



SL Power 3rd edition Presentation

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Overview of 3rd edition



- **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**
- **SL Power provides a COMPONENT – risk management at component level is not required**
- **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**
- **Products approved to prior editions are still allowed by UL**
- **So far, very few power supplies are approved to 3rd edition**
- **SL Power has started the 3rd edition upgrade**

IEC/EN 60601-1 2nd Ed. and IEC/EN 60601-1 3rd Ed. DIFFERENCES

| DESCRIPTION | 2 ND EDITION | 3 RD EDITION |
|---|--|--|
| Earth Leakage Current: | 300/500 uA NC, 500/1000 uA SFC | 5 mA NC, 10 mA SFC |
| Temperatures determined using operating ambient: | Components in Table XA at highest ambient and components in Table XB corrected for 25 C ambient. | All components tested for highest ambient. |
| Temperature for accessible surfaces: | Less stringent | More stringent |
| Dielectric test voltage determined using : | Vrms: Less stringent. | Vpk or Vdc: More stringent with switch-mode power supplies. |
| Creepage and clearance | More stringent and no interpolation allowed. | Same for MOPP, but MOOP is less stringent (based on 60950-1 requirements). Interpolation is permitted for creepage requirements for MOOP and MOPP. |
| Clearance for operating altitude: | Clearance table for up to 3000 m. | 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. |

IEC/EN 60601-1 2nd Ed. and IEC/EN 60601-1 3rd Ed.

DIFFERENCES Continued

| DESCRIPTION | 2 ND EDITION | 3 RD EDITION |
|---|---|--|
| Enamel coating on magnet wire in transformers: | Considered as providing 1 mm creepage. | Insulation not considered. |
| 240 VA Limit for Accessible Part (Output): | Not applicable. | Added requirement. |
| Y1 & Y2 type capacitors: | 1-Y2 considered as Basic insulation from Primary to Ground; 2-Y2s in series or 1-Y1 considered as Double/Reinforced insulation. | <p>MOOP: 1-Y2 considered as 1-MOOP (Basic insulation); 2-Y2s in series or 1-Y1 considered as 2-MOOPs (Double/Reinforced insulation).</p> <p>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.</p> |
| Attention, consult Accompanying Documents Symbol |  |  |

SL Power Timeline

- **SLPE will have all standard products developed in the last 2 years validated to 3rd edition MOOP by end Q4. (90% should qualify)**
 - MINT1065 received approval expected
 - Priority list for 3rd edition upgrade has been generated and estimated approval dates are slated accordingly
- **If the *SYSTEM* requires MOPP - a redesign may be necessary with the attendant testing. This is due to constructional / isolation requirements.**
- **Legacy products need to be analyzed to match customer application and requirements.**

EN60601-1 3rd Edition Summary

- **EN60601-1 3rd edition is a system specification**
- **Four questions - We need to know details about the customer's application:**
 - AC Grounding – class I or class II
 - MOOP or MOPP
 - If MOPP – isolation “B”, “BF” or “CF”
 - Touch temperature in customer's system



Thank you!