Safety of Medical Equipment

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
- 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

What's New in Edition 3.0?

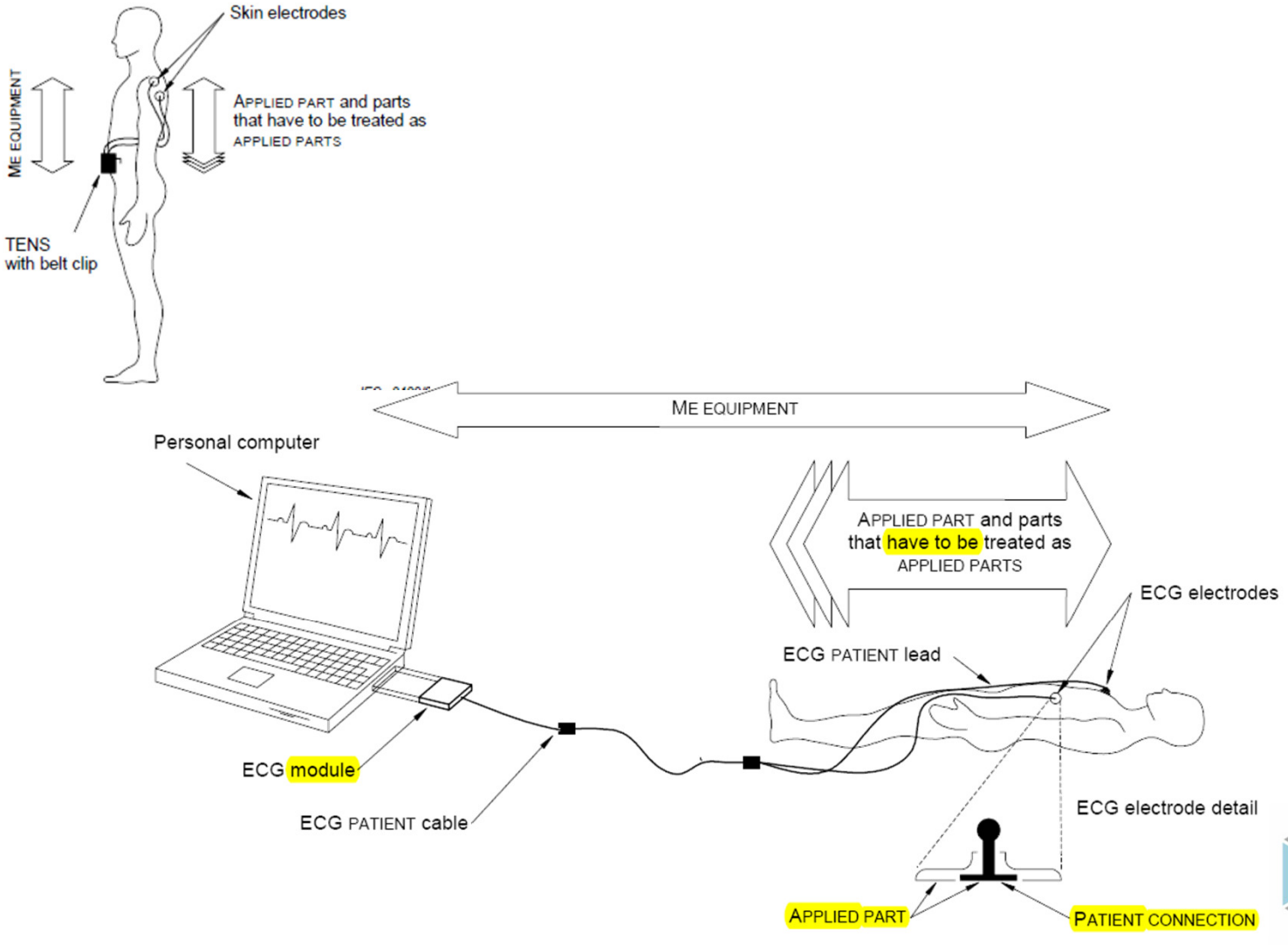
- Essential Performance 的導入
  - 導入可用性確效要求 (原IEC 60601-1-6)
  - 導入軟體確效要求 (原IEC 60601-1-4)
  - Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

