

Safety Requirements for Power Supplies Intended for Medical Applications



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Introduction

- **IEC 60950-1** is the reference standard for power supplies under Information Technology Equipment.
- **IEC60601-1** is the international basic safety and essential performance standard for electrical medical equipment and medical electrical systems.
- This module will provide the additional requirements to IEC 60950-1 standard to meet the requirements of a medical grade power supplies.

Introduction cont.

The requirements of IEC 60950-1 and IEC60601-1 will address the prevention of the following hazards

- Electric shock
- Energy related hazards
- Fire
- Heat related hazards
- Mechanical hazards
- Chemical hazards
- Radiation

Introduction cont.

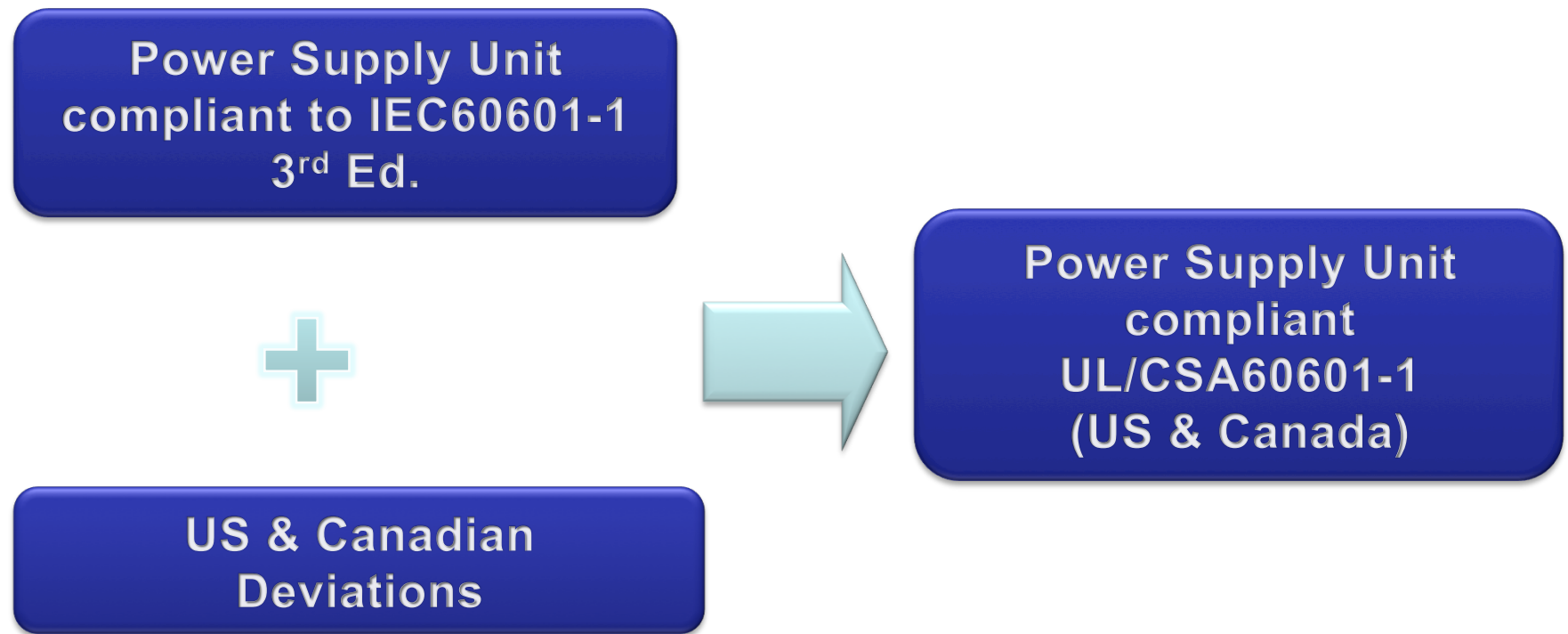
IEC60950-1
(ITE)



Power Supply Unit
compliant
IEC60601-1 3rd Ed.

Additional Compliance
Criteria according to
IEC60601-1 3rd Ed.

Introduction cont.



