Are your electro-medical devices compliant to medical safety standards?

Steve Taranovich - August 01, 2012

The IEC 60601-1 standard – which addresses many of the risks associated with electronic medical devices – has become a de facto requirement by most companies for electro-medical products. The IEC 60601-1 standard addresses many of the risks associated with electro-medical devices and applies to all medical devices.

The third edition of IEC 60601-1 represents a major overhaul of the IEC 60601 family of medical electrical equipment safety standards.

There exist some national deviations to IEC 60601-1.

In the United States, UL 2601-1 is the national harmonized 60601-1 standard for medical electrical equipment. U.S. manufacturers (and those importing into the U.S.) may also be required to comply with regulations from the FDA, AAMI and NFPA 99 among others.

The national 60601-1 harmonized standard in Canada is CAN/CSA C22.2 No. 601.1, in the European Union it is EN60601-1 and in Japan it is JSA JIS T0601-1.

Although IEC60601-1 is the international governing standard to which most medical manufacturers comply, national standards may specify additional test requirements or altered test specifications.

Why do you need to meet the IEC/UL/ES/CSA/EN 60601-1 standards?

The following information on the standard is from Medical Equipment Compliance Associates (MECA), an engineering team of biomedical engineers, led by Brian R. Biersach, President and Sr. Biomedical engineer. MECA helps medical companies with safety certification, compliance, and regulatory needs, including compliance assistance in the design and development phase, compliance evaluation and reports, safety certification, and global regulatory support.

- The FDA requires safety performance testing.

IEC 60601-1 is the key FDA recognized consensus standard for medical electrical equipment (with US Deviations).
Without a Compliance Report, you will not be able to establish that you meet these required standards.

- In the US, the Occupational Safety and Health Administration (OSHA) requires a safety mark from a National Recognized Testing Laboratory (NRTL) for use in a public facility.

  This is specified in OSHA Standards Part 1910, Subpart S-Electrical, Sec. 1910.399.

  (NRTLs include UL, TUV Rheinland, TUV SUD, CSA, Intertek/ETL, and others)

- Most Local AHJs (Authorities Having Jurisdiction) and nearly all hospitals and clinics in the US require 3rd party safety marks on equipment to be purchased.

  These safety marks rely on compliance with the UL 60601-1 standard in the US.

- The CE Mark is required on a product to place it on the market in the European Union.

  For medical equipment, the CE Marking requirements are in the MDD (Medical Device Directive), which is European Law.

  - The MDD requires documentation of compliance to the applicable safety standards (such as EN 60601-1).

    You may not legally place a medical device on the market in the European Union without meeting the Medical Device Directive requirements.

    For all medical equipment, except (per MDD) Class 1, non-measuring, non-sterile, an Audit by a Notified Body (from Europe) is required before the CE Mark may be placed on a medical device.

    The CE Mark will have a 4-digit number under it, denoting the Notified Body used.

- By meeting the requirements of the IEC60601-1 series of standards with National Deviations, you officially meet the requirements of most of the world's nations, and unofficially meet the requirements of all.

This opens your marketing potential to the entire world market.

SL Power Electronics (SLPE) has introduced the MINT1275 high-density, single output, open frame AC/DC medical-grade power supply. The supply is suited for medical devices with space and airflow constraints – especially in table-top in-vitro diagnostics and laboratory instruments as well as in surgical and therapeutic medical devices and portable home healthcare appliances.
In the safety area it provides 2 MOPP (means of patient protection) safety and has reinforced isolation requirements – IEC 60601-1 3rd edition, Class I and Class II configurations.

It has active current share for redundancy and claims the lowest earth leakage current with less than 400µ amps.

SLPE will have all standard products developed in the last 2 years validated to 3rd edition MOOP by end Q4. (90% should qualify)

**System risk management needs to be managed by the customer.**

Most applications are categorized as:

MOOP: Means of Operator Protection

MOPP: Means of Patient Protection

**Timeline and specification changes regarding EN60601-1 3rd edition**

After June 2012 all Europe medical Safety submissions must be to 3rd edition.