Part 1:
General requirements for basic safety and essential performance

- 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

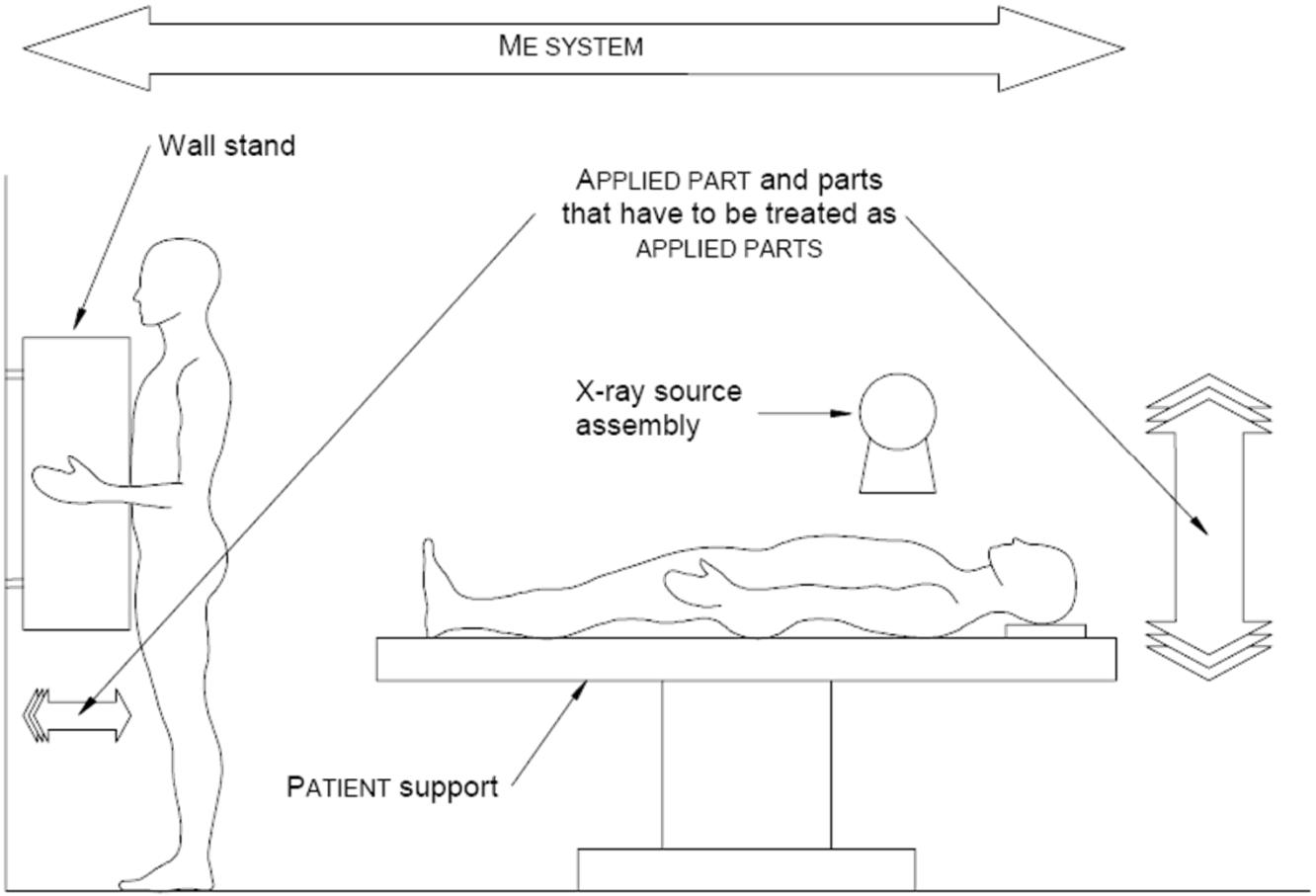
Terminology and Definitions

- ACCESSIBLE PART, APPLIED PART, PATIENT CONNECTION



Terminology and Definitions

- APPLIED PART



Terminology and Definitions

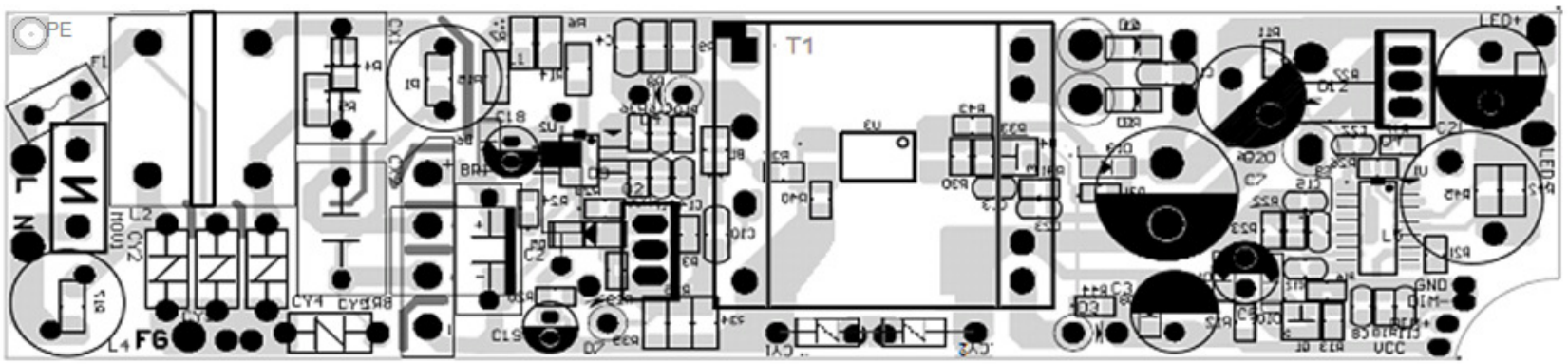
- Type B APPLIED PART
  - APPLIED PART that has no PATIENT CONNECTION

- Type BF APPLIED PART
  - APPLIED PART with PATIENT CONNECTION

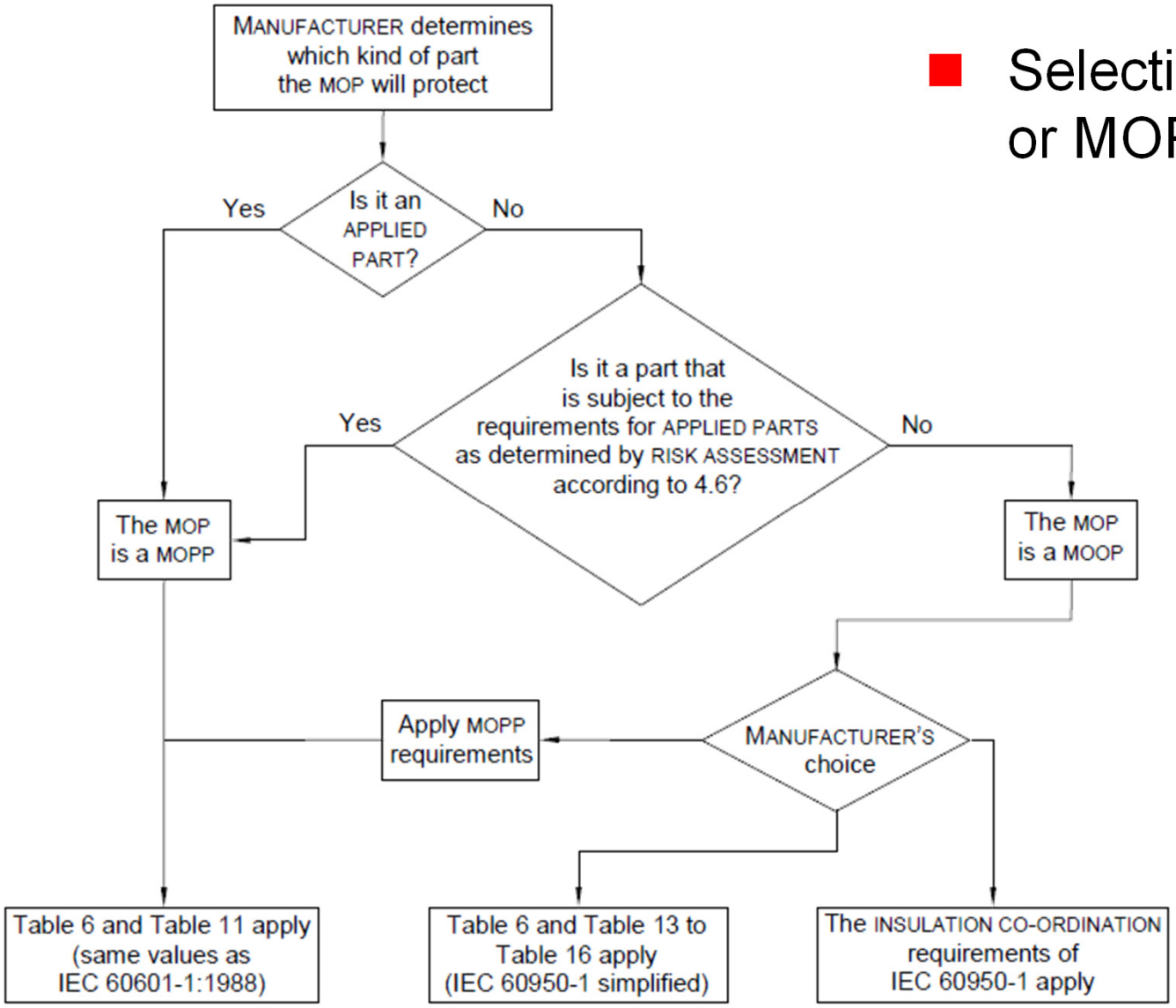
- Type CF APPLIED PART
  - APPLIED PART with PATIENT CONNECTION and suitable for cardiac use.

