POWER ELECTRONICS

Risk Assessment for Power Supplies to Comply with IEC60601-1 3rd Edition

By: Cohise Mapa
Director Global Product Management
SL Power Electronics

Experts have concluded that Electrostatic discharge (ESD) caused the Hindenburg to ignite leading to the historic explosion. The Hindenburg, filled with hydrogen gas and having gone thru a thunderstorm, had built up static electricity. While the ship was being moored, ESD generated sparks, causing the flammable hydrogen gas to ignite and burn completely in 34 seconds. ESD is the release of charge from one object to another. While not as catastrophic as the Hindenburg, ESD can damage electronic devices. Hence, electronic equipment is tested to withstand ESD to a certain degree. These tests are spelled out in IEC61000-4-2, Electrostatic discharge.

The IEC 61000-4-2 standard defines four standard levels of ESD protection, using two different testing methodologies. Contact discharge involves discharging an ESD pulse directly from the ESD test gun that is touching the device under test. This is the preferred method of testing. However, the standard provides for an alternate test methodology known as air discharge for cases where contact discharge testing is not possible. In the air discharge test, the ESD test gun is brought close to the device under test until a discharge occurs. Although this is an alternate method, it is not intended to imply that the test severity is equivalent between the test methods.

Medical device OEMs are required to meet this standard for their end products and are responsible for the risk management and applications categorized as MOOP or MOPP. Even though the 3rd edition standard really does not apply to components, a few power supply manufacturers are working closely with their medical device customers to comply with this new regulation. For next generation medical device products, it is easier to start requiring power supplies certified to the 3rd edition. For existing electromedical devices especially those in the EU market, complying may mean requalifying another power supply thru end-device verification and validation or doing risk assessment of the continued use of current power supply.

IEC 60601-1 3rd Edition Standard

The IEC 60601-1 standard is a globally recognized standard for electro-medical equipment safety, and a parent standard over 60 particular device standards. The next evolution in the IEC 60601-1 third edition, requires a risk management file and process conforming to ISO 14971, the international standard for Application of Risk Management to Medical Devices. In Europe, the standard went into effect in June of 2012 for all medical products, new or existing. In North America, the FDA announced that it has adopted and recognized ANSI/ AAMI 60601-1 third edition and established June 30, 2013 as the mandatory transition date applicable for new medical device submissions only – existing medical devices in the market are “grandfathered” under the regulation.