Important Terminologies

Safety Extra – Low Voltage (SELV) (clause 2.4.3 of IEC60601-1)

Voltage which does not exceed a NOMINAL value of 25V a.c. or 60V d.c. at RATED supply voltage on the transformer or converter, between conductors in an earth-free circuit which is isolated from the SUPPLY MAINS by a SAFETY EXTRA-LOW VOLTAGE TRANSFORMER or by a device with an equivalent separation.

Live (clause 2.1.10 of IEC60601-1)

State of a part which, when connection is made to that part, can cause a current exceeding the allowable LEAKAGE CURRENT for the part concerned to flow from that part to earth or from that part to an ACCESSIBLE PART of the same EQUIPMENT.

Important Terminologies cont.

Applied Parts (clause 2.1.5 of IEC60601-1)

Part of Medical Electrical Equipment that in normal use necessarily comes into physical contact with the patient for Medical Electrical Equipment or a Medical Electrical System to perform its function.

Classification Types of Applied Parts (clause 2.1.24-2.1.28, 5.2 of IEC60601-



Type B – No electrical contact with Patient and maybe earthed



Type BF – Electrically connected to Patient but not directly to heart



Type CF – Electrically connected to the heart of the Patient.

Power supplies are “unclassified” in terms of applied parts. Requirements for Type B (least requirement) will apply for all accessible parts power supply (including output terminals) unless otherwise specified by the customer.

Important Terminologies cont.

Enclosure Leakage Current (Reference: clause 2.5.2 of IEC60601-1)

- Current flowing from the enclosure 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.

Enclosure (Reference: clause 2.1.6 of IEC60601-1)

- Exterior surface of equipment including all accessible metal parts, knobs, grips and the like accessible shafts.

Important: Output connector conductive terminals are considered part of enclosure.

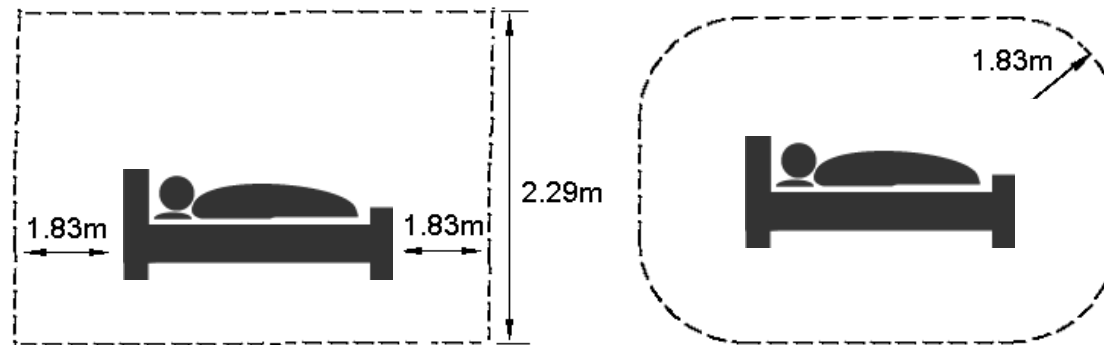
Earth Leakage Current (Reference: clause 2.5.1 of IEC60601-1)

- Current flowing from the mains part through or across the insulation into the protective earth conductor.

Important Terminologies cont.

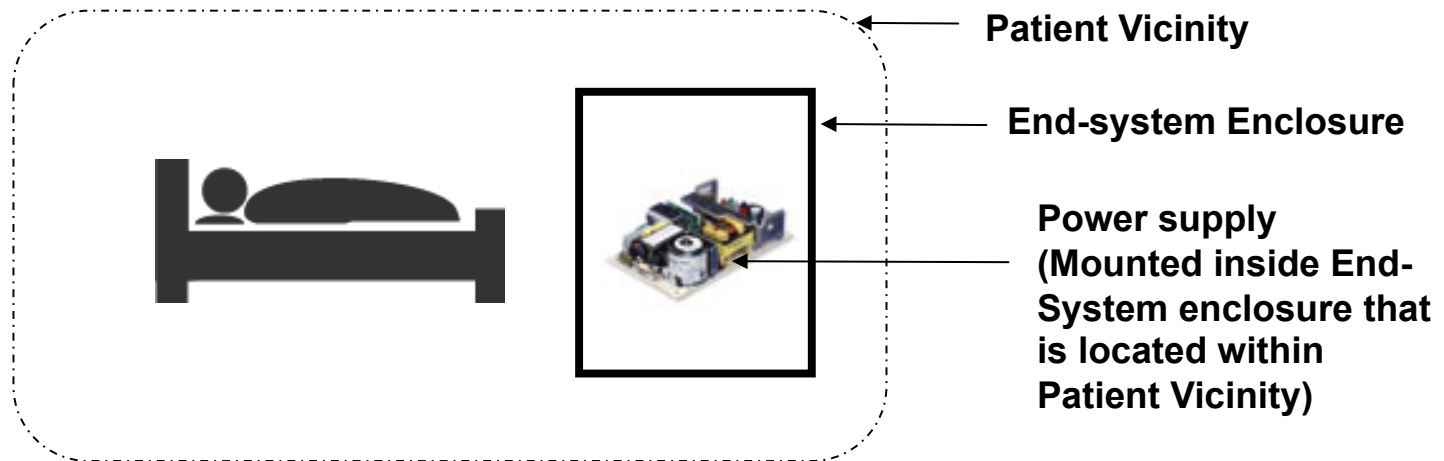
Patient Vicinity (Reference: clause 2.12.20DV of UL60601-1)