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

Terminology and Definitions



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

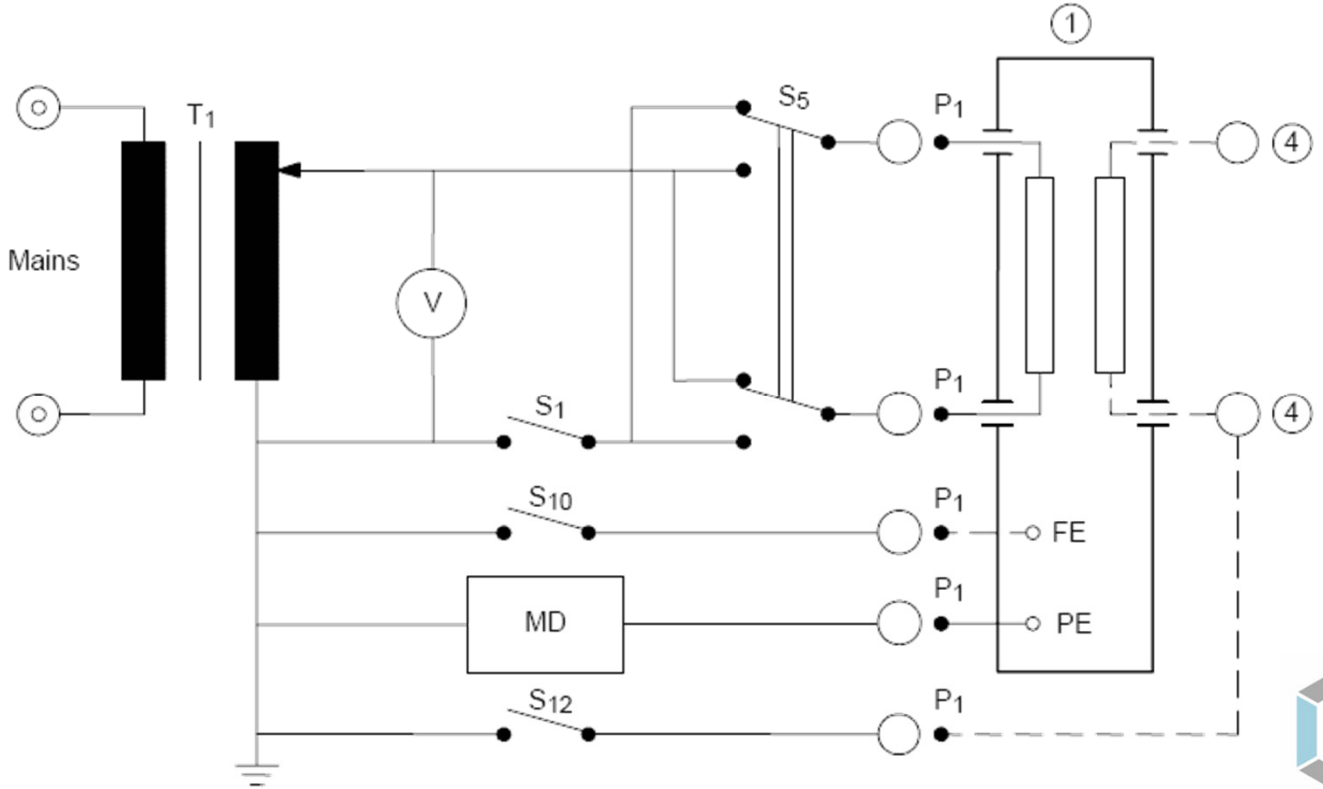
- Short any parts of less than 1MOP is a NC.

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 .

