Rabinovich Evgeny, TDK-Lambda, 2020.

Choosing a Power supply for medical equipment: some aspects of selection.

Introduction

The Medical Equipment industry in developed countries had already been showing steady growth over the past decades. Moreover, based on the events of recent months, medical instrumentation is doomed to become a critical industry across the globe. The production of Lung ventilators, blood analyzers, automated pharmaceutical dispensers DNA equipment, MRI, CT scanners, ultrasound, diagnostic equipment and simple patient monitors is becoming a strategic element of national healthcare system security, of course, including our country. As a result, there is growing interest and demand for electronic components that can be built into the final medical equipment and comply with medical standards.

An integral part of almost any medical device is a power source, which not only ensures the smooth functioning of nodes, components and sensors, but also protects the patient from the dangerous effects of electrical circuits. The determination of parameters and the selection of food sources for medical applications is a specific task, which must be approached with due understanding and responsibility.

Medical Equipment Classification

As with all electronics, the trend in medical equipment is to make them smaller, lighter in weight, more efficient, more reliable and competitively priced. But in the design of ME electronics there is one consideration which takes precedence over all others, and this is the safety of 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.

Hospital patients are frequently in a weak condition, which is expressed both in the general resistance of the body to biological factors, and in physical resistance to electric current. 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. 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 that might have these applied parts are as shown in Table 1.

Table 1. Medical Equipment Applied Parts Classification and their Icon Symbology

Medical Equipment Category	Icon Symbology	Categories Brief Definition	Examples of Medical Equipment
B (Body)		Relates to applied parts that are generally not conductive although can deliver a current to the patient, is not intended to do so as part of its function.	• Automated pill dispenser's • Motorised patient tables, beds; • Operating room lights;
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. Must not have connection to heart of the patient.	• ECG equipment;; • Electrosurgical instruments; • Ultrasound
CF (Cardiac Floating)		This 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. May be connected directly to patient's heart.	• Electrosurgical instruments; • External pacemakers
BFD (CFD)		Equipment of CF/BF category with further extended protection.	• Defibrillator

Medical Standards Evolution in brief

The safety standards for medical equipment vary dependent upon the application, proximity to patients and operators, and the location and environment of the equipment.

The special requirements of curtain medical equipment are reflected in "particular" standards, denoted as IEC-X-Y. For example, 60601-2-4 defines specific requirements for heart defibrillators, and 60601-2-16 covers blood dialysis and filtration equipment. But the "core" standard is IEC 60601-1 which has a long history with a number of revisions and is spread in most of the world, including Europe and North. National and continental standards like UL, CSA and EN are derived from the IEC, or International Electrotechnical Committee, standards.

The original IEC 60601-1 for medical devices was published in 1977. The 2nd edition, published in 1988, focused on safety within the vicinity of a patient. In 2005, the IEC released the 3rd edition, which reflected a further change of perspective: while the basic

provisions of the 2nd and 3rd editions to guard against failure remain, the 3rd edition recognizes that the potential hazards seen by each user can be quite different. An operator has access to a control panel, for example, while the patient may be “connected” via probes. Hence looking at “means of protection” (MOP) separately as for “means of operator protection” (MOOP) and “means of patient protection” (MOPP). A substantial amendment to the 3rd edition, known as Edition 3.1, was introduced in 2012. This addressed numerous ambiguities arising from evolving medical equipment technology. Most recently, in 2014, the 4th edition of collateral standard IEC 60601-1-2, “Electromagnetic disturbances – Requirements and tests,” was published. Edition following afterwards will require even more rigorous treatment of EMC. It is not possible in this article to fully cover all of the specifications of existing 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 (all 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.

The development and testing of TDK-Lambda power supplies for medical use by today is in accordance with the latest amendment to the 3rd edition of IEC 60601. Conformance to IEC 60601 Edition 3.1 also requires a “Risk Management Process” and record/file retention in compliance with the ISO14971 standards.

Common Philosophy and Safety Criteria for the Patient and the Operator

According to IEC 60950 approach "Equipment shall be so designed and constructed that, under all conditions of normal use and under a likely fault condition, it protects against risk of personal injury from electric shock and other hazards, and against serious fire originating in the equipment, within the meaning of this standard."