In areas in which patients are normally cared for, the Patient Vicinity is the space with surfaces likely to be contacted by the patient or an attendant who can touch the patient. This encloses a space within the room 1,83 m (6 feet) beyond the perimeter of the bed (examination table, dental chair, treatment booth, and the like) in its intended location, and extending vertically 2,29 m (7-1/2 feet) above the floor.



Important Terminologies cont.

Patient Care Equipment (Reference: clause 2.12.19DV of UL60601-1)
Equipment intended for use in or likely to be used in the patient vicinity



Important:

Power supplies located within the Patient Vicinity is considered Patient Care Equipment EVEN if:

- Power supply is covered by an enclosure in the end system.
- There are no accessible parts to the patient.

Major Differences Between IEC60950-1 & IEC60601-1

The following are items are compliance considerations for IEC60601-1 that exceeds the requirement of IEC60950-1

- 3.1 Safety Spacing – Creepage and Clearance
- 3.2 Safety Insulation for Transformers
- 3.3 Hipot Voltage
- 3.4 Leakage Current
- 3.5 Mains Fuses and Over-current releases
- 3.6 Bridging capacitor
- 3.7 Wiring of Mains Part
- 3.8 Plug Part and Power Supply Cords
- 3.9 Marking (Label, Fuse marking, Ground Symbol)
- 3.10 Ball Pressure Test for Plastic Enclosure

3.1 Safety Spacing – Creepage & Clearance

Major Differences Between IEC60950-1 & IEC60601-1

Refer to Table XVI of IEC60601-1 for the Creepage & Clearance requirement based on the corresponding working voltages across insulation or upper rated input voltage which ever is higher.

Table XVI
CREEPAGE DISTANCES and AIR CLEARANCES in millimetres¹⁾

	d.c. voltage	15	36	75	150	300	450	600	800	900	1 200	
	a.c. voltage	12	30	60	125	250	400	500	660	750	1 000	
Equivalent to BASIC INSULATION between parts of opposite polarity	A-f	0,4	0,5	0,7	1	1,6	2,4	3	4	4,5	6	AIR CLEARANCES
		0,8	1	1,3	2	3	4	5,5	7	8	11	CREEPAGE DISTANCES
BASIC INSULATION OF SUPPLEMENTARY INSULATION	A-a1, A-b, A-c, A-j B-d, B-c	0,8	1	1,2	1,6	2,5	3,5	4,5	6	6,5	9	AIR CLEARANCES
		1,7	2	2,3	3	4	6	8	10,5	12	16	CREEPAGE DISTANCES
DOUBLE INSULATION OF REINFORCED INSULATION	A-a2, A-e, A-k B-a, B-e	1,6	2	2,4	3,2	5	7	9	12	13	18	AIR CLEARANCES
		3,4	4	4,6	6	8	12	16	21	24	32	CREEPAGE DISTANCES

¹⁾ This table replaces Tables XVI and XVII of the first edition.

