Chroma Systems Solutions, Inc.

IEC60601-1 And Your Electrical Medical Products

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(purchased by Chroma Systems Solution in 2012)

Keywords: Litigation Risks, Risk Analyses, Safety testing, Certification Mark

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Scope

When last we left off we were discussing just why we had to product safety test our electrical medical products. Refer to application note "Why Product Safety Test Your Electrical Medical Products?" for a discussion of how legal requirements may affect product safety, acceptance and utilization. Regulatory practices may at the onset seem cumbersome, expensive or even redundant but there is **no** substitute for patient safety. Would you care to have a medical sensor placed in you that had not had extensive dielectric withstand (hipot) and leakage current tests? What could a few milliamps of current possibly do to a suppressed immune system?

Beyond user safety and legal requirements, lets look at two other reasons why a manufacturer would benefit from having its product tested and potentially certified by a Third Party (Independent) Test Agency to IEC60601-1 or equivalent National Standards.

- Litigation Risks: Reduce risks with increased product safety testing.
- Market Recognition: Third Party Certification Mark or a self Certification Mark.

Litigation Risks

In today's society it is all too common for litigation to occur especially when one party is not satisfied with the product under question. Electrical medical products have tremendously advanced medical care and research but they are truly 'under the microscope' when it comes to determining their safety. Electrical medical product manufacturers can reduce the risk of litigation by a comprehensive risk analysis from design conception through device production and thorough product safety testing at each phase of product development. Consider the following points.

Meet a minimum level of safety by meeting the appropriate safety standards such as UL2601-1 (USA), CSA C22.2 No. 601.1 (Canada), EN60601-1 (European Union), etc. These national standards may call out additional IEC60601-2-XX 'particular' standards (a vertical standard that is related to specific product

types), one or more IEC 60601-1-X 'collateral' (horizontal) standards and/or other applicable standards to meet the safety tests within.

To find the appropriate standards for your product takes a lot of diligence, research and time. Standards services can be very helpful in locating and updating your test standard(s). To sign up for an advisory service of standard updates contact Standards@EisnerSafety.com. This service provides information on medical devices, active implantable, in vitro diagnostics and biologics/device combination industries.

Risk Analyses And Safety Testing

It is important to note that the ultimate responsibility for product safety rests with the manufacturer not the standard. Compliance with the standard does not fully protect the manufacturer from liability and conversely compliance with the text of a standard does not mean a product will comply with the standard should examination of the product reveal a design which compromises safety that was not considered in the standard.

Conduct risk analysis to determine any safety hazards and design in mitigations. This process should commence in the early stages of product research and development and continue throughout the life cycle of the product, including when the product is on the market.

Inputs to the risk analysis data bank may include customer surveys, customer complaints, user test data as well as design changes. Examples are product safety test data, EMC test reports, HALT/HASS (Highly Accelerated Life Testing/Highly Accelerated Stress Screening) reports and software and hardware validation data. To inquire further about risk analysis, refer to http://www.EisnerSafety.com/eu_risk_analysis.htm.

Conduct safety tests such as Earth, Enclosure & Patient Leakage, Ground Impedance (Bond/Continuity) and Dielectric Withstand (AC/DC Hipot) tests at various stages of device production. Most importantly, at the end of production conduct 100% testing of all products built to confirm the basic safety of the device.

Mark Recognition

Market forces and customer recognition of a Third Party Certification Mark may help the manufacturer become competitive or just meet the minimum competitive market requirements. Typically in the medical product field most electrical products need to have some type of Third Party Certification Mark

to stay competitive with similar products on the market. A certification-marked product is increasingly demanded not only within the national market but across the global market as well.

For the United States testing to UL2601-1, UL544 or UL187 (note: UL544 & UL187 are slated for withdrawal January 1 2005) and associated product specific standards is important to meet the FDA and NEC requirements and should be conducted by an OSHA approved NRTL (Nationally Recognized Testing Laboratory). Refer to http://www.osha.gov for information on approved NRTLs. Listed here are some NRTLs certified by OSHA for UL2601-1. Always verify information with the governing agency.

- Canadian Standards Association (CSA International)
- Underwriters Laboratories Inc. (UL)
- TUV Rheinland of North America, Inc.
- National Technical Systems, Inc.
- Entela, Inc.
- MET Laboratories, Inc.
- SGS US Testing Company, Inc.
- Intertek Testing Services NA, Inc.
- Curtis-Straus LLC

Europe, the CE Mark and the CB Scheme

1. **Getting into Europe** under the Medical Device Directive (MDD) requires a CE (Certified European) Mark.

Class I products that do not have a measuring function or are provided sterile can be self-certified by the manufacturer and the CE marked placed on the product once that manufacturer fulfills the MDD requirements. Some consumers, customers, bio-meds etc may not feel the self certification mark is sufficient to meet their needs and request that the manufacturer obtain a Third Party Certification Mark in addition to the CE Mark required by the directive and transposed into national law by the European Union.

All class IIa, IIb, III products or a class I product with a measuring function or provided sterile are required to go through a combination of type testing, batch testing, statistical testing, technical file or design dossier review and/or a combination of Quality System Registration by a Notified Body based on the class and route through the directive. Each Notified Body is notified by publication in the Official Journal of the European Community (OJEC) of the specific areas of competencies the Competent Authority has verified said Body is able to provide. It is important to note that some Notified Bodies are only allowed to perform specific testing and/or Quality System Registration.

Some Notified Bodies are allowed to work on all product classes, perform product testing and perform Quality System Registration. Prior to selecting a Notified Body, confirm what they have been notified for by checking with the OJEC. Does this mean that some market drivers do not require a Third Party Certification Mark? No. It truly depends on the particular market drivers. Electrical medical manufacturers should perform market analysis to determine if a Third Party Certification Mark will benefit the product acceptance into the target market.

Another helpful tool in obtaining Certification Marks from additional International Agencies is through the CB scheme. To inquire about the CB Scheme (IEC's System for Conformity Testing and Certification of Electrical Equipment) visit the CB Scheme website at http://www.iecee.org/cbscheme/default.htm for details.

The CB scheme test report and CB certificate are useful because they are transportable. The manufacturer can have one of the Agencies in the CB scheme test his product to IEC60601-1 and any additional IEC60601-2-XX standards. In addition, depending upon the countries the manufacturer plans on obtaining more Certification Marks for, the Agency can also test the product to the National Deviations for those countries. Once the manufacturer has the product successfully tested to the appropriate standards and National Deviations, he can send the product, product information, CB test report and CB certificate to another Agency in the CB scheme for a Certification Mark **without** full retesting of said product.