In a similar manner, IEC 60601-1, Clause 3.1 states that "Equipment shall, when transported, stored, installed, operated in normal use, and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen and which is not connected with its intended application, in normal condition and in single-fault condition." As with ITE, medical equipment must be "safe" in normal and likely fault condition, and a common strategy for designing such equipment is to design in two levels of protection.

At established threshold levels, an electrical current passing through the body can cause electric shock. This current depends on the voltage and the body impedance.

Fundamentally, the basic strategy to limit the accessible current, and therefore protect against electrical shock, is to place high impedance in the current path, which might be the Insulation barrier between the primary and secondary parts of the circuit. The second way of protection strategy is to provide a parallel current path with a significantly lower impedance compared to that of the human body or, in other words, to limit the accessible voltage. This is what we used to call protective earthing or grounding. Figure 1 shows creating 2 leves of protection using Basic insulation plus Protective Earthing, (b) Basic plus Supplementary insulation, and (c) Reinforced insulation.

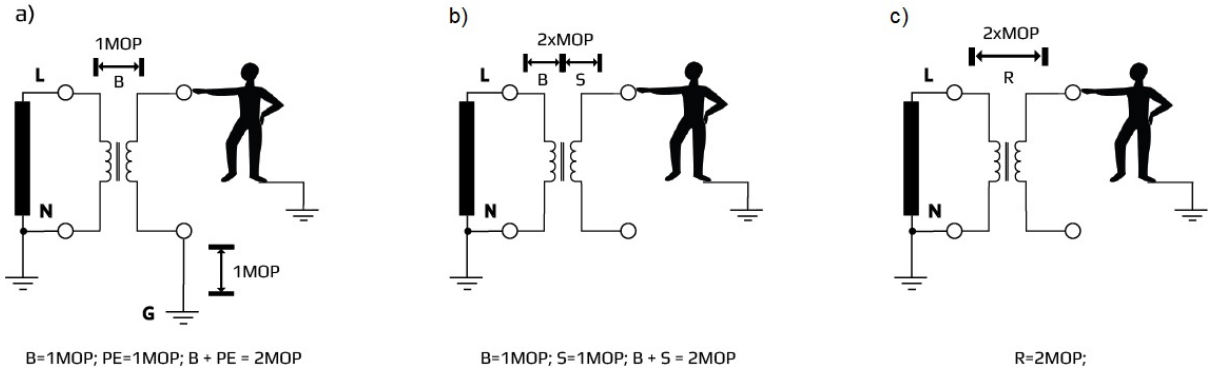

Figure 1. Means of Protection of Electrical Device: (a) Basic insulation plus protective earthing, (b) basic plus supplementary insulation, and (c) reinforced insulation.

Each safety threshold is determined by special requirements for their implementation, for example, the minimum resistance of the grounding conductor, the material of the interlayer insulation and the thickness of the transformer windings. In addition, the standard defines the minimum requirements for air and surface gaps between components (creepages and air clearances) when designing an insulation barrier and a printed circuit board. Table 2 gives us a very interesting picture for understanding.

Table 2. Isolation Requirements for Medical Equipment With Universal Input Voltage *

Means of Protection	Parameter	Input to Output Isolation (2 x MOP)	Input to Ground Isolation (1 x MOP)	Output to Ground Isolation	
				Type “B”	Type “BF”-”CF”
MOOP	Test Voltage	3000V AC	1500V AC	500V AC	500V AC
	Creepage Requirement	5.0mm	2.5mm		
	Clearance Requirement	4.0mm	2.0mm		
MOPP	Test Voltage	4000V AC	1500V AC	500V AC	1500V AC
	Creepage Requirement	8.0mm	4.0mm		4.0mm
	Clearance Requirement	5.0mm	2.5mm		2.5mm

* Isolation voltages for universal or worldwide input, or max rated input voltage of 264VAC RMS.

