# Selection Guide:
# Power supplies for medical equipment

## Abstract
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. Mel Berman, David Norton, Andrew Skinner and Bob Taylor of TDK-Lambda pool their experience to show you how to go about it.

## Introduction
Modern switch-mode 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. Previously, it was the medical equipment which was classified depending upon its application, but now it is the Applied Parts of the medical equipment which is classified. These classifications and examples of medical equipment having these applied parts are as follows:

**Type B:** A type B (Body) applied part is one which, although it can deliver a current to the patient, is not intended to do so as part of its function (e.g., automated pill dispenser's at nurses stations, operating room lights).

**Type BF**: The BF (Body Floating) applied part has a patient connection which is designed and intended to deliver electrical energy or an electrophysiological signal to or from the patient (e.g., ECG equipment).

**Type CF:** The CF (Cardiac Floating) applied part has a patient connection which is designed and intended to deliver electrical energy or an electrophysiological signal to or from the patient and is specified as being suitable for direct cardiac application (e.g., External pacemakers).


*PC Board Mountable Medical Power Supply; TDK-Lambda's KM Series (Class II, No Ground Needed)*

## 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. National and continental standards like UL, CSA and EN are derived from the IEC, or International Electrotechnical Committee, standards. At the time of 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 IEC60601-1, 3rd edition may include an audit of the manufacturer's compliance with ISO14971. The

exact date that the 3rd edition of IEC60601-1 may replace the 2nd has not yet been firmed up, but some predict that the phase in may commence as early as 2010.

It is not possible in this article to fully cover all of the specifications of the 2nd and 3rd editions of the IEC60601-1, but it's important to consider how these standards can affect the design and specification of power supplies used in medical applications, now and in the future. 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.

Once again, 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, meeting EMC compliance requirements. 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. This leads to an interesting challenge since EMC performance is another crucial issue for medical power supplies.

All modern power supplies are of the switch-mode type, as these are smaller and more efficient than the old linear types. Switch-mode supplies, however, generate electromagnetic interference (EMI), both conducted and radiated, and require the incorporation of EMI filters. 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. It seems, therefore, that there is 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 is to minimize the

amount of interference that the power supply generates in the first place. To explain how this can be achieved 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 that 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 outputs from the transformer are rectified and smoothed to produce the required DC output voltage. The switching circuit in the power supply, coupled with the stray capacitance of switching components to earth and between primary circuits and the output, is main source of EMI from a switch-mode power supply.

## Improving Power Supply Efficiencies and Reducing Pollution

Economic and environmental factors are playing an ever increasing part in the drive to improve the efficiencies of, and reduce pollution from, electronic equipment. Towards this goal, a number of voluntary and mandatory initiatives have been established. Among these are the EMC standards for reducing/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, to name but a few.

Up to now "medical devices" and "monitoring and control instruments" have been exempt from the RoHS and WEEE Directives. However, there is a planned change to these directives that will remove these exceptions for many medical devices and monitoring/control instruments. These changes are expected to be mandatory sometime between 2010 and 2012. Fortunately, many medical equipment manufacturers have already completed or are in the process of modifying their products to comply with these directives.

## Techniques for Improving Medical Power Supplies

The FETs (field effect transistors) used as electronic switches in modern switch-mode power supplies are usually configured to switch as quickly as possible because this helps to minimize losses. Unfortunately the faster the FETs switch, the more interference the switching circuit generates.

Some of the best modern power supply designs, therefore, deliberately slow down the switching operation using special 'zero-voltage switching' or 'ZVS' circuits so that the power supply's efficiency is not compromised. ZVS circuitry still allows relatively fast switching of the transistors while achieving voltage transitions (rise and fall times) that are much slower – in of the order of 100 ns (nano seconds) compared to 20 ns in conventional hard-switching power supplies.

In turn, the amount of electromagnetic interference generated is greatly reduced and therefore 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 modest amount of filtering needed, leakage currents can also be kept to a minimum, satisfying another important requirement.