After June 2013 all UL medical Safety submissions must be to 3rd edition.

Going from IEC/EN 60601-1 2nd Ed. to IEC/EN 60601-1 3rd Ed., some changes in spec will necessitate qualification modifications in the supply. See Figures 1 and 2 below.
<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>2ND EDITION</th>
<th>3RD EDITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Earth Leakage Current:</td>
<td>300/500 µA NC, 500/1000 µA SFC</td>
<td>5 mA NC, 10 mA SFC</td>
</tr>
<tr>
<td>Temperatures determined using operating ambient:</td>
<td>Components in Table XA at highest ambient and components in Table XB corrected for 25°C ambient.</td>
<td>All components tested for highest ambient.</td>
</tr>
<tr>
<td>Temperature for accessible surfaces:</td>
<td>Less stringent</td>
<td>More stringent</td>
</tr>
<tr>
<td>Creepage and clearance</td>
<td>More stringent and no interpolation allowed.</td>
<td>Same for MOPP, but MOOP is less stringent (based on 60950-1 requirements). Interpolation is permitted for creepage requirements for MOOP and MOPP.</td>
</tr>
<tr>
<td>Clearance for operating altitude:</td>
<td>Clearance table for up to 3000 m.</td>
<td>Clearance table for MOOP for up to 2000 m, and 3000 m for MOPP. Multiplication factors added for higher altitudes up to 5000 m using Table 8.</td>
</tr>
</tbody>
</table>

Figure 1: A chart shows the differences between the 2nd and 3rd editions of IEC/EN60601-1

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>2ND EDITION</th>
<th>3RD EDITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enamel coating on magnet wire in transformers:</td>
<td>Considered as providing 1 mm creepage.</td>
<td>Insulation not considered.</td>
</tr>
<tr>
<td>240 VA Limit for Accessible Part (Output):</td>
<td>Not applicable.</td>
<td>Added requirement.</td>
</tr>
<tr>
<td>Y1 &amp; Y2 type capacitors:</td>
<td>1-Y2 considered as Basic insulation from Primary to Ground; 2-Y2s in series or 1-Y1 considered as Double/Reinforced insulation.</td>
<td>MOOP: 1-Y2 considered as 1-MOOP (Basic insulation); 2-Y2s in series or 1-Y1 considered as 2-MOPPs (Double/Reinforced insulation). MOPP: 1-Y1 considered as 1-MOPP (Basic insulation); 2-Y1s in series considered as 2-MOPPs (Double/Reinforced insulation). NOTE: Use of Y2 type is not acceptable for MOPP.</td>
</tr>
</tbody>
</table>

Figure 2: Differences between the 2nd and 3rd editions of IEC/EN60601-1 (continued)
Since EN60601-1 3rd edition is a system specification, there are four questions that power supply manufacturers like SLPE need to know regarding details about the customer’s application:

1. AC Grounding - class I or class II
2. MOOP or MOPP
3. If MOPP - isolation “B”, “BF” or “CF”
4. Touch temperature in customer’s system

**MINT1275 Power supply technical features**

The footprint is well suited for 1U (1.75”) high applications in a 3 X 5 X 1.38 inch package.

The supply will deliver to the load 275 watts with forced air and 180 watts with convection cooling.

It will deliver full-rated output power while operating within an ambient temperature range of -40°C to 70°C with standard interface signals.

Certification adheres to the stringent EMC requirements for applications requiring Class B EMI and Class A, B, C & D of harmonic distortion part of IEC61000 standards. In addition, the models have been HALT tested for durability and have more than 400,000 hours of demonstrated MTBF with UL, CSA, CE, CB, NEMKO and VDE approvals.

For more information and pricing contact SL power at [www.slpower.com](http://www.slpower.com)