First of all, we see that two levels of protection requires, besides Isolation test Voltage, two times bigger creepages and air clearances. Secondly, it reflects IEC60601 last edition

approach to separate requirements for patient and operator, to put it out more specifically, devices that make patient contact require two means of patient protection (2xMOPP) from the Mains Power Supply and devices that do not make patient contact require 2xMOOP. And finally, more stringent ME category, like BF or CF, require the power supply to have 4000VAC/2xMOPP for I/P-O/P isolation, 1500VAC/1xMOPP for I/P-FG and an additional 1500VAC/1xMOPP for O/P-FG isolations. Let's note again, these isolation requirements are higher than IEC 60950-1 (ITE) safety standard's isolation levels in order to achieve better protection for patient care in medical applications.

The table data actually changes the existing opinion that a IEC60601 certified product should have 4000 VAC of "Input-Output" insulating strength as a must. If the device does not imply operation in strait contact with the patient isolation barrier can be defined as 2xMOOP with input-output test voltage of 3kV. It is important to understand that it is the final medical device that the requirements of medical standards apply to and which must pass all the safety evaluations, not the embedded components. Therefore, if the final system provides an additional isolation threshold, a power module may have a prior MOP level. But target of lowering design time as well as cost and complexity of the actual ME equipment in many cases puts a wish to choose a medical grade power supply can meet all of the isolation and leakage current requirements of an applied part.

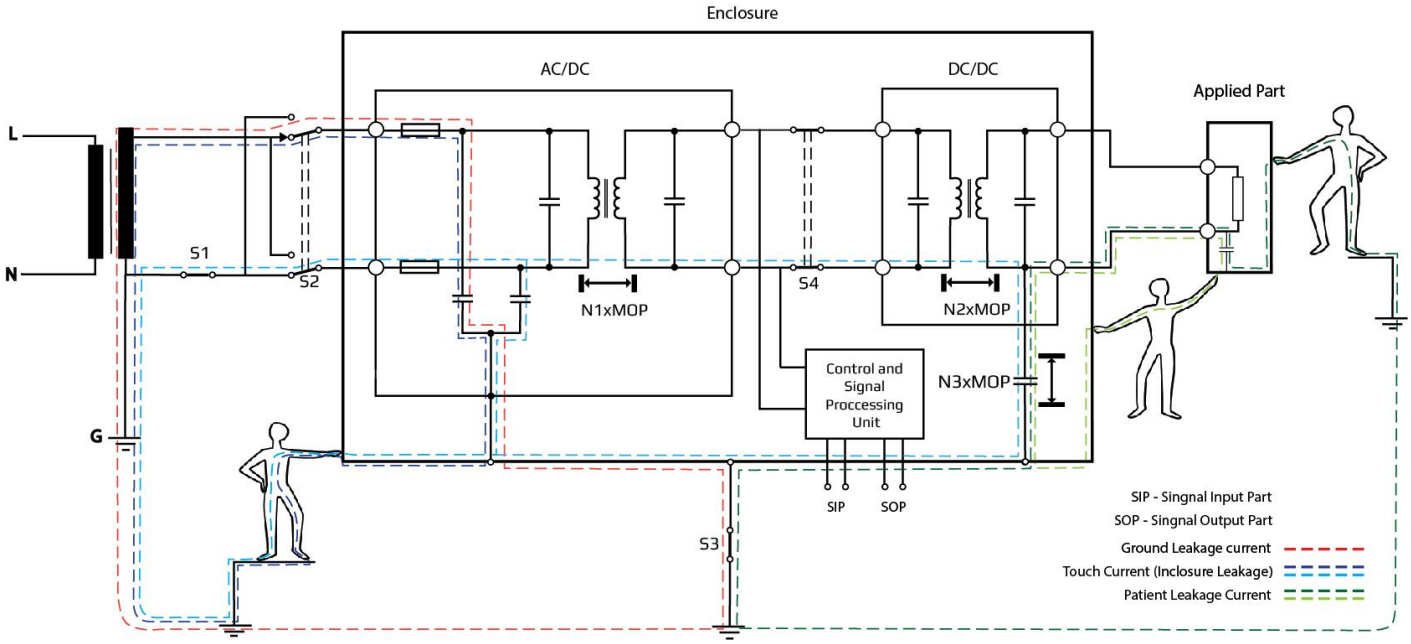

Figure 2. Three types of Leakage Current and Isolation Barriers on example of Final Medical System.