A further benefit is that the ZVS circuitry eliminates the need for an inter-winding shield within the transformer, another technique which was traditionally employed to improve EMC performance. Eliminating this shield not only allows a physically smaller transformer to be used, thereby reducing the overall size of the power supply, but also further increases the efficiency.

The majority of switch-mode power supplies designed over the last 10-20 years use hard switching pulse-width modulated circuits; the latest generations however are using resonant and multi-resonant circuits to achieve the highest possible efficiencies. Some manufacturers also offer power supplies with a number of leakage current options to allow OEMs to find the best trade-off between EMI and earth leakage current for their application.

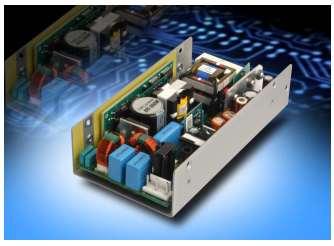
## "Digital Control" Employed in Medical Power Supplies

The most recent advancement in medical power supply design is the implementation of digital control technologies. A number of manufacturers are replacing analogue "housekeeping" circuits (under voltage lockout, fan speed control, customer signals, etc.) with microcontroller based solutions to achieve a reduction in parts count and circuit complexity. Some are also introducing new products that incorporate full digital control of the power supply, which enables improved characteristics, such as a significant peak power rating under all input voltage conditions, further parts count reduction and greater reliability.

Digital control combined with a 4kVac reinforced input to output isolation and other specifications such as an output-to-ground isolation of 1500Vac, enables these supplies to 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 these power supplies to be smaller in size and much more efficient, consistent with the trend towards environmentally friendly products. So, in addition to medical equipment, these digitally controlled power supplies can be incorporated in industrial and commercial designs where space is limited, providing a smaller and cooler operating end-product.

Some of these new designs include other space saving techniques that also improve efficiency such as "integrated magnetics", where multiple transformer and inductor windings are wound on the same magnetic core. The digital control element of these supplies employs a very small microcontroller that replaces bulky and less efficient analogue circuits, which are needed to regulate the DC outputs and handle the housekeeping routines that are intrinsic to all power supplies.



*The EFE300M digitally controlled power supply meets the rigorous international safety standards for medical equipment, making it suitable for use in B and BF type medical applications*

For example, the EFE300M series of digitally controlled medical power supplies, which was designed by TDK-Lambda UK engineers, brings a 25% parts count reduction, resulting in a 45% smaller and up to 56% lighter power supply when compared to similar products on the market today. Typical power densities of up to 16.6W/in$^3$ are achieved under peak load conditions and 12.5W/in$^3$ under continuous loading. Combining digital control with a patented Multi Resonant Topology results in typical efficiencies above 90%

Digital power supplies include active PFC (power factor correction) which ensures EN61000-3-2 compliance and operation from a wide-range input of from 90 to 264Vac for global applications. Earth leakage current is less than 300µA at up to 264Vac input, fully complying with most medical safety requirements. Other EMC improving design features include the use of low-loss Silicon Carbide (SiC) Schottky diodes in the PFC circuit which combined with a ZVS topology for the DC:DC conversion ensure Curve B EMC performance with a significant margin. These new digital power supplies are of course certified per the IEC, EN, UL and CSA 60601-1 standards for medical equipment, and may also be approved to IEC/EN/UL/CSA 60950-1 for general purpose (ITE) and industrial applications, and IEC/EN/UL/CSA 61010-1 for laboratory and process control applications.

## 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 care should be taken to select a suitable product and vendor. With the rapid miniaturization of power supplies, reputable vendors employing knowledgeable Application Engineers and dedicated Product Safety Engineers will be able to demonstrate clearly that all creepage and clearance distances have been correctly observed as well as providing valuable advice and support to assist your overall system compliance when requested.

## For further information

To learn more about the EFE series, please visit:
http://uk.tdk-lambda.com/efe

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