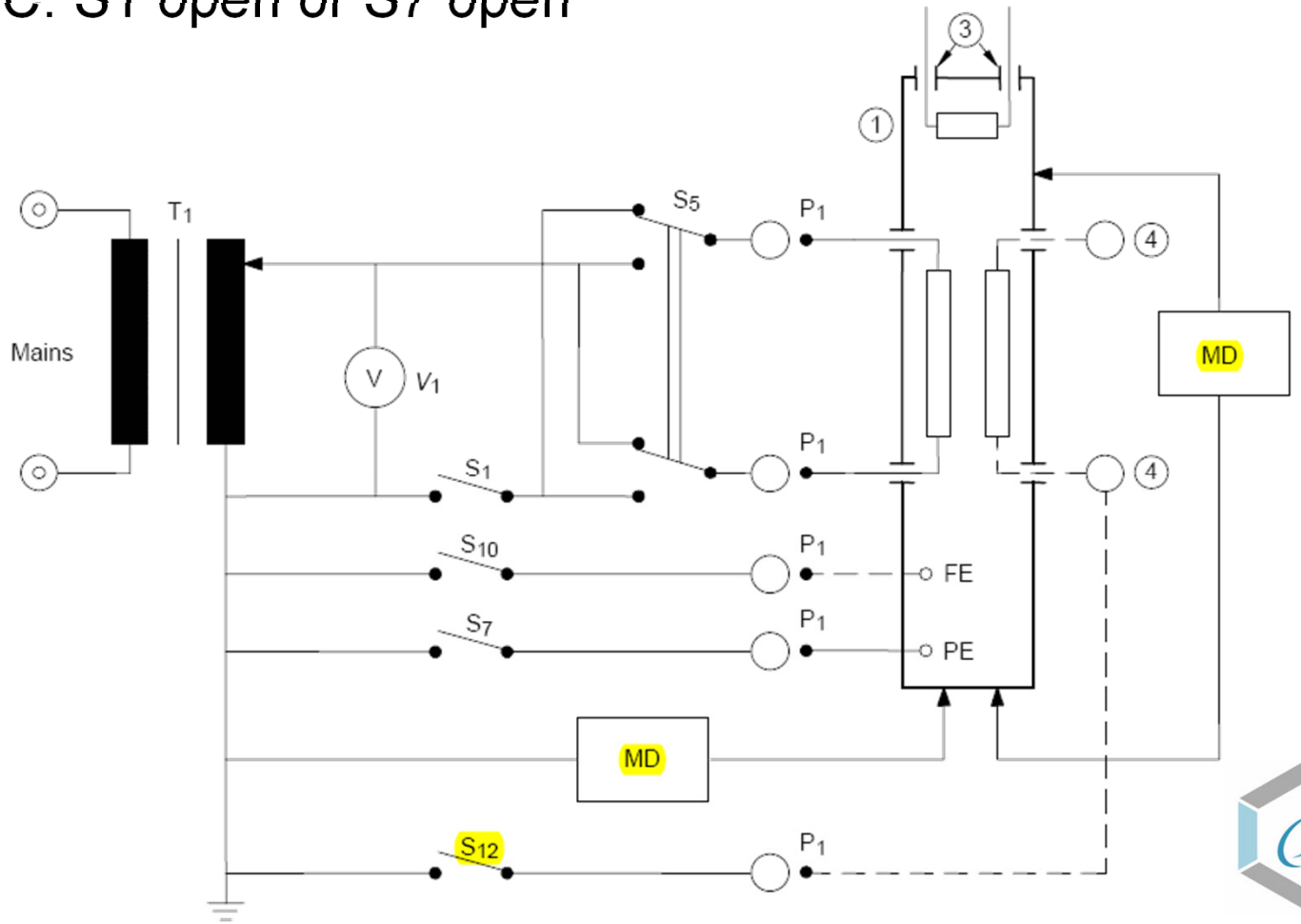
Leakage Currents in 60601-1

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



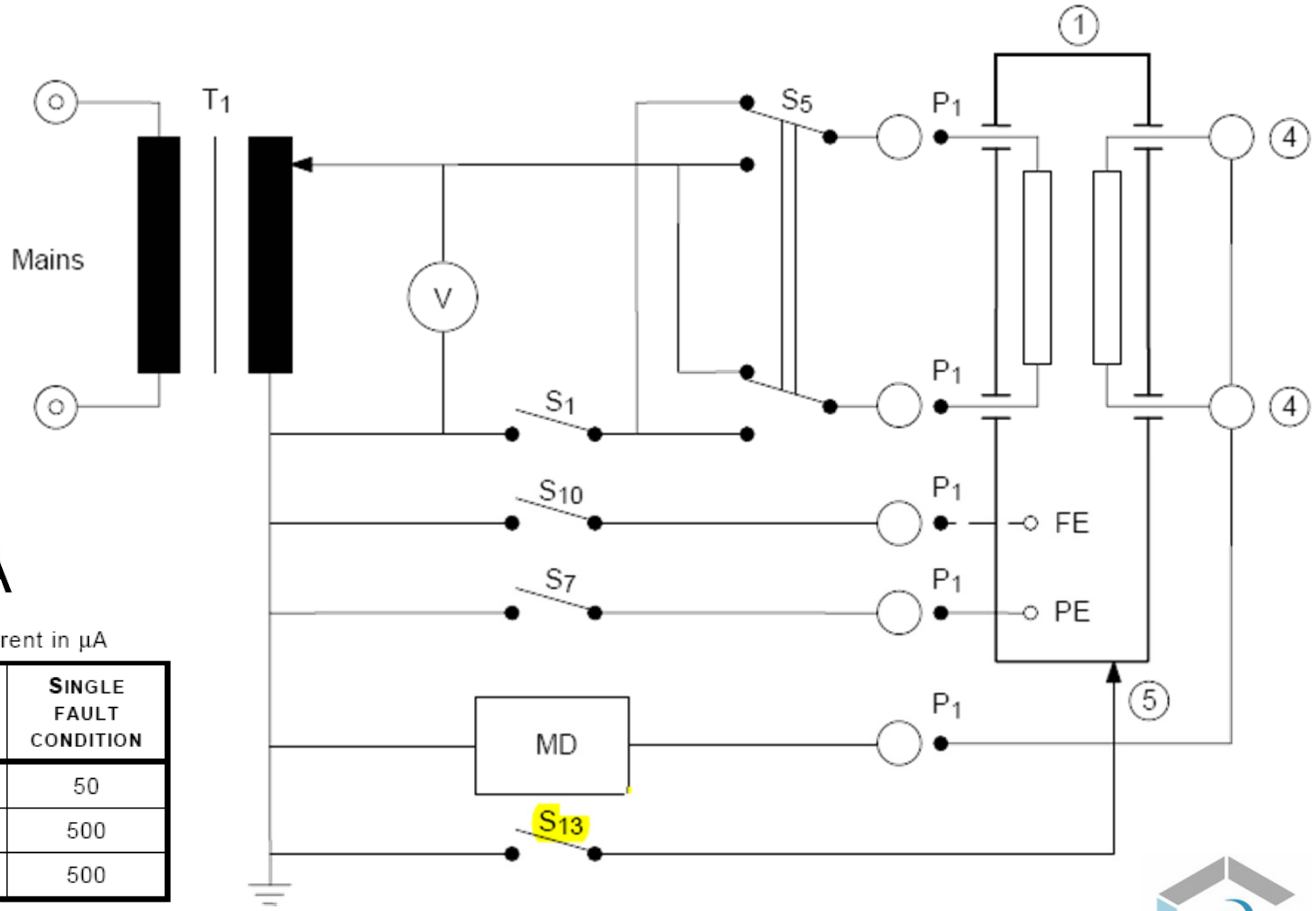
Leakage Currents in 60601-1

- 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

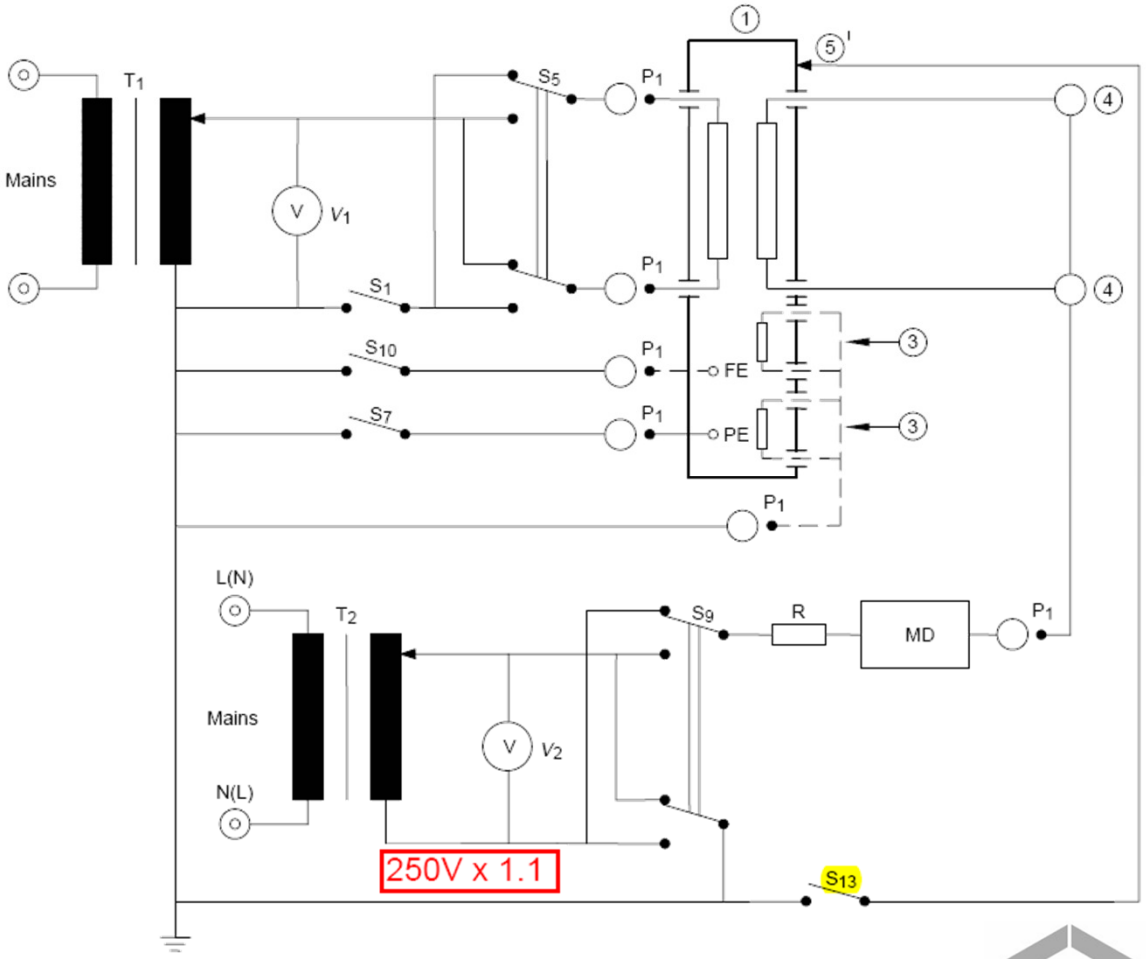
APPLIED PART TYPE	NORMAL CONDITION	SINGLE FAULT CONDITION
CF	10	50
BF	100	500
B	100	500