Picture 2 shows separate modules as part of End Medical System and may serve as a clue to model different practical situations. Suppose this system is of BF category and requires 2MOPP Input-Output Isolation and additional basic 1MOPP between output and ground. If a AC-DC power supply is fairly equipped with 2MOPP, then minimum IEC60601 requirements are met even following after DC-DC converter has no isolation barrier. In other words, it may be non-insulated DC-DC stage, of course, provided there is 1MOPP for O/P-FG and rest of norms met.

In case if AC-DC stage has single level of protection or double of MOOP-type, an additional threshold may be created by following transformer or 2MOPP isolated DC-DC module, for example PXC-M series from TDK-Lambda (Fig.3).

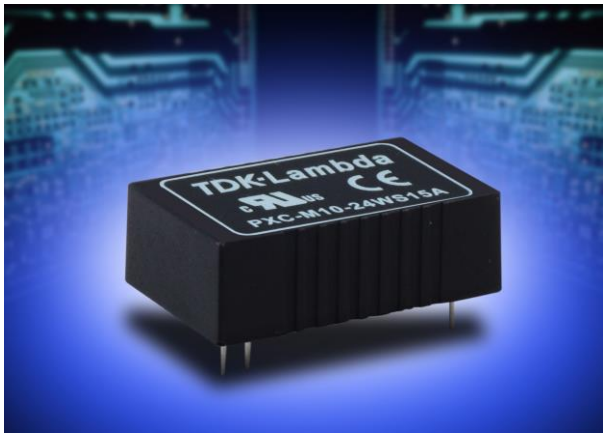

Figure 3. DC-DC module of PXC-M series from TDK-Lambda is equipped with 2MOPP I/P-O/P Isolation and Test Voltage of 5000VAC.

PXC-M converter is certified with 2MOPP I/P-O/P Isolation, High Pot Tested with 5000VAC and has maximum ground leakage current of 0.25µA. In case such module is embeded into CF applied part, AC-DC grade is becoming not a critical issue.

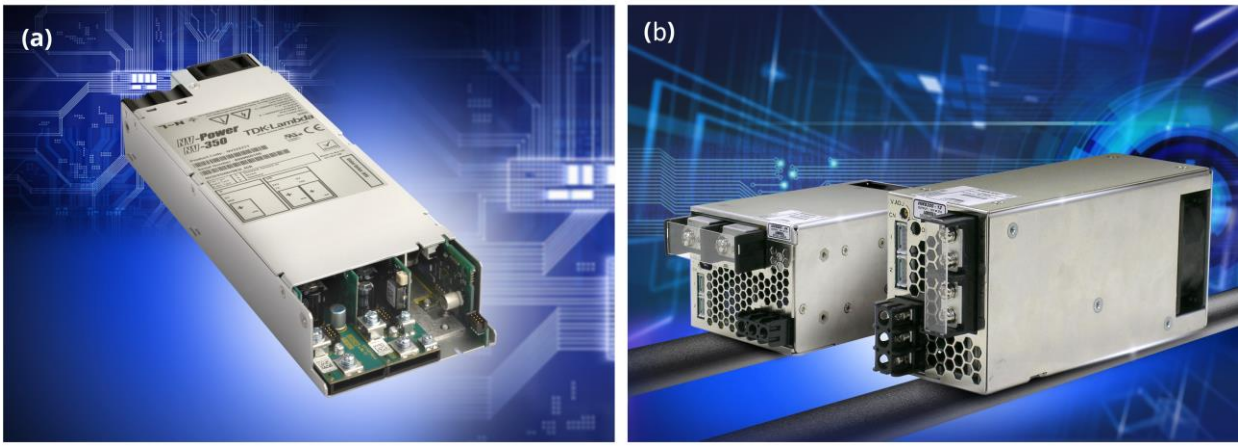

Figure 4. AC-DC Power Supplies examples from TDK-Lambda equipped with 2MOOP I/P-O/P Isolation and Test Voltage of 3000VAC: a) NV-350 series; b) HWS/ME series.

