

# What to look for in a medical power supply

**Changing safety and environmental standards are added to an already long list of factors.**

**M**odern switch-mode power supplies are used in a wide range of devices that include MRI, X-ray, CT and PET scanners, blood analyzers, patient monitors, and robotic surgical devices. As with all electronics, the trend in medical equipment is to make them smaller, lighter, more efficient, more reliable, and competitively priced. An added challenge is medical-equipment safety standards that vary according to application, proximity to patients and operators, and location and environment of equipment.

Patient and operator safety takes precedence over all other design considerations when it comes to medical equipment. While it might be tempting to think power supplies that have been designed and certified safe in industrial applications might be suitable for use in medical equipment, this usually is not the case because the risks involved are much different. Much of the electronic equipment used in hospitals, such as patient monitors, operates with low-level signals. Such medical equipment tends to be more sensitive to electromagnetic interference (EMI) than most of industrial equipment, which also makes EMC (electromagnetic compatibility) compliance and performance a key concern in medical applications.

## Protecting patients and operators

Hospital patients are often physically weak, so 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. The "allowed leakage current" from the end-product medical equipment (not the power supply alone) can vary from a few  $\mu\text{A}$  to a few hundred  $\mu\text{A}$ . "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 its leakage current to the lowest prescribed levels. At one time, medical equipment that was classified on its application, but now it is the applied parts of the medical equipment. For example:

- Type B (body) applied part can deliver a current to the patient, though that is not its intended function. Examples include automated pill dispensers at nurses' stations and operating room lights.

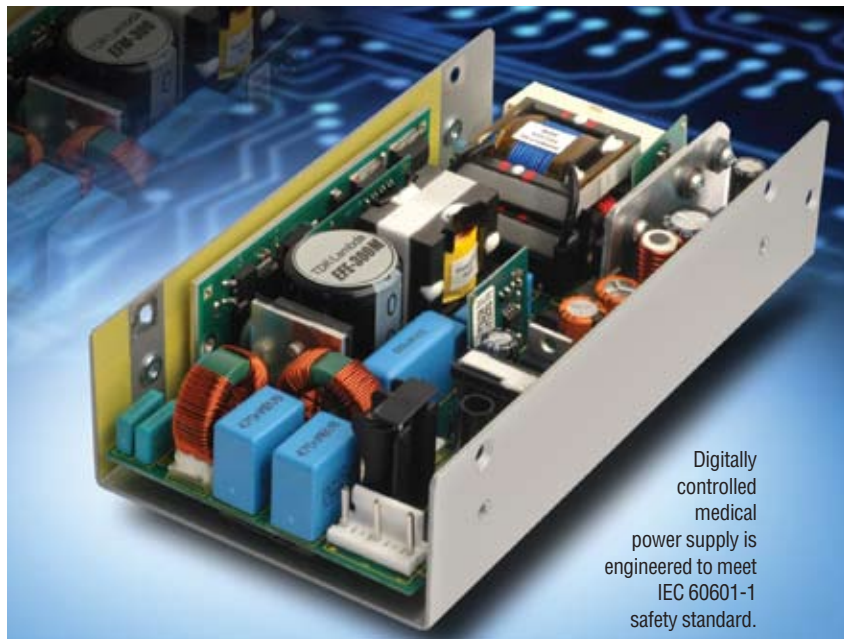
- Type BF (body floating) applied part has a patient connection, intended to deliver electrical energy or an electrophysiological signal to or from the patient. Examples include ECG equipment.

- Type CF (cardiac floating) applied part has a patient connection, intended to deliver electrical energy or an electrophysical signal to or from the patient and is specified as being suitable for direct cardiac application. Examples include dialysis equipment.