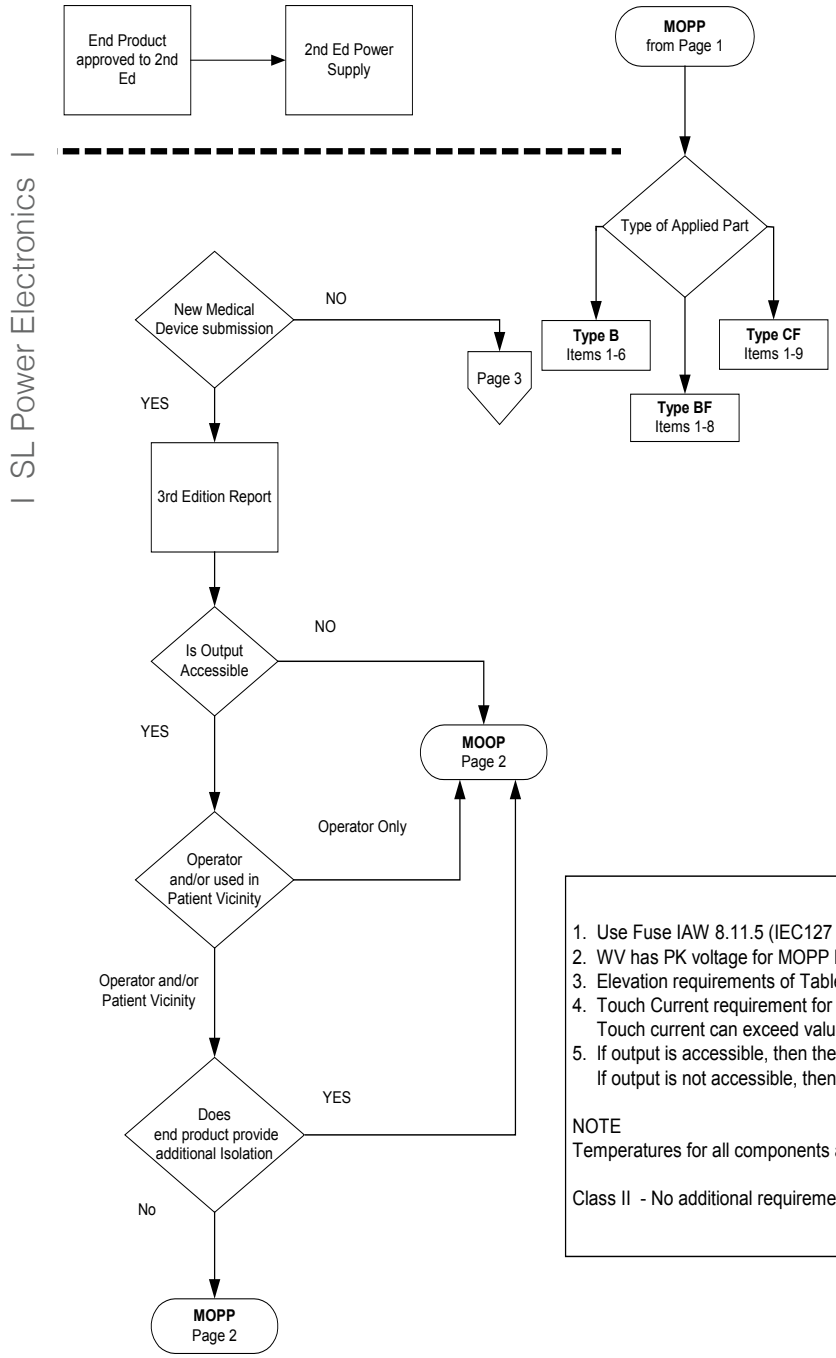
Medical device OEMs are required to meet this standard for their end products and are responsible for the risk management and applications categorized as MOOP or MOPP. Even though the 3rd edition standard really does not apply to components, a few power supply manufacturers are working closely with their medical device customers to comply with this new regulation. For next generation medical device products, it is easier to start requiring power supplies certified to the 3rd edition. For existing electromedical devices especially those in the EU market, complying may mean requalifying another power supply

thru end-device verification and validation or doing risk assessment of the continued use of current power supply.

Risk Management

Risk Management covers risk analysis and evaluation followed by risk control to bring overall risk to an acceptable level, with continuous monitoring and feedback process. Below is a table typically used to identify hazards and conditions affecting safety and critical performance of the medical device, to gauge the severity of harm done, to identify the cause of the condition, assign probability of occurrence and to define activities to mitigate the risks. To include the power supply in the risk assessment, the medical device product team (i.e. staff coming from regulatory affairs, engineering, marketing, quality, etc.) should consider feedback from their power supply partner in identifying the hazard conditions as well as the probability of those events occurring. The four items listed below are common failure modes recorded in the FDA adverse events database as well as causes in product recalls. The probability of occurrence can be provided by the power supply partner based on their field failure data (parts per million failures on those corresponding product or family). The nature of the clinical or therapeutic function of the electromedical device affects heavily the severity and hence the risk of each failure mode. Typically, a power failure merely causes postponing the use of the medical device until another unit comes along. However, when the need for the medical device is urgent and essential to administering therapy quickly, then any delay due to non-operation can be a real issue. The rest of the information written below are generic examples and require more detail in a true risk assessment documentation.

Risk No.	Failure Modes	Potential Harm	"S" Severity	Hazard Causing Harm	Pre-Mitigated Risk "S" x "P" = "R"		Risk Control Measures		
					"P" Probability	"R" Risks	Design	Detection Control	Labeling
1.	Power Fail	Device stops working	S2	Component or Circuit Failure	P1	2% Low	HALT	Lot sampling	N/A
2.	No Power	Device will not start	S1	Component failure	P1	<1% Low	Burn-in	Lot sampling	N/A
3.	Overheating	Device stops working on thermal shock	S1	Overload or low input voltage	P2	2% Low	OTP feature	N/A	N/A
4.	Leakage current too high	Electric shock	S2	Component Failure	P1	2% Low	HALT	Lot sampling	N/A



1. Use Fuse per 8.11.5 (IEC127 1500A, UL10,000A breaking Capacity)
2. WV has PK voltage for MOPP Electric Strength Test (Legacy Units)
3. Elevation requirements of Table 8 factored into WV Clearance Table.
4. Touch and/or Patient Leakage Current meet requirement for MOPP.
   Touch current can exceed values if output voltage is not accessible.
5. Transformer wiring - 0mm for enamel coated wire.
   - 3Layer wire not acceptable by itself per Annex L
6. Only Y1 Caps allowed:
   a) L-G - 1 Y1 cap
   b) Pri-Sec 2 Y1 caps
   c) Type B Only - Sec to Gnd can be any cap. No Dielectric Strength Test.
7. Secondary to Ground Isolation for BF and CF (CR and CL) and Y1 Cap required.
8. Sec-Gnd Electrical Strength to 1500V required.
9. Patient Leakage - Required for CF 10uA NC, 500uA SFC

NOTES

Temperatures for all components are at elevated Max temperatures.