- A-f = Between Live to Neutral before fuse
- A-a1 = Between primary circuits to protective earth
- A-a2 = Between primary to secondary

IMPORTANT:

- * Linear interpolation is NOT allowed.
- * See next page for method of measuring working voltage

3.1 Safety Spacing – Creepage & Clearance

Major Differences Between IEC60950-1 & IEC60601-1

Clearance Calculation if altitude is greater than 3000 meters:

– Clearance will be calculated as follows:

- Clearance = Clearance from Table XVI of IEC60601-1 X Multiplication factor per Table A.2 corresponding to Altitude

1.14

Altitude m	Normal barometric pressure kPa	Multiplication factor for clearances
2 000	80,0	1,00
3 000	70,0	1,14
4 000	62,0	1,29
5 000	54,0	1,48
6 000	47,0	1,70
7 000	41,0	1,95
8 000	35,5	2,25
9 000	30,5	2,62
10 000	26,5	3,02
15 000	12,0	6,67
20 000	5,5	14,5

Important:

1. The values in Table XVI of UL60601-1 already considered the 1.14 multiplication factor of Table A.2 of IEC60664-1.
2. Linear interpolation is NOT allowed.

3.2 Safety Insulation for Transformers

Major Differences Between IEC60950-1 & IEC60601-1

Insulation for Reinforced or Double Insulation on Transformer Construction (clause 57.9.4 e of IEC60601-1)

IEC60601-1 (Medical)	
Solid Insulation (1 layer) OR	For isolation transformer: Min 1.0mm #
Thin Sheet (2 layers) OR	Total thickness of at least 0.3mm
Thin Sheet (3 layers)	No thickness requirement (Same as IEC60950-1)

Other than isolating
transformer: Min. 0.4mm

3.3 Hipot Test Voltage

Major Differences Between IEC60950-1 & IEC60601-1

Hipot Test Voltages is referred to Table V of IEC60601-1 for according to working voltages across insulation or upper rated input voltage which ever is higher.

Table V
Test voltages

Insulation to be tested	Test voltages for reference voltage U (V)					
	$U \leq 50$	$50 < U \leq 150$	$150 < U \leq 250$	$250 < U \leq 1000$	$1000 < U \leq 10000$	$10000 < U$
BASIC INSULATION	500	1 000	1 500	$2U + 1000$	$U + 2000$	¹⁾
SUPPLEMENTARY INSULATION	500	2 000	2 500	$2U + 2000$	$U + 3000$	¹⁾
REINFORCED and DOUBLE INSULATION	500	3 000	4 000	$2(2U + 1000)$	$2(U + 2500)$	¹⁾

¹⁾ If necessary, to be prescribed by Particular Standards.

NOTES

1 Tables VI and VII, not used.

2 Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal a.c., the test may be performed using a sinusoidal 50 Hz test voltage. In this case the value of the test voltage shall be determined from table V using a reference voltage (U) equal to the measured peak-to-peak voltage divided by $2\sqrt{2}$.

Important: Hipot Test is conducted before & after humidity conditioning at 93% +/- 3% RH. Components shall be kept in the humidity cabinet for:

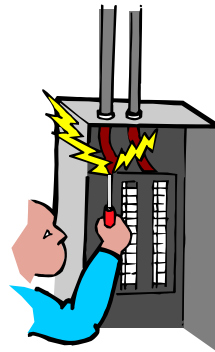
- 2 days (48 h) for ordinary components (IPX0- No marking are required);
- 7 days (168 h) for components rated IPX1 to IPX7. (Exception for IPX8)

Refer to page 12 for the method of measuring working voltage (U). UL Method must be used. (Reference: Clause 4.10 of IEC60601-1)

3.4 Leakage Test

Major Differences Between IEC60950-1 & IEC60601-1

Leakage current is measured to ensure that direct contact with the medical equipment is highly unlikely to result in electrical shock. Leakage tests are designed to simulate a human body coming in contact with different parts of the equipment. The measured leakage current values are compared with acceptable limits.



