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Choosing Power Supplies for Medical Applications

The selection and specification of power supplies for medical applications is a task that must be approached with great care; especially in these times where key safety and environmental standards for medical equipment are undergoing substantial changes that will affect large segments of the medical industry.

Modern switchmode power supplies are employed in a wide array of medical equipment including: MRI, X-ray, CT and PET scanners, blood analyzers, DNA equipment, patient monitors, ultrasound, robotic surgical devices, heart-lung machines, diagnostic equipment and automated pharmaceutical dispensers, to name but a few. As with all electronics, the trend in medical equipment is to make them smaller, lighter in weight, more efficient, more reliable and competitively priced. The safety standards for medical equipment vary dependent upon the application, proximity to patients and operators, and the location and environment of the equipment.

In the design of medical electronic equipment there is one consideration which takes precedence over all others, and this is the safety of the patient and operator. In some cases, it might be tempting to think that power supplies that have been designed and certified to be safe in industrial applications might be equally suitable for use in medical equipment. This is not usually the case because the risks involved are much different. Furthermore, much of the electronic equipment used in hospitals, such as patient monitors, operate with very low-level signals. Medical equipment like this tends to be more sensitive to electromagnetic interference (EMI) than most of the equipment used in industry, which also makes EMC (electromagnetic compatibility) compliance and performance a key concern in medical applications.

Protecting the Patient & Operator

Hospital patients are frequently in a weak condition. Exposure to even small leakage currents can have an adverse effect on their well-being. The same small leakage currents could have little to no effect on a healthy person and might be acceptable in industrial applications. Depending upon the application, the "allowed leakage current" from the end-product medical equipment (not the power supply alone) can vary from a few µA (microamps) to a few hundred µA. The "leakage current" can be defined as the unintended, and potentially harmful, electric current that may pass through the human body. Obviously, medical equipment that has direct physical contact with patients must limit their leakage current to the lowest prescribed levels.

Changing Medical Power Supply Safety Standards

The special requirements of medical equipment are reflected in international standards. For most of the world, including Europe and North America, the safety standards for medical power supplies are contained in the IEC60601-1 standards. As of the writing of this article, the present version of IEC60601-1 is the 2nd edition (originated in 1988). The 3rd edition of the IEC 60601-1 (originated in 2005) is being reviewed by power supply manufacturers and global safety certifying agencies for future adaptation. There are many differences between the 2nd and 3rd editions, foremost of which is the requirement in the 3rd edition for the establishment of a "Risk Management Process" and record/file retention in compliance with the ISO14971 standards. It is therefore expected that future product certifications to the IEC60601-1, 3rd edition may include an audit of the manufacturer's compliance with ISO14971 (Risk Management Process). The exact date that the 3rd edition of IEC60601-1 may replace the 2nd has not yet been firmed up, but some predict it will occur as early as 2010.

The first and foremost requirement of the IEC60601-1 (both editions) is for the effective and reliable isolation between the AC input to the power supply, its internal high voltage stages, and its DC output, as any shortcoming in isolation would result in the risk of electric shock. Several factors contribute to effective isolation including the spacing between conductors and the electronic components. The IEC60601-1, 2nd edition sets minimum distances for spacing between these elements and it is important to note that these are greater than the spacing distances prescribed within the relevant standards for ITE (Information Technology Equipment) and industrial power supplies, which is covered by IEC60950-1.

In addition to adequate spacings between conductors/components, effective isolation also depends on reliable insulation. Most modern medical power supplies use double insulation or reinforced insulation, the effectiveness of which is verified by dielectric strength testing. This involves subjecting the insulation to a much higher voltage than that at which it operates, and ensuring that no failure occurs.

Medical requirements differ from those for standard power supplies. Reinforced or double insulation in supplies, which operate from a 240Vac mains for example, must withstand a dielectric test at 4kVac for medical applications, whereas the corresponding figure for ITE/industrial use is only 3kVac. As with the spacings, this difference must be taken into account when choosing a power supply. Power supplies that are approved to less than 4kVac may be used in medical applications as part of a reinforced barrier, provided that the insulation within the power supply is regarded as a lesser "basic" or "supplementary" barrier. In this case, additional isolation must be provided within the end-product medical equipment by the equipment's manufacturer to achieve the requirements of a reinforced barrier between the AC mains supply and the patient. The 3rd edition of the IEC60601-1 separates the requirements for the patient and operator whereas the 2nd edition treated them as equal.

The leakage current requirements of the IEC60601-1, 2nd edition are difficult to achieve, while at the same time keeping the RFI low. The maximum permissible earth leakage is 300µA for worldwide approvals, but this figure applies to the end-product as a whole, not just the power supply. To allow for additional leakage in other components it is highly desirable for the power supply to have an even lower leakage current and/or for the medical OEM to install additional layers of insulation and isolation within their end product.

This leads to an interesting challenge since EMC performance is another crucial issue for medical power supplies. All modern power supplies are of the switchmode type, as these are smaller and more efficient than the old linear types. Switchmode supplies, however, generate electromagnetic interference (EMI), both conducted and radiated and require the incorporation of EMI filters to limit this unwanted electrical noise. The capacitors in these EMI filters allow a small amount of leakage current to flow and the more effective the filter at suppressing the interference, the more leakage it is likely to produce. Therefore, there is a trade-off between EMC performance and leakage current.

Tips for Selecting Medical Power Supplies

Modern medical equipment requires power supplies that are compact, lightweight, efficient, cost-effective, RoHS compliant, reliable and super-safe. Switch-mode power supplies can meet all of these needs, but not all supplies are created equal. OEMs of medical equipment should take care to choose power supplies from a reputable supplier, preferably with proven experience in the medical electronics field, and with a good understanding of the special demands and changing standards involved in this specialized industry.

Obviously, selecting medical power supplies based on the lowest price is foolish because of the high costs of potential law suits, product recalls, brand name damage, and warranty repairs far exceed any front end potential cost savings. Medical OEMs should also take care to ensure that their choice of power supplies fully satisfies, and is certified to meet, the prevailing edition of the IEC, EN, UL and CSA safety standards for medical supplies. Taking these precautions will make it much easier for newly developed medical equipment to be certified by the responsible safety agency and the FDA (Food & Drug Administration). More information concerning medical power supplies is available at: http://us.tdk-lambda.com/lp/products/medical.htm

Posted by Power Guy