Class II - 6a), 7 and 8 are Not Applicable

MOOP from Page 1

1. Use Fuse IAW 8.11.5 (IEC127 1500A, UL10,000A breaking Capacity)
2. WV has PK voltage for MOPP Electric Strength Test (Legacy Units)
3. Elevation requirements of Table 8 factored into WV Clearance Table.
4. Touch Current requirement for MOOP 100uA NC, 500uA SFC.
   Touch current can exceed values if output is not accessible.
5. If output is accessible, then the output cannot exceed 240VA and Voltages are limited to 42.2Vpk, 60Vdc.
   If output is not accessible, then the values can be exceeded.

NOTE

Temperatures for all components are at elevated Max temperatures.

Class II - No additional requirements.

Collaboration

Beyond the risk management file, doing the gap analysis between 2nd and 3rd editions of the IEC60601-1 is critical for those medical device OEMs intent on using their current 2nd edition power supply for existing and/or new designs. Discussion between the OEM and power supply vendor is vital. This collaboration can help identify any obstacles in the power supply and how to properly adjust. Looking at the specifications together can go a long way in minimizing the work done to make the medical device including the power supply component comply to 3rd edition. Important discussion points include:

- MOOP or MOPP classification
- Classification of Applied Parts: Type B, BF or CF
- Main Fuses and over-current releases
- Elevation
- Leakage Current
- Safety insulation for transformers
- Y1 &Y2 Capacitors
- Hipot voltage
- Creepage and clearance

Classifying the particular medical device application into MOOP, MOPP, Type B/BF/CF are key questions since these determine the degree of evaluation the power supply and medical device need to undergo. MOOP is less stringent than MOPP. Within MOPP, Type B has the least stringent requirements, followed by BF. Type CF has the strictest specifications. These classifications have to be determined by the medical device OEMs by properly considering the device's intended use and particular application environment. On several occasions, forcing an existing power supply to comply with the demands of the 3rd edition, especially on MOPP, requires a handful of component changes and a complete PCB re-spin. That entails practically repeating the power supply qualification (i.e. DVT build and QA verification), if not an abbreviated one. This in turn may force verification and validation on the medical device level as well using the upgraded power supply.

Also, if some of the requirements listed in the bullets above are not met by the power supply, the medical device design engineers may look at the system level if such requirements are considered outside of the power supply, but within the medical device like having redundant fuses, capacitors and insulation.

Conclusion

While change is never easy, implementation of risk management touches not only the end-product manufacturer, but the component supplier as well. The implementation of the third edition helps to ensure performance and safety throughout the lifetime of a given device. Forward planning and upfront collaboration with suppliers will help mitigate problems later down the road. Moreover, the gap analysis of the differences between 3rd and 2nd editions at the power supply level becomes an easier and more directed task. Sometimes, it is easier to change a component outside the power supply rather than forcing power supply to upgrade to IEC 60601-1 3rd edition.

North America
SL Power Electronics Headquarters
6050 King Drive
Ventura, CA 93003
Phone: 800-235-5929
Fax: 805-832-6135
Email: info@slpower.com

Sales & Engineering Office - East Coast USA
60 Shawmut Road, Suite 2
Canton, MA 02121
Phone: 781.828.1085
Fax: 858.712.2040
Email: info@slpower.com

Europe
Sales & Engineering Office
Crown Yealm House, Pathfields Business Park
South Molton, EX36 3LH UK
Phone: +44 (0) 1769 579505
Fax: +44 (0) 1769 579494
Email: euinfo@slpower.com

Asia
Sales & Engineering Office
Fourth Floor Building 53
1089 Qing Zhou Road North
Shanghai, China 200233
Phone: +86 21 64857422
Fax: +866 21 64857433
Email: infor@slpower.com

SL Power.com

facebook twitter YouTube