Medical-Grade Power Supplies: Safety and Reliability Set Them Apart
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Many technical factors distinguish the medical grade power supply from commercial units. Commercially available power supplies are generally manufactured to the IEC-950 or UL-1950 standards. Although commercial power supplies may meet safety standards, there are a number of features that separate them from the true medical-grade power supply, which must comply with IEC601-1 or UL2601-1.

The fundamental differences between commercial- and medical-grade power supplies relate to the design and test criteria that seek to eliminate the shock hazard to patients and medical attendants. Leakage currents represent the primary source of shock hazard, and limits on the allowed levels of leakage are defined by IEC601-1 and UL2601-1. These standards establish very stringent leakage-current requirements for medical-grade power supplies. In some cases, the limits on leakage current are just one-tenth of the levels allowed by specifications aimed at commercial-grade supplies. In addition, IEC601-1 and UL2601-1 set higher standards for hi-pot testing.

However, these are not the only demands placed on medical supplies. Medical-grade supplies also must satisfy recently activated standards for power factor correction as well as established standards for electromagnetic interference (EMI).

Leakage

Two factors account for leakage current. One is the parasitic capacitance of the isolating transformer and its surrounding components. The second is the capacitance contributed by the "Y" capacitors that connect from ac line to ground. Of these two factors, "Y" capacitance is the major contributor to leakage current.

The UL and IEC standards specify leakage current limits under a number of test conditions. According to UL544, one of the requirements for medical-grade supplies is enclosure or chassis leakage. This parameter is tested by inserting a measuring device in series with the ground conductor. The maximum allowed leakage current is 300 microamps, which is tested at a line voltage of 132 V ac, 60 Hz.

On the other hand, the IEC601-1 standard, which is akin to UL2601-1, specifies measurements for earth leakage and enclosure leakage. Earth leakage current is determined by inserting a measuring device in series with the ground conductor and opening the neutral at 264 V ac. Opening the neutral is considered a single fault condition and represents the worst-case scenario. The current limit for this measurement is 1 milliamp.

Enclosure leakage current, according to IEC601-1/UL2601-1, is determined by inserting a measuring device in series with ground post on the chassis and earth ground. The single-fault condition is obtained by opening the ground wire and measuring the leakage current with the neutral connected. The current limit is 500 microamps. However, the UL2601-1 standard for North America deviates from this specification. When 264-V ac center-tapped mains circuitry is employed, the specified maximum for enclosure leakage current is only 300 microamps.

Hi-Pot Requirements

For medical supplies, hi-pot specifications generally exceed those of commercial power supplies. Medical power supply standards require that the unit withstand various hi-pot potentials based on the maximum line voltage and the level of insulation used.

Power supplies have two types of insulation--basic and double. For supplies constructed with basic insulation, the hi-pot requirement for primary-to-ground testing is 1500 V rms for one minute. For double insulation, the specification is 4000 V rms for one minute. As an alternative to ac hi-pot testing, dc hi-pot may be used. In that case, the dc voltage specifications are determined by multiplying the ac rms voltages by 1.414.

Designers should be aware that medical power supplies tested for conformance by various agencies are tested with 4000 V rms placed from the input to output. Such a test could present difficulties for most power supplies (both commercial- and medical-grade), which have the secondary ground referenced. The concern is that the potential from primary to ground could be 4000 V rms, a level that could overstress basic insulation.

Another issue that arises during hi-pot testing relates to input line filters. In most commercial-grade power supplies, the input line filters are designed to withstand 1500 V rms. Fortunately, the safety agencies will allow the input filter to be removed for hi-pot testing. Nevertheless, designers must keep in mind that once the power supply is installed in the product, the hi-pot potentials should only be applied from primary to chassis. The required maximum is 1500 V ac or 2121V dc.

Power Factor Correction (PFC)

All switching power supplies draw current from the line in narrow, high-amplitude pulses instead of a smooth, sinusoidal flow from the ac mains. The power factor is the ratio of real power (Pr) to apparent power (Pa). The power factor of a typical switching power supply is 0.6 to 0.7. The power factor of a corrected power supply is typically 0.95 or greater.

Medical-grade power-factor-corrected supplies allow medical facilities to operate more equipment off the same line because the peak current is less for the same power. Lower power consumption is becoming increasingly important as more electronic devices are being put into service at medical facilities.

In terms of agency requirements for PFC, there are currently two standards in effect in Europe--the EN 61000-3-2 specification for power line harmonics, and the EN 1000-3-3 specification for power line flicker. As of January 1, 2001, all products shipped to Europe must be tested to and pass these standards. To comply with the harmonic standard it is necessary to add PFC circuitry to the power supply.

Environmental Standards

Emissions and susceptibility to emissions are issues that affect the design of medical-grade power supplies. A properly designed medical power supply will comply with IEC601-1-2, and this standard demands compliance with a number of emissions-related standards. Specifically, the supply must meet EN61000-4-2 ESD Level 3, EN61000-4-3 RF Susceptibility of 3 V per meter, EN61000-4-4 EFT (electrical fast transient) Level 3; EN61000-4-5 Surge Level 3, EN61000-3-2 Harmonics, EN61000-3-3 Power Line Flicker, and EN55011 Class A or B.

In the last standard, the A and B categories refer to the levels of both conducted and radiated emissions. Class B is the more stringent requirement, requiring about a 10-dB reduction in emissions versus Class A. The difference in allowable emissions reflects differences in the intended application of the product. Class A devices are those medical devices used in a hospital or other health-care facility, while Class B devices are intended for use in the home. Class A devices may also be used in the home if they are operated by a qualified person.

These emissions standards, taken together with the related safety specifications, complete a set of stringent regulatory requirements. Although, these requirements were developed specifically for the medical world, they offer potential benefits in other environments as well since conformance demands high levels of quality in the design, manufacturing, and testing of medical-grade supplies. Consequently, these supplies may be the choice in those non-medical applications where safety, power savings, and reliability are critical goals of the product design.