

Teaser: Many different safety standards exist for electrical products. The application of those safety standards to products depends upon the nature of the product and the application environment in which the product is used. As an example, safety standard IEC 60601-1 applies to medical products used in both home and professional settings. While the final product is required to be certified to the safety standard, it is also often beneficial for major subsystems which affect the safety performance of the product (such as power supplies) to be independently certified. Medical safety standard IEC 60601-1 is an unusual standard in that it addresses more than just safety issues.

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Categories: Medical, Power

IEC 60601-1 and Power Supplies

Before a medical product can be sold for use in either a home or in a professional environment it will need to be demonstrated that the product complies to the IEC 60601-1 regulatory standards. While the company designing the product can use any components which enable the final product to meet the IEC 60601-1 standards, the regulatory approval process for the final product will be simpler if the major sub-systems (such as the power supply) already have been certified to meet the regulatory standards. There are specific requirements in the IEC 60601-1 documents that apply to power supplies and the ability to protect users from hazardous voltages (i.e., the ac input wall voltage). As is the case with many documents, the IEC 60601-1 regulatory standards have been revised over time, and probably will continue to be revised in the future.

Types of Medical Products

The IEC 60601-1 regulatory documents address the concept that safety requirements should depend upon how close the equipment is to the patient. The second edition of IEC 60601-1 established that this set of regulations will apply when the equipment is operated within six feet of the patient. In addition to how close the equipment is to the patient; the IEC 60601-1 regulations also recognize the need to provide guidance based upon how the equipment will connect to the patient. When addressing the connection of the equipment to the patient, IEC 60601-1 defines three separate categories.

Type B (Body) – This type of equipment is used within a six-foot radius of the patient but typically does not contact the patient. Examples of Type B equipment include hospital beds, lighting, and x-ray machines

Type BF (Body Floating) – This type of equipment is used in physical contact with the patient and may or may not be electrically connected to the patient. A few examples of Type BF equipment include thermometers, blood pressure cuffs, and ultrasound equipment.

Type CF (Cardiac Floating) – This type of equipment will have electrical contact with the patient's heart when it is used. Some examples of Type CF equipment are dialysis machines and defibrillators.

Some of the requirements for the designs of power supplies for the different type classifications of equipment address insulation category and creepage distance. Two of the categories of insulation which are required for medical products are basic insulation and double insulation. The web article [Insulation, Isolation, and Working Voltage](#) provides additional information regarding electrical insulation categories. Creepage distance in an electrical circuit refers to distance between two conductors as measured over the surfaces of the insulator that separates the conductors. Specifying a minimum creepage distance is important because contamination of the surface of electrical insulators can reduce the effectiveness of the insulation. This web article, [IEC 60335-1 Explained: Safety Standards for Household Appliances](#), provides additional discussion regarding conductor creepage distance. A list of voltage isolation requirements for the different IEC 60601-1 product types is shown in **Figure 1**.

2nd Edition Requirements by Classification

Classification	Isolation	Creepage	Insulation
Type B	1500Vac	2.5mm	Basic
Type BF	3000Vac	5mm	Double
Type CF	4000Vac	8mm	Double

Figure 1: Isolation requirements for the IEC 60601-1 product types B, BF, and CF consists of isolation voltage, creepage distance, and insulation category.

Operator versus Patient Protection

The third edition of IEC 60601-1 describes different protection requirements for operators of medical equipment as compared to patients using the equipment; operator protection and patient protection. In addition to defining Means of Operator Protection (MOOP) and Means of Patient Protection (MOPP), the regulations also discuss the need for one versus two levels of isolation when providing those means of protection (one versus two MOOPs and MOPPs). The information in **Figure 2** describes the isolation, creepage and insulation requirements of the combinations of one versus two levels of protection and operator versus patient protection.

3rd Edition Requirements by Classification

Classification	Isolation	Creepage	Insulation
One MOOP	1500Vac	2.5mm	Basic
Two MOOP	3000Vac	5mm	Double
One MOPP	1500Vac	4mm	Basic
Two MOPP	4000Vac	8mm	Double

Figure 2: Isolation requirements for one or two MOOP or MOPP protection consists of isolation voltage, creepage distance, and insulation category.

In addition to concerns of hazards to the operator or patient, the collateral standard IEC 60601-1-2, currently in its fourth edition, includes requirements for EMI and EMC performance of medical equipment. The concepts of EMI and EMC can be described as how well the equipment functions around other electronic equipment, both in electromagnetic energy the equipment radiates and the sensitivity of the equipment to electromagnetic radiation received from other electronic equipment. A more detailed discussion of the EMI and EMC requirements can be found [here](#).

Conclusion

The IEC 60601-1 regulations address many characteristics required in medical products and can be challenging to meet. Some of the design and regulatory challenges can be minimized by selecting power supplies, from companies such as CUI, which are certified for compliance to the IEC 60601-1 regulations.