## Changing safety standards

The special requirements of medical equipment are reflected in international standards. For most of the world, including Europe and North America, safety standards for medical power supplies are contained in the IEC60601-1 standards. (IEC is the International Electrotechnical Committee. UL, CSA and EN standards are derived from the IEC standards.) The present version of IEC60601-1 (as of this writing) is the 2nd edition (originated in 1988). A 3rd edition of the IEC 60601-1 (originated in 2005) is under review by power-supply manufacturers and global safety certifying agencies for future adaptation. There are many differences between the

**Mel Berman**  
Product Manager  
**David Norton**  
Vice President of Marketing  
**Andrew Skinner**  
Advanced Development Manager  
**Robert Taylor**  
Safety Engineering Manager  
[us.tdk-lambda.com](mailto:us.tdk-lambda.com)



Digitally controlled medical power supply is engineered to meet IEC 60601-1 safety standard.



KM Series PC board-mountable medical power supplies are available in two package sizes: 64 x 45.5 x 23.4mm (15W models) and 88.9 x 63.5 x 26.9mm (40W models.) Also, no ground connection is required because they're Class II devices.

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 been set, but some predict it will occur as early as 2010.

It is not possible in this article to cover all the specifications of IEC60601-1's 2nd and 3rd editions, but it's important to consider how these standards affect the design and specification of power supplies used in medical applications. 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 because any shortcoming in isolation risks electric shock. Several factors contribute to effective isolation including the spacing between conductors and 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, covered by IEC60950-1.

In addition to adequate spacings between conductors and components, effective isolation depends on reliable insulation. Most modern medical power supplies use double or reinforced insulation, the effectiveness of which is verified by dielectric strength testing. This means subjecting the insulation to a higher voltage than that at which it operates, and ensuring no failures. Other differences from standard power supplies include reinforced or double insulation. This allows operating from a 240 Vac mains, for example, and so must withstand a dielectric test at 4 kVac for medical applications. The corresponding figure for ITE/industrial use is only 3kVac. 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 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 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 from other components, it is best for the power supply to have an even lower leakage current, or for the medical OEM to install additional layers of insulation and isolation within its end product, or both.

Low current leakage leads to an interesting challenge because EMC performance is another crucial issue for medical power supplies. All modern power supplies are of the switch-mode type because as these are smaller and more efficient than old linear versions. Switch-mode supplies, however, generate electromagnetic interference (EMI), conducted and radiated, and require use of EMI filters to limit unwanted electrical noise. Capacitors in these EMI filters allow a small amount of leakage current. The more effective the filter at suppressing the interference, the more leakage it is likely to produce. So it seems designers may have to accept a trade-off between EMC performance and leakage current. For conventionally designed switch-mode supplies this is indeed true, but EMC performance can be improved by methods other than simply providing more filtering. A better approach minimizes the amount of interference the power supply generates in the first place. To explain this, it's necessary to understand a little about how switch-mode power supplies work. Essentially, they first convert ac power from the mains into dc. This dc is then converted or switched on and off to provide pulsed-dc, but at a much higher frequency than the mains supply, so it can be applied to a lightweight and compact transformer to produce the required output voltages. This dc-to-pulsed-dc conversion is carried out by a switching circuit, which is why these products are called switch-mode supplies. The output from the transformer is converted back to dc and fed to regulators, which ensure that the output voltages remain stable as the current drawn from the supply varies. Current limiters, to protect against overloads, are also usually incorporated. From the EMC point of view, however, it is the switching circuit which is of most interest.

**Improving power supplies**

Economic and environmental factors are playing an ever-increasing part in the drive to improve efficiencies and reduce pollution from electronic equipment. Towards this goal, a number of voluntary and mandatory initiatives have been established. Among these are EMC standards for reducing and controlling radiated and conducted electrical noise, the Energy Star efficiency improvement program, and the expanding RoHS (controls hazardous substances) and WEEE (waste controls and recycling) directives. Up to now "medical devices" and "monitoring and control instruments" have been exempt from

the RoHS and WEEE directives.