It's very wished to mention that TDK-Lambda medical portfolio is very wide and, besides DC-DC products, comprised with both 2MOOP/3000VAC (fig.4) and 2MOPP/4000VAC certified series (fig.5) of AC-DC power converters.

Figure 5. AC-DC Power Supplies examples from TDK-Lambda equipped with 2MOPP I/P-O/P Isolation and Test Voltage of 4000VAC: a) QM8 series; b) CUS600 series; c) KMS-A series.

Surely, it would be unfair not to mention another important parameter of medical standards – leakage current. This term is frequently used by engineers and typed in datasheets but not always with full comprehension. Generally, “leakage current” can be defined as the unintended and potentially harmful, electric current that may pass through the human body. Physically It’s a flow of electricity in an electrical circuit caused by non-ideal characteristics of electrical components, insulators, or as a byproduct of electrical filtering. Specifically, in AC-DC power supplies there is leakage current caused by the capacitive coupling from Y-Class capacitors used for EMC filtering and from parasitic capacitance across the isolation transformer. Leakage current sources are categorized into three main types, which are Earth Leakage Current, Enclosure Leakage (or Touch Current), and Patient Leakage Current.

Earth leakage current is defined as current flowing from the mains part through or across insulation into the protective earth supply connection through protective ground conductor. Enclosure leakage current is current flowing from the enclosure through external path or the operator, excluding protective wire, to ground or to another part of the enclosure. Patient Leakage is specified for each type of Applied Parts, but the patient leakage is only considered for the end system. It is current flowing from applied part through the patient to ground or to another part of system enclosure.

The above leakage currents types are demonstrated in figure 2 each by separate color. Current Paths may significantly vary depending on topology, circuit impedance, signal frequency, enclosure material and other reasons and thus shown just as an example.

Table 2. Leakage current maximum requirements for each source as defined by IEC 60601-1 3th edition.

Leakage current	Type “B”		Type “BF”		Type “CF”	
	NC	NFC	NC	NFC	NC	NFC
Earth Leakage current	500 µA	1mA	500 µA	1mA	500 µA	1mA
Enclosure Leakage current	100µA	500 µA	100µA	500 µA	100µA	500 µA
Patient Leakage current	100µA	500 µA	100µA	500 µA	10µA	50 µA

Since safety philosophy is built on prediction principle, Leakage current measurements are made under both normal and single-fault conditions. For instance, how would the leakage currents change when opening the ground conductor or losing the neutral line wire? For such fault cases simulation switches are provided in the actual test circuits: opening of S1 or S3 creates a single-fault condition whereas, S2 reverse polarity switch position may be any of two for both normal and single fault condition. Only one single fault can be simulated at a time. The outputs of power supplies should never be connected directly to a patient as part of the Applied Parts, so only Earth and Enclosure Leakage currents are tested for compliance in practice. IEC 60601-1 3th edition defines norms for all types of leakage currents and applied parts categories, as shown in table 2.

Many other problematic issues may also arise when choosing suitable switching power supplies, for example, EMC requirements. Many of medical equipment types works with low level signals and 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. But at the same time there is a trade-off between EMC performance and leakage current characteristics, which is surely worse of separate speaking but is not the scope of this article.

Summary and Recommendations

So, on the one hand, since medical equipment is very specific application related to the patient's safety, it imposes great responsibility on technical specialists when working on medical projects. On the other hand, it is very useful and good to understand that ME developer's requirements for demanded components often times do not coincide with the requirements of the medical standard itself, since the last one may allow the use of devices of a less stringing category in many end systems examples.

This paper disclosed the core concept of medical "electrical safety", described the basic techniques for its implementation and partially covered the norms of the latest edition of the IEC60601-1 standard. We hope this will allow the reader to more confidently find a reasonable compromise in such life realities and more professionally choose not only power supplies, but also other final medical systems elements. Surely, TDK-Lambda experts can help you find the right power supply upon you technical specification and provide support to help your system meet medical requirements.