Important: Leakage Test is conducted before and after humidity conditioning at 93% +/- 3% RH. Components shall be kept in the humidity cabinet for:

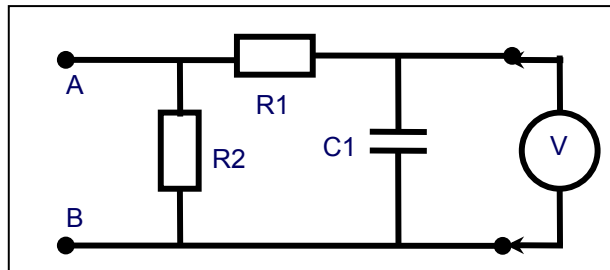
- 2 days (48 h) for ordinary components (IPX0- No marking are required);
- 7days (168 h) for components rated IPX1 to IPX7. (Exception for IPX8)

(Reference: Clause 4.10 of IEC60601-1)

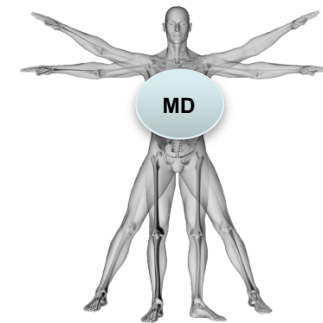
3.4 Leakage Test cont.

Major Differences Between IEC60950-1 & IEC60601-1

Measuring Device (MD) internal circuit & its frequency characteristics



Component	Value	Tolerance
R1	10K Ω	+ 5%
R2	1 K Ω	+ 1%
C1	0.015 μ F	+ 5%

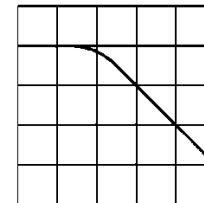


The MD represents the impedance across human body.

The measuring instrument (V) shall have a impedance of at least 1M Ω and capable for frequencies from d.c. to 1MHz. It shall indicate the true RMS reading of the voltage across terminal as shown above.

Frequency Characteristics

Relative magnitude (dB): 20 log



Reference: Figure 16 of IEC60601-1

3.4 Leakage Test cont.

Major Differences Between IEC60950-1 & IEC60601-1

There are 2 types of Leakage Current applicable to Power Supplies:

- **Earth leakage current**
(i.e. earthed enclosure, earthed parts)
- **Enclosure leakage current**
(i.e. unearthed enclosure, plastic enclosure)

3.4 Leakage Test cont.

Major Differences Between IEC60950-1 & IEC60601-1

Earth Leakage Current Test for Medical Equipment Power Supplies

The earth leakage current test specified in Table 1 and Figure 1 are carried out only for Class I product (product with protective earth connection) as identified according to IEC terms.

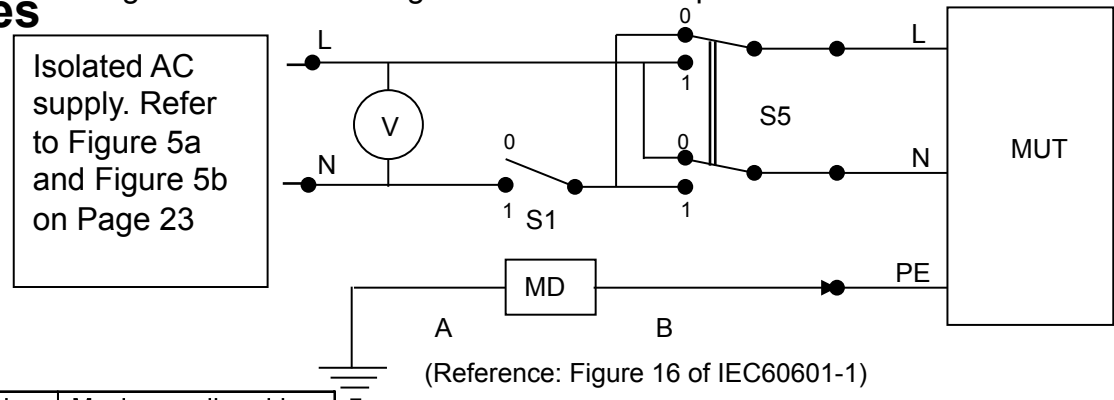
Follow the set up as shown in Figure 1 and test must be conducted at upper rated voltage and upper rated frequency with the corresponding switch S1 and S5 conditions per Table 1.

Table 1 – Maximum allowable earth leakage current.

