Introduction

- **IEC 60950-1** is the reference standard for power supplies under Information Technology Equipment.
- **IEC 60601-1** 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.
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) + Additional Compliance Criteria according to IEC60601-1 3\textsuperscript{rd} Ed. \rightarrow Power Supply Unit compliant IEC60601-1 3\textsuperscript{rd} Ed.
Introduction cont.

Power Supply Unit compliant to IEC60601-1 3rd Ed.

US & Canadian Deviations

Power Supply Unit compliant UL/CSA60601-1 (US & Canada)

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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.
**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.
**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 exceed 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

<table>
<thead>
<tr>
<th>Equivalent to basic insulation between parts of opposite polarity</th>
<th>d.c. voltage</th>
<th>a.c. voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-f</td>
<td>0.4</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>0.8</td>
<td>1</td>
</tr>
<tr>
<td>BASIC INSULATION OF SUPPLEMENTARY INSULATION</td>
<td>0.8</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>1.7</td>
<td>2</td>
</tr>
<tr>
<td>DOUBLE INSULATION OF REINFORCED INSULATION</td>
<td>1.6</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>3.4</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>15</th>
<th>30</th>
<th>60</th>
<th>125</th>
<th>250</th>
<th>450</th>
<th>600</th>
<th>800</th>
<th>900</th>
<th>1200</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-f</td>
<td>15</td>
<td>30</td>
<td>60</td>
<td>125</td>
<td>250</td>
<td>450</td>
<td>600</td>
<td>800</td>
<td>900</td>
<td>1200</td>
</tr>
<tr>
<td>A-a1</td>
<td>2.4</td>
<td>3</td>
<td>4</td>
<td>4.5</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A-a2</td>
<td>2.4</td>
<td>3</td>
<td>4</td>
<td>4.5</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 \times \text{Multiplication factor per Table A.2 corresponding to Altitude}

1.14

<table>
<thead>
<tr>
<th>Altitude m</th>
<th>Normal barometric pressure kPa</th>
<th>Multiplication factor for clearances</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>80.0</td>
<td>1.00</td>
</tr>
<tr>
<td>3000</td>
<td>70.0</td>
<td>1.14</td>
</tr>
<tr>
<td>4000</td>
<td>62.0</td>
<td>1.29</td>
</tr>
<tr>
<td>5000</td>
<td>54.0</td>
<td>1.48</td>
</tr>
<tr>
<td>6000</td>
<td>47.0</td>
<td>1.70</td>
</tr>
<tr>
<td>7000</td>
<td>41.0</td>
<td>1.95</td>
</tr>
<tr>
<td>8000</td>
<td>35.5</td>
<td>2.25</td>
</tr>
<tr>
<td>9000</td>
<td>30.5</td>
<td>2.62</td>
</tr>
<tr>
<td>10000</td>
<td>26.5</td>
<td>3.02</td>
</tr>
<tr>
<td>15000</td>
<td>12.0</td>
<td>6.67</td>
</tr>
<tr>
<td>20000</td>
<td>5.5</td>
<td>14.5</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>IEC60601-1 (Medical)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Insulation</td>
<td>For isolation transformer: Min 1.0mm</td>
</tr>
<tr>
<td>(1 layer)</td>
<td>#</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Thin Sheet (2 layers)</td>
<td>Total thickness of at least 0.3mm</td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Thin Sheet (3 layers)</td>
<td>No thickness requirement (Same as</td>
</tr>
<tr>
<td></td>
<td>IEC60950-1)</td>
</tr>
</tbody>
</table>

# 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>
<thead>
<tr>
<th>Insulation to be tested</th>
<th>Test voltages for reference voltage $U$ (V)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$U&lt;50$</td>
</tr>
<tr>
<td>Basic Insulation</td>
<td>500</td>
</tr>
<tr>
<td>Supplementary Insulation</td>
<td>500</td>
</tr>
<tr>
<td>Reinforced and Double Insulation</td>
<td>500</td>
</tr>
</tbody>
</table>

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);
- 7 days (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

The MD represents the impedance across human body.

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Value</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>R1</td>
<td>10kΩ</td>
<td>± 5%</td>
</tr>
<tr>
<td>R2</td>
<td>1 kΩ</td>
<td>± 1%</td>
</tr>
<tr>
<td>C1</td>
<td>0.015μF</td>
<td>± 5%</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Test Condition</th>
<th>Maximum allowable leakage current (mA)</th>
<th>Maximum allowable leakage current (mA)</th>
<th>Maximum allowable leakage current (mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IEC requirement</td>
<td>– For PSU intended for Patient care equipment (US requirement)</td>
<td>– For PSU intended for NON Patient care equipment (US requirement)</td>
</tr>
<tr>
<td>S5=0, S1=0 (SFC)</td>
<td>1.0</td>
<td>0.3</td>
<td>0.5</td>
</tr>
<tr>
<td>S5=0, S1=1 (NC)</td>
<td>0.5</td>
<td>0.3</td>
<td>0.5</td>
</tr>
<tr>
<td>S5=1, S1=0 (SFC)</td>
<td>1.0</td>
<td>0.3</td>
<td>0.5</td>
</tr>
<tr>
<td>S5=1, S1=1 (NC)</td>
<td>0.5</td>
<td>0.3</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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

Figure 1 – Earth leakage Current test set-up

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)

Important:
Earth 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 and Figure 5a and 5b for Isolated AC supply. Refer to Figure 5a and Figure 5b on Page 23.

SFC = Single Fault Condition
NC = Normal Condition
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.

<table>
<thead>
<tr>
<th>Test Condition</th>
<th>Maximum allowable leakage current (mA)</th>
<th>Maximum allowable leakage current (mA)</th>
<th>Maximum allowable leakage current (mA)</th>
<th>Maximum allowable leakage current (mA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S7=1, S5=0, S1=0 (SFC)</td>
<td>0.5</td>
<td>0.3</td>
<td>0.15</td>
<td>0.5</td>
</tr>
<tr>
<td>S7=1, S5=0, S1=1 (NC)</td>
<td>0.1</td>
<td>0.3</td>
<td>0.15</td>
<td>0.5</td>
</tr>
<tr>
<td>S7=1, S5=1, S1=1 (NC)</td>
<td>0.1</td>
<td>0.3</td>
<td>0.15</td>
<td>0.5</td>
</tr>
<tr>
<td>S7=1, S5=1, S1=0 (SFC)</td>
<td>0.5</td>
<td>0.3</td>
<td>0.15</td>
<td>0.5</td>
</tr>
<tr>
<td>S7=0, S5=1, S1=1 (SFC)</td>
<td>0.5</td>
<td>0.3</td>
<td>0.15</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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.

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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
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

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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°C± 2°C plus the temperature rise of material or 75°C± 2°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 ≤ 2.0mm.