Leakage Currents in 60601-1

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

Current in µA

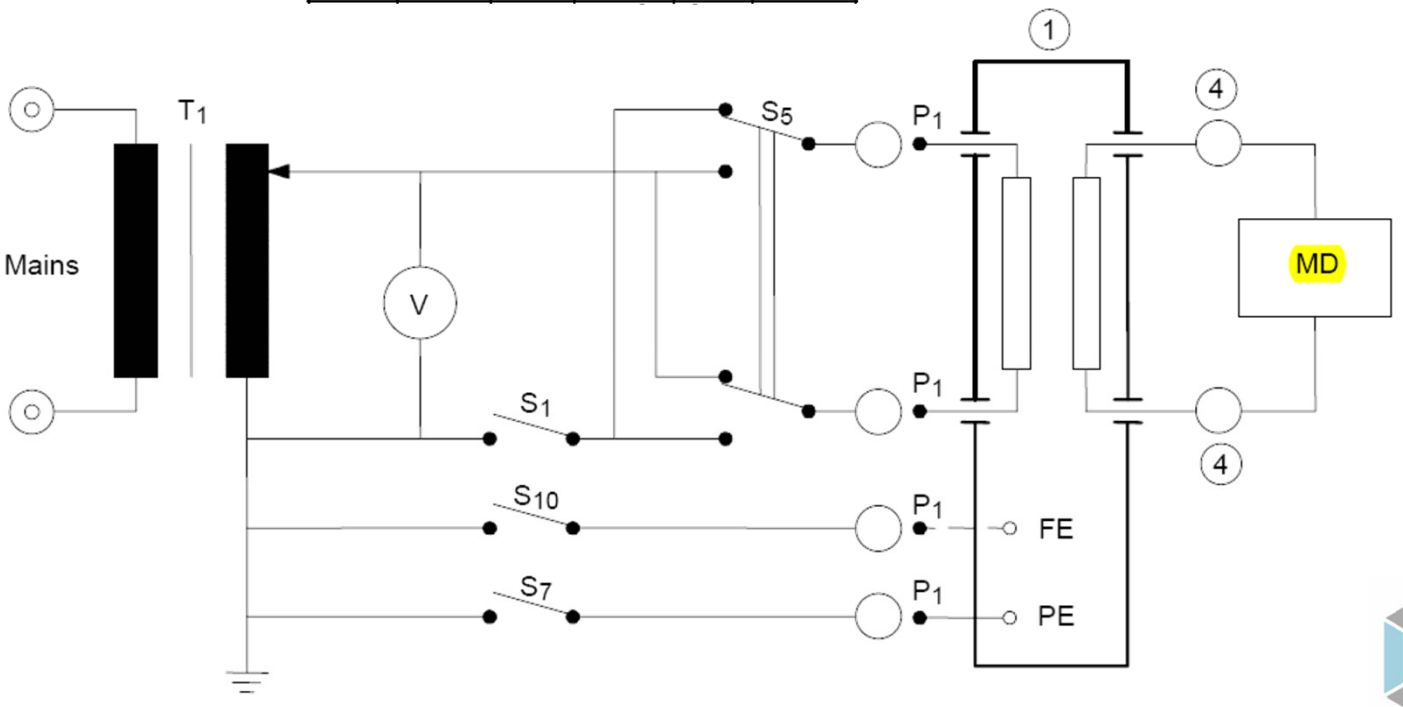
APPLIED PART TYPE	Special test condition
CF	50
BF	5 000
B	—



Leakage Currents in 60601-1

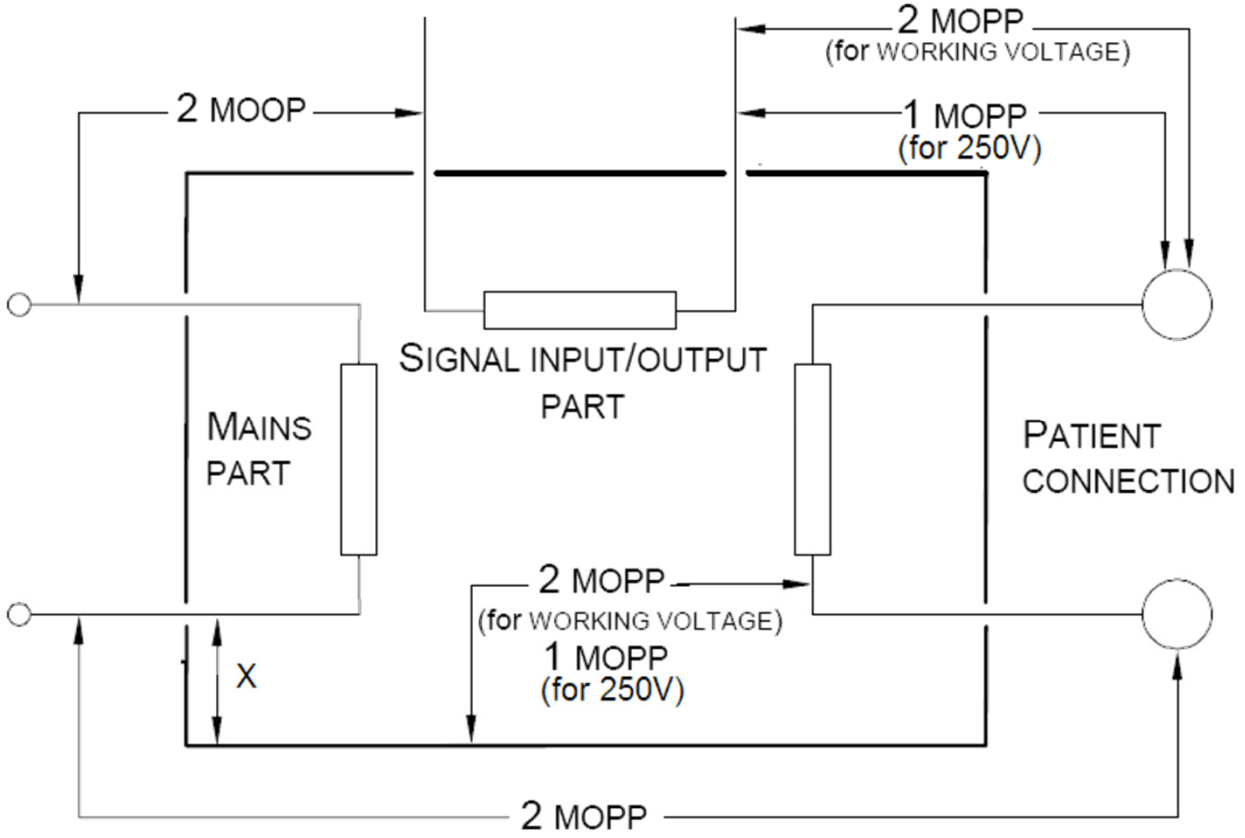
- Patient Auxiliary Current Testing:
  - SFC: S1 open or S7 open (see also page 25)
  - Limit: uA

