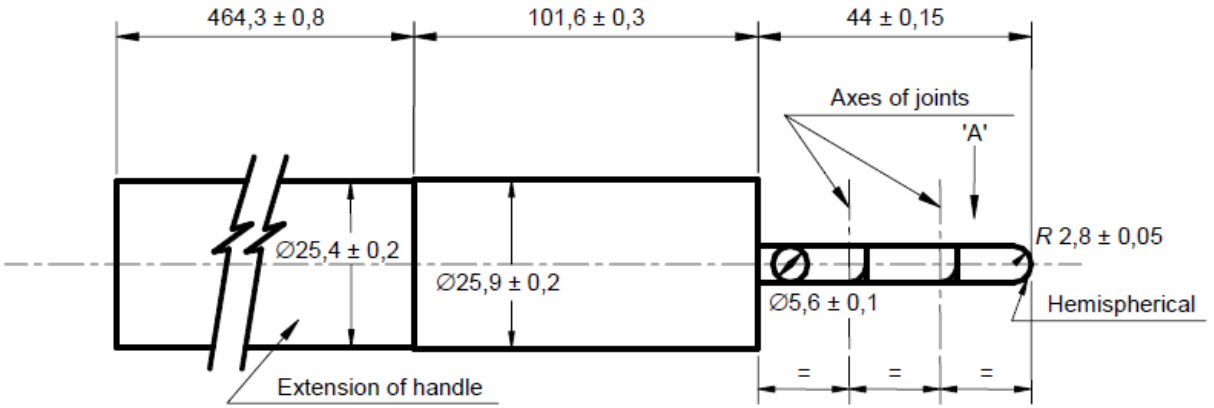
- Change ISO 14971:2000 to ISO 14971:2007
  - deleted nearly 50 RMF requirement in 60601-1
- Where the working voltage across a MOPP is <42.4Vp or 60Vd.c., a single Y1 capacitor is acceptable for two MOPP.
- The spacing for opposite polarity of the mains part reduced from 3.0mm/1.6mm to 2.5mm/2.0mm

Changing in IEC 60601-1/A1

- Body-Worn ME is considered as Portable ME during the mechanical strength tests except for the Drop Test
- Primary lithium batteries shall comply with IEC 60086-4
- Secondary lithium batteries shall comply with IEC 62133
- Humidity conditioning duration:
  - IPX0: 48h
  - IPx1 or above: 168h

Briefing on IEC 60601-1-11

- **“Used In The Home Healthcare Environment”**
- Voltage tolerance:
  - Non-Life-Supporting ME: 85% to 110 %
  - Life-Supporting ME: 80% to 110 %
- Minimum operating temperature range: +5˚C to +40˚C
- Transport and storage temperature: -25˚C
- Smaller test finger(∅5.6) is used:



Briefing on IEC 60601-1-11

- Should be Class II or internally powered, and no functional earth terminal provided
- Applied part shall be either Type BF or CF
- Enclosure of the ME shall be:
  - Mark with “Keep Dry” or  or comply with the IP rating:

	Non-TRANSIT-OPERABLE use				TRANSIT-OPERABLE use			
	MOBILE	PORTABLE	HAND-HELD	BODY-WORN	MOBILE	PORTABLE	HAND-HELD	BODY-WORN
IEC 60529 Ingress protection	IP21	IP21	IP22	IP22	IP22	IP22	IP22	IP22

Briefing on IEC 60601-1-11

- ME should be provided with Alarm Signal

- Mechanical strength test:

	Non-TRANSIT-OPERABLE use				TRANSIT-OPERABLE use[a]			
	MOBILE	PORTABLE	HAND-HELD	BODY-WORN	MOBILE	PORTABLE	HAND-HELD	BODY-WORN
Vibration	1	1	1	1	2	2	2	1
Shock	1	1	1	1	2	2	3	2
Drop	1	1	3	2	2	2	3	3
Mechanical Strength 0=no test, 1=least severe or 7M1[b], 2=moderately severe or 7M2, 3=most severe or 7M3								

Briefing on IEC 60601-1-11

- ME with Internal Electrical Power Source shall be indicated with:
  - number of procedures remaining;
  - remaining operating time;
  - percentage of the remaining operating time or energy; or
  - "fuel" gauge.
- The state of the Internal Electrical Power Source may be indicated continuously or by operator action
- *Taiwan not yet require 60601-1-11*

Thanks a lot……