Test Condition	Maximum allowable leakage current (mA) <u>IEC requirement</u> – See Note A	Maximum allowable leakage current (mA) – For PSU intended for <u>Patient care equipment (US requirement)</u> – See Note B	Maximum allowable leakage current (mA) – For PSU intended for <u>NON Patient care equipment (US requirement)</u> – See Note B
S5=0, S1=0 (SFC)	1.0	0.3	0.5
S5=0, S1=1 (NC)	0.5	0.3	0.5
S5=1, S1=0 (SFC)	1.0	0.3	0.5
S5=1, S1=1 (NC)	0.5	0.3	0.5

(Reference: Clause 19, Table IV of IEC60601-1, 9.5DV.1 of UL60601-1)

Figure 1 – Earth leakage Current test set-up



(Reference: Figure 16 of IEC60601-1)

SFC = Single Fault Condition
NC = Normal Condition

Note:

A – Tested at +10% of the upper rated Input Voltage, Use Figure 5A on Page 23

B – Tested at upper rated Input Voltage. Use Figure 5a for PSU with low line rating only (i.e. 110 to 120Vac) and Figure 5b for PSU with high line rating (i.e. 200-250Vac)

3.4 Leakage Test cont.

Major Differences Between IEC60950-1 & IEC60601-1

Enclosure Leakage Current (Plastic Enclosure) Test for Medical Equipment Power Supplies

The enclosure leakage current test specified in Table 2 and Figure 2 are carried out on the secondary outputs AC/DC power supplies and plastic enclosure of AC/DC adapters.

Follow the set up as shown in Figure 2 and test must be conducted at upper rated voltage and upper rated frequency with the corresponding switch S1 and S5 conditions per Table 2.

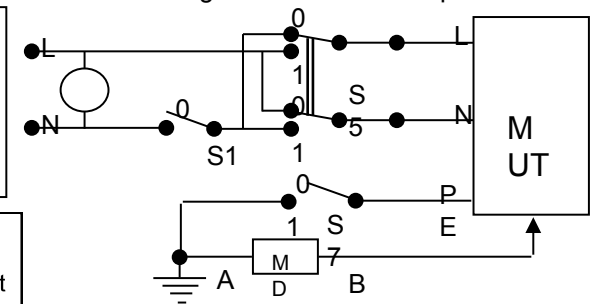
Table 2 – Maximum allowable enclosure leakage current.

Test Condition	Maximum allowable leakage current (mA) IEC requirement -See Note A and Figure 5a.	Maximum allowable leakage current (mA) - For Class I PSU intended for Patient Care Equipment (US Requirement) - See Note B	Maximum allowable leakage current (mA) - For Class II PSU intended for Patient Care Equipment (US Requirement) - See Note B.	Maximum allowable leakage current (mA) - For Class I PSU intended for NON Patient Care Equipment (US Requirement) - See Note B	Maximum allowable leakage current (mA) - For Class II PSU intended for NON Patient Care Equipment (US Requirement) - See Note B
S7=1, S5=0, S1=0 (SFC)	0.5	0.3	0.15	0.5	0.25
S7=1, S5=0, S1=1 (NC)	0.1	0.3	0.15	0.5	0.25
S7=1, S5=1, S1=1 (NC)	0.1	0.3	0.15	0.5	0.25
S7=1, S5=1, S1=0 (SFC)	0.5	0.3	0.15	0.5	0.25
S7=0, S5=1, S1=1 (SFC)	0.5	0.3	0.15	0.5	0.25
S7=0, S5=0, S1=1 (SFC)	0.5	0.3	0.15	0.5	0.25

Important: - Enclosure Leakage Test must be conducted using both IEC and US deviation test conditions and limits. See Note A and B for Input voltage test condition. Leakage current at secondary output is also an enclosure leakage current in IEC60601-1 definition.

(Reference: Table IV of IEC60601-1, 19.5DV.1 of UL60601-1)
Figure 2 – Plastic enclosure leakage Current test set-up

Isolated AC supply. Refer to Figure 5a and Figure 5b on Page 23



(Reference: Figure 18 of IEC60601-1)

SFC = Single Fault Condition
NC = Normal Condition

Note:
A – Tested at +10% of the upper rated Input Voltage, Use Figure 5A on Page 23
B – Tested at upper rated Input Voltage. Use Figure 5a for PSU with low line rating only (i.e. 110 to 120Vac) and Figure 5b for PSU with high line rating (i.e. 200-250Vac)

3.5 Mains Fuses & Over-Current Releases

Major Differences Between IEC60950-1 & IEC60601-1

Fuses or over-current releases:

In each supply lead (L and N) for Class I equipment and for Class II equipment having a functional earth, and in at least one supply lead for other single-phase Class II equipment. (Supplementary fuses or protectors are not acceptable)

Current rating of mains fuses and over-current releases:

Sufficient to carry normal operating current and not greater than current rating of any component in mains circuit.