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



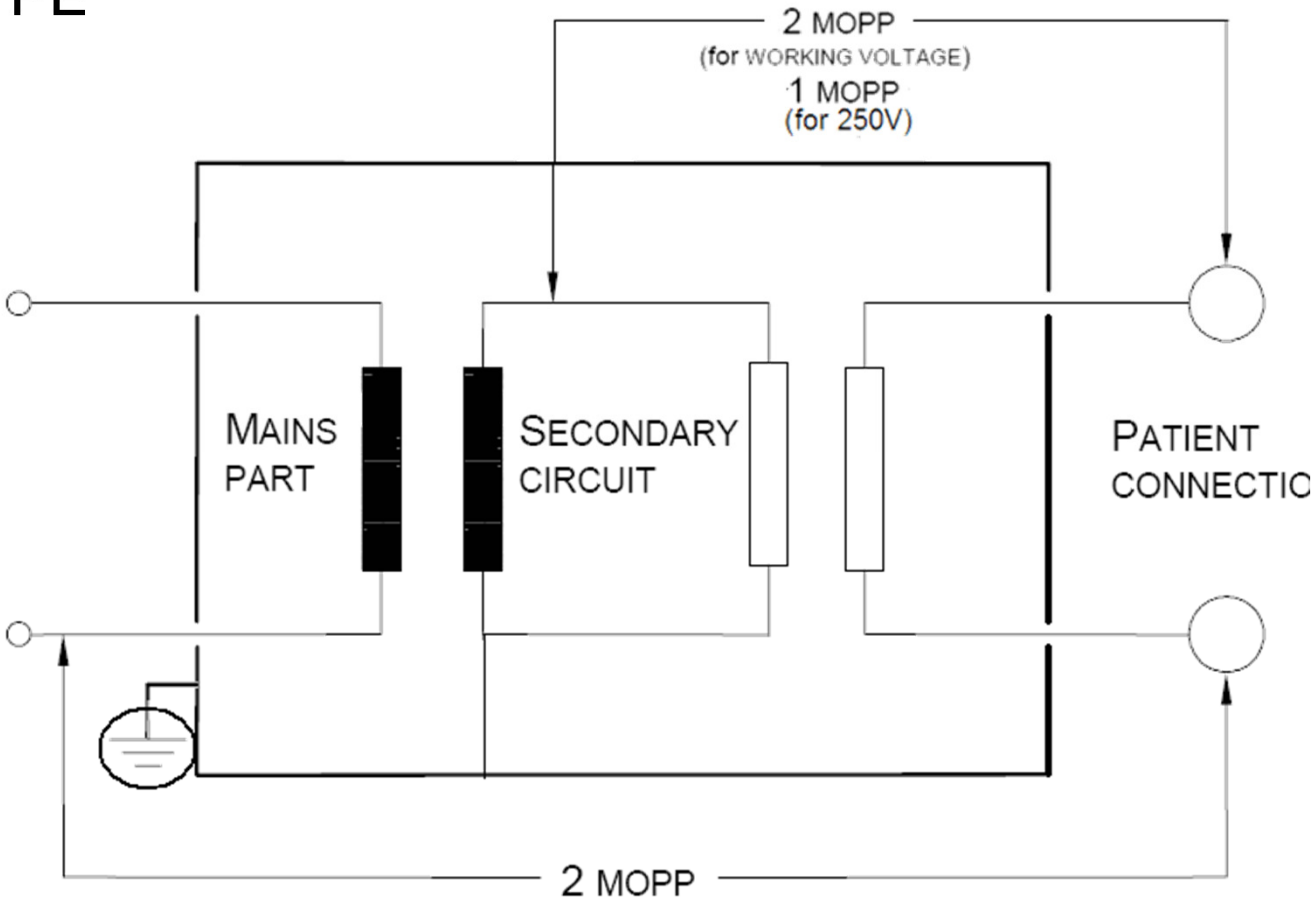
Isolation in 60601-1

- 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

- 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* ≤ 71	60 < *U* ≤ 71	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
71 < *U* ≤ 184	71 < *U* ≤ 184	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
184 < *U* ≤ 212	184 < *U* ≤ 212	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
212 < *U* ≤ 354	212 < *U* ≤ 354	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
354 < *U* ≤ 848	354 < *U* ≤ 848	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
848 < *U* ≤ 1 414	848 < *U* ≤ 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* ≤ 10 000	1 414 < *U* ≤ 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* ≤ 14 140	10 000 < *U* ≤ 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

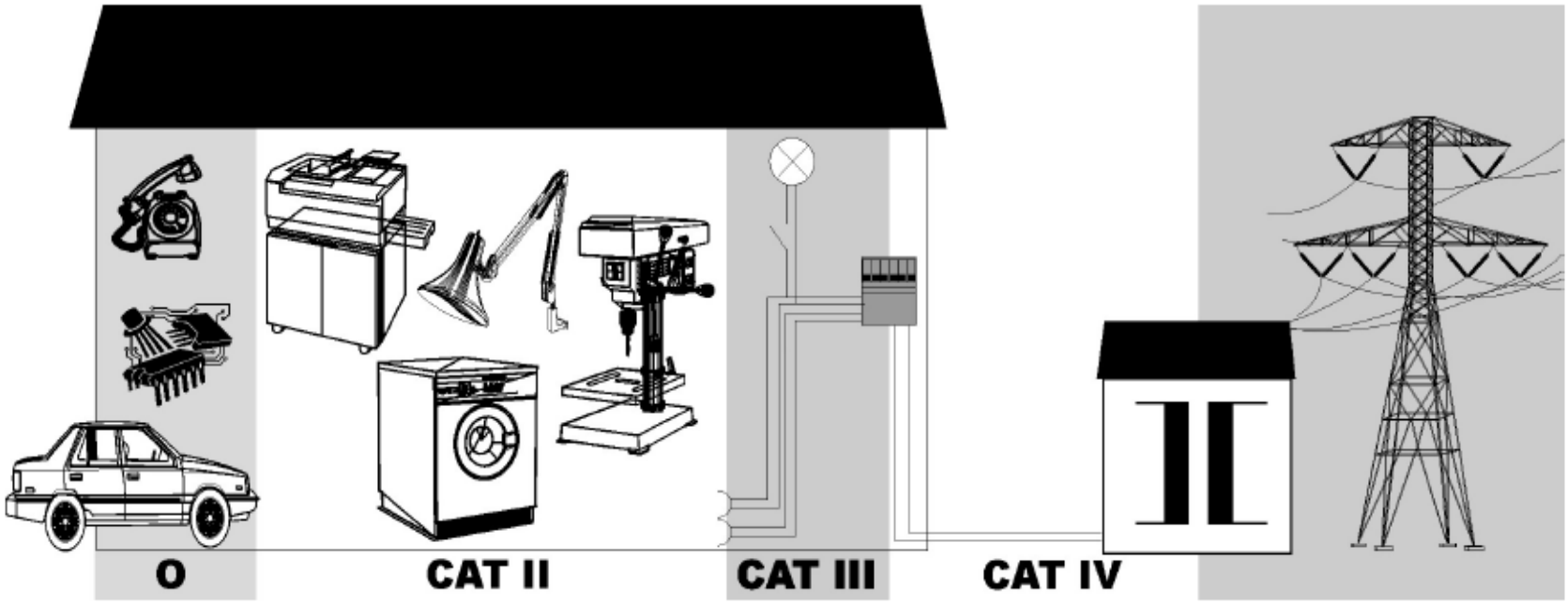
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION

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

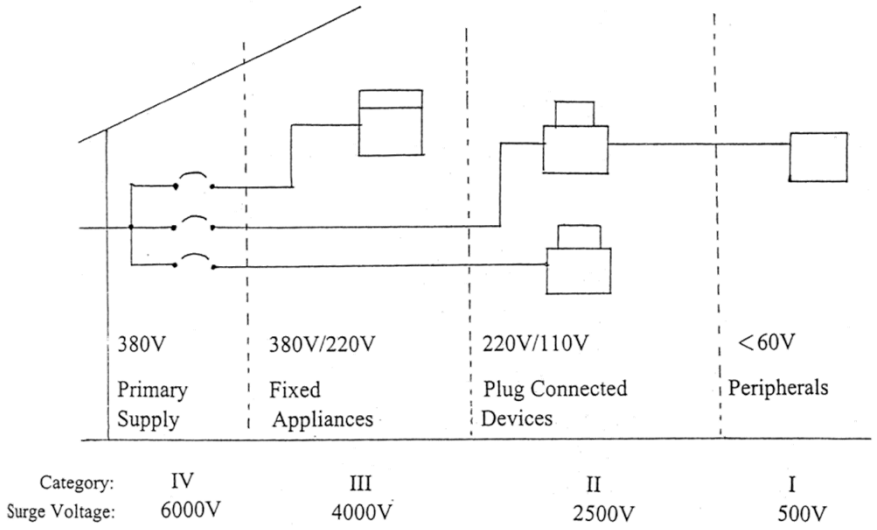
Isolation in 60601-1

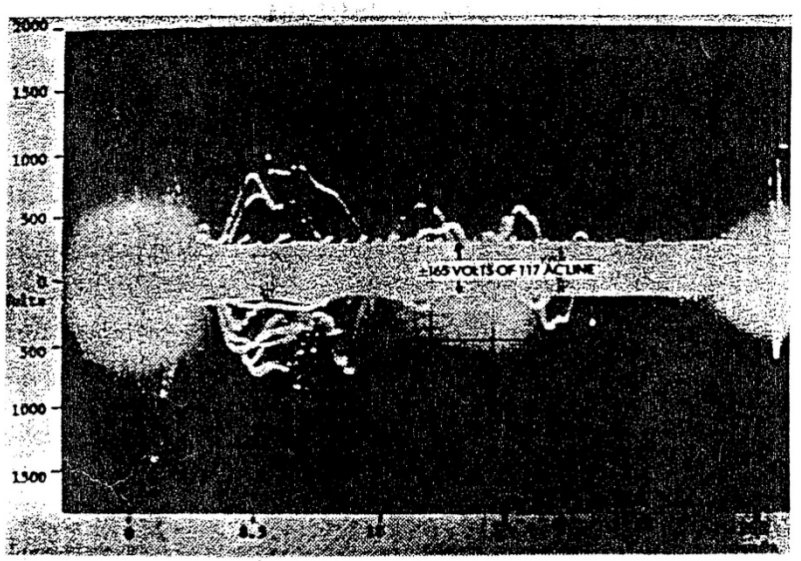
- Installation Category (CAT)



Isolation in 60601-1

- Installation Category (CAT)

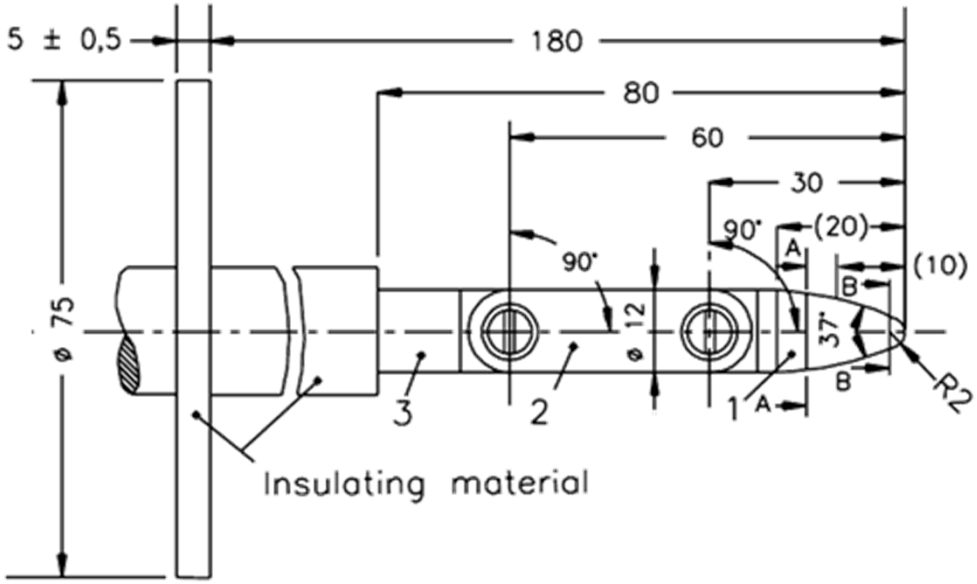


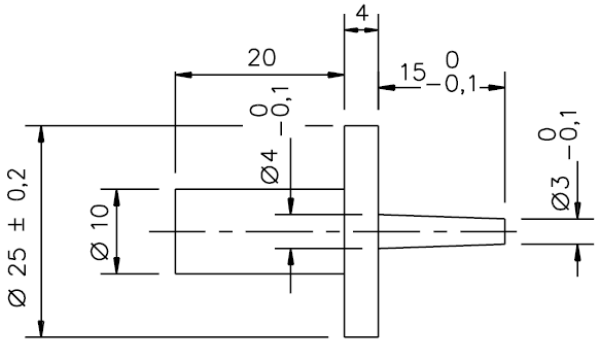


Typical surge voltages on residential power line; recordings taken over 24-hour period *(Photography courtesy F. Martzloff, General Electric Company)*