However, a planned change to these directives will remove the exceptions for many medical devices, and monitoring and control instruments. These changes are expected to be mandatory sometime between 2010 and 2012. Many medical equipment manufacturers have already completed or are in the process of modifying their products to comply with these directives, which are especially important for international and EU (European Union) sales. Among the factors medical OEMs should keep in mind is that the power supply they use in their equipment must also comply with the RoHS directives, which may not have been the case in the past if their products were sold or used primarily in North America.

## How to improve power supplies

The electronic switches in modern switch-mode power supplies are typically FETs (field effect transistors) and are usually configured to switch as quickly as possible because it helps minimize losses. Unfortunately, the faster the FETs switch the more interference the switching circuit generates. Some of the best modern power-supply designs deliberately slow the switching using special 'zero-voltage switching' or 'ZVS' circuits. These still allow a fast transistor switching while achieving much slower voltage transitions (rise and fall times). These transitions in a ZVS circuit may be 100 ns (nanoseconds) compared to 20 ns in a conventional power supply.

Zero-voltage-switching circuitry lets power-supply designers achieve the slower switching without compromising the power supply's efficiency. The amount of electromagnetic interference generated is greatly reduced and only a small EMI filter is needed for these supplies to meet the EMC requirements of even the most demanding medical applications. With only a small amount of filtering, leakage currents are also kept low, satisfying another important requirement. A further benefit is that the new circuitry eliminates the need for an interwinding shield within the transformer, a technique traditionally employed to improve EMC performance. Eliminating this shield allows using a smaller transformer, thereby reducing the size of the power supply, which increases the design's efficiency.

## Multi-resonant topology (MRT)

Another technique used in designing high-efficiency, switch-mode power supplies is called Multi-Resonant Topology or MRT. Rather than using traditional regulation circuits, MRT uses closed-loop control of the main outputs, a single conversion stage and auxiliary channels with high efficiency dc-dc post regulation. The inherent low internal

voltages on the secondary side of the transformer allow using low-voltage synchronous rectifiers with much lower losses, thus improving efficiency. This topology allows use of smaller inductors and transformers. The use of MRT over traditional regulation methods can provide up to 5% efficiency improvement for multiple output power supplies.

## Digital control

The most recent advance in medical power supplies implements digital control technologies. Many power-supply manufacturers have introduced new digitally controlled power supplies for medical applications. With a 4 kVac reinforced input to output isolation and other specifications such as an output-to-ground isolation of 1,500 Vac, these supplies meet the rigorous international safety standards of IEC 60601-1 for medical equipment, making them suitable for use in B and BF type medical applications.

The use of digital control (microcontroller-based) allows making these power supplies smaller and more efficient, consistent with the trend towards greener and earth-friendlier products. In addition to medical equipment, these digitally controlled power supplies can be built to industrial and commercial designs where space is limited, providing a smaller and cooler operating end-product.

Many of these new designs include "integrated magnetics" in which multiple transformer and inductor windings are wound on the same magnetic core. This results in efficiencies on the order of 90% or better. The digital control portion of these supplies use small microcontrollers that replace bulky and less efficient analog circuits. Digital control is needed to regulate the dc outputs and handle housekeeping routines that are intrinsic to all power supplies. In a typical supply, digital control reduces parts count by 25%, size by 45%, and weight by 56%. Typical power densities of up to 16.6 W/in<sup>3</sup> are possible at peak load conditions and 12.5 W/in<sup>3</sup> under continuous loading.

Digital power supplies include active power factor correction, which ensures EN61000-3-2 compliance and operation from a wide input range input from 90 to 264Vac for global applications. Earth leakage current is less than 300µA at up to 264Vac input, complying with most medical safety requirements. Other EMC improving design features include use of low-loss, silicon carbide Schottky diodes that ensure conformance with EN55022 Class B EMC. The new digital power supplies are certified per the IEC or UL 60601-1 standards for medical equipment and may also be approved to IEC/EN/UL 60950-1 for general purpose (ITE) and industrial applications, and IEC/EN61010-1 for laboratory and process control applications. ¶