A protective earth conductor for permanently installed equipment shall not be fused

Reference: Clause 57.6 of IEC60601-1

3.7 Wiring of Mains Part

Major Differences Between IEC60950-1 & IEC60601-1

Insulation of individual conductor in mains part:

- Otherwise considered to be bare conductor

Internal wiring between mains terminal device and protective devices:

- Cross-sectional area not less than power supply cord

Cross-sectional area of other wiring in mains part and sizes of tracks on printed wiring circuits:

- Sufficient to prevent any fire hazard

Reference: Clause 57.3DV of UL60950-1

3.8 Plug Parts & Power Supply Cords

Major Differences Between IEC60950-1 & IEC60601-1

Mains plug of non-permanently installed equipment:

- If molded on type - hospital grade attachment plug (mains plug) complies with CSA C22.2, No. 21, or hospital grade disassembly type attachment plug (mains plug) complies with CSA C22.2, No. 42, or if Class II equipment - CSA configuration 1-15P with polarized blade & meets all applicable requirements for hospital grade in C22.2 No. 21 & C22.2 No. 42

- Detachable power supply cord complies with the following requirements:
 - (a) not less than that of Type SJ for mobile equipment
 - (b) not less than that of Type SV, or Type HPN for high temperature applications, for other equipment Power cord mains plug is "Hospital Grade" type

Important: Plug part of Direct Plug-in adapters / chargers must comply with CSA configuration 1-15P with "polarized blade" and meets all applicable requirements for hospital grade in C22.2 No. 21 and C22.2 No. 42.

Reference: Clause 57.3DV of UL60601-1 & Clause 57.2 (g) and 57.3 (b) of CAN/CSA-C22.2 No. 601.1-M90

3.9 Markings

Major Differences Between IEC60950-1 & IEC60601-1

The rated input shall be given in A (Amperes) or VA (Volt-Amperes) or W (Watts) if the power factor is greater than 0.9.

Component types shall include:

- Indication of Origin (If equipment produced in more than one factory, factory identification marked on the equipment)

- Model or type reference

- Supply frequency

- Power input

- Fuses (rating & fusing characteristic i.e. fast/slow blow, high/low breaking)

- Earth terminal

- Power output

- Mode of Operation (If not continuous)

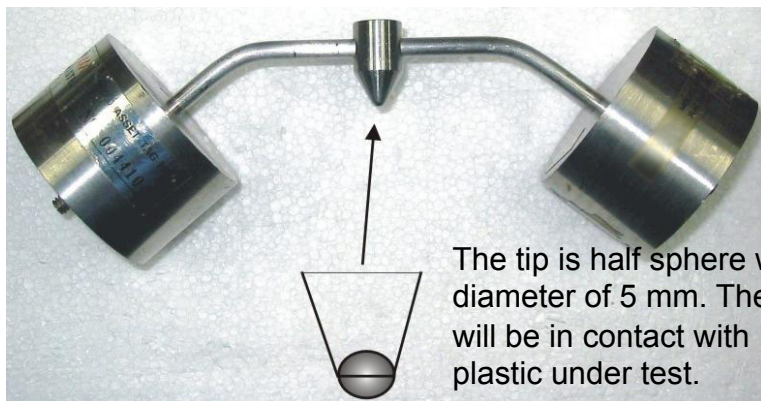
This information can be included in Operating Instruction for component type power supplies

United States requirement: All words in markings at least 1.6 mm (1/16 inch) high signal words "CAUTION", "WARNING", and "DANGER" at least 2.8 mm (7/64 inch) raised or indented letters that do not have contrasting colors maybe used for words in "CAUTION", "WARNING", and "DANGER" markings

3.10 Ball Pressure Test for Plastic Enclosure

Major Differences Between IEC60950-1 & IEC60601-1

Enclosures and other external parts of insulating material must be subjected to Ball pressure test for a period of 1 hr at temperature equal to $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$ plus the temperature rise of material or $75^{\circ}\text{C} \pm 2^{\circ}\text{C}$ whichever is greater. The Whole assembly of the apparatus exerts a downward force of 20N



Material is considered to comply if impression diameter after the test is $\leq 2.0\text{mm}$