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

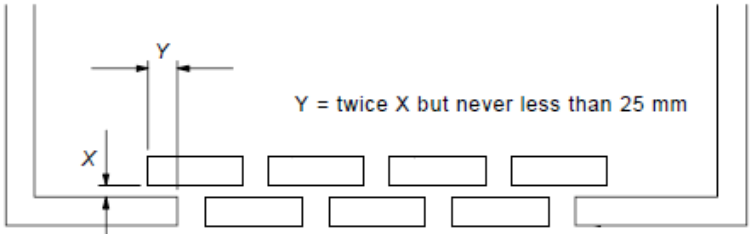


Table 25 – Acceptable perforation of the bottom of an ENCLOSURE

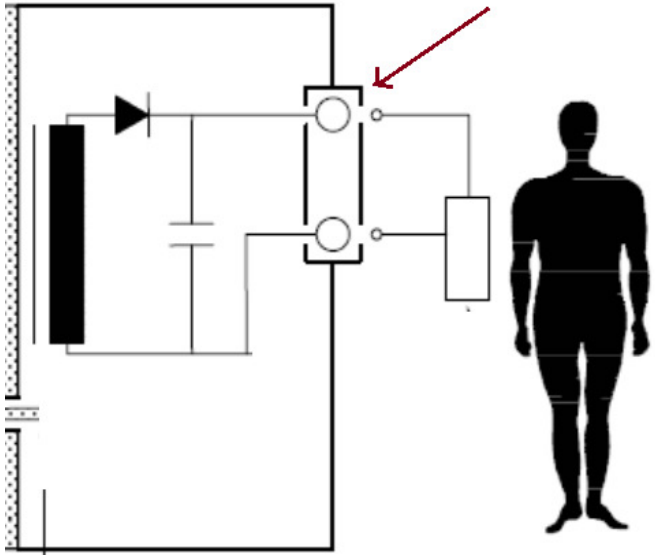
Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm^2)
0,66	1,19	2,36
0,76	1.15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm^2)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

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

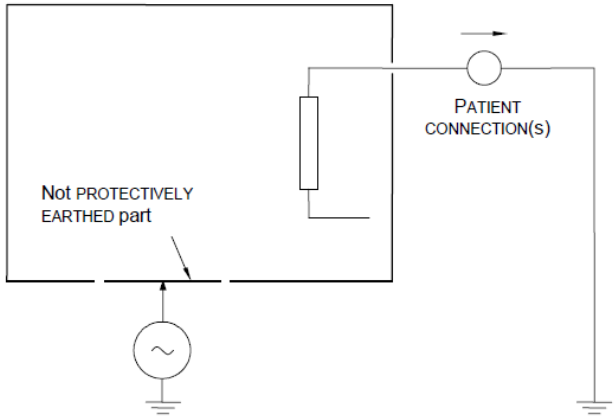
Requirement on Enclosure

- 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

- Treatment Head of ultrasonic physiotherapy equipment shall be rated IPX7

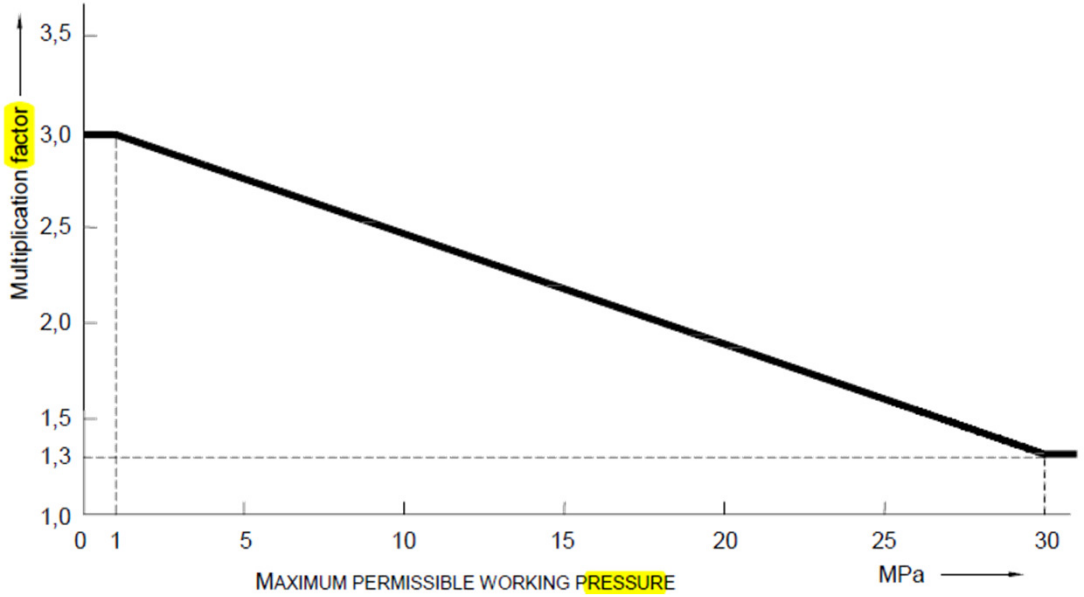
Mechanical Hazards

- 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

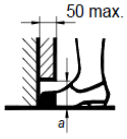
Mechanical Hazards

- 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

Table 20 – Acceptable gaps [a]

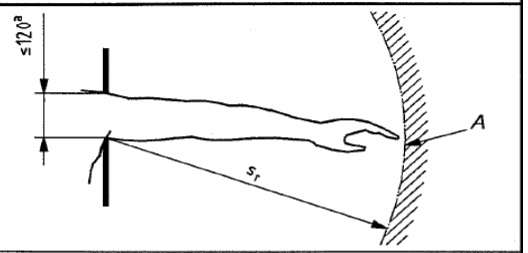
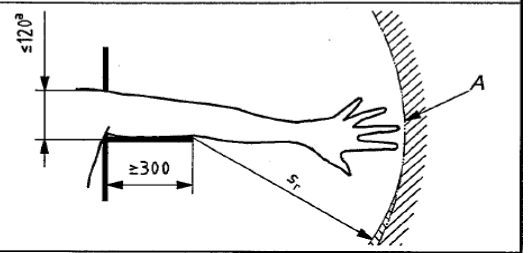
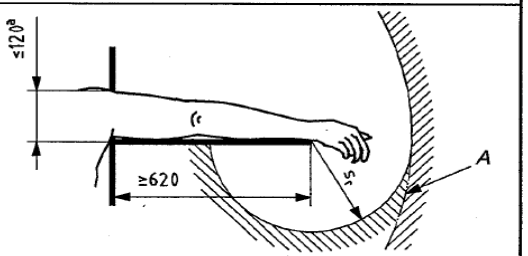
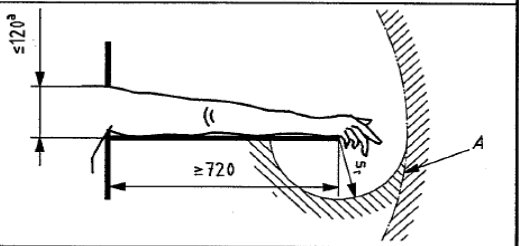
Part of body	Adult gap *a* mm	Children gap *a* mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, wrist, fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	

[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

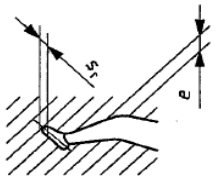
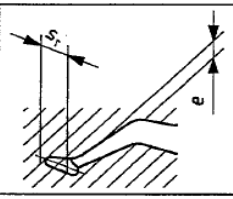
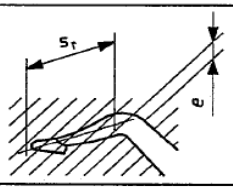
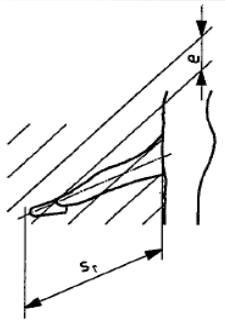
s_r radial safety distance

[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

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: