Technical Article

Power Supplies in Medical Electronics

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THE XPERTS IN POWER

Introduction

There can be few more critical applications for power supplies in electronic equipment than in the field of medical electronics. Medical equipment will often have lives dependent upon its reliable operation. Power supplies must not only deliver the specified electrical performance but must also meet stringent specifications with respect to isolation in order that patients and medical staff are protected from the risk of electric shock. EMC is a critical issue too, both in terms of immunity and emissions. As a result, the design of power supplies for use in the medical industry is driven as much by legislation as it is by the technical requirements of powering the end equipment. System designers therefore need an understanding of this legislation, and of the markets into which their products will be sold if power solutions are not to be over-specified, over-engineered and excessively expensive as a result of building in too much safety margin when it comes to meeting legislative requirements.

In practice, there is often some confusion over the relevant requirements and a tendency for companies to adopt custom power solutions involving long development times, long approval times, high costs, and high risks of ending up with a less than optimal power system. The use of standard commercial power supplies, with or without input and output conditioning, is often possible and can be the most cost-effective solution without compromising equipment safety or performance. EN60950 is the safety specification internationally applicable to the majority of electronic equipment connected to the mains. Medical power supplies also need to meet the minimum requirements set out in this specification. The international safety standard for medical equipment is IEC60601-1 and there are three regional variants: EN60601-1 in Europe, UL60601-1 in the US, and CSA22.2 No 60601.1 in Canada. In all cases, the legislation covers protection against electric shock, protection against fire and mechanical hazards.

The degree of protection needed in any particular medical application is related to the proximity of equipment to the patient, equipment that is directly applied to patients needing the highest specification with respect to isolation. We therefore have three progressive safety levels to consider regarding isolation and protection when designing medical electronic equipment:

- The basic safety requirements of EN60950 that apply to all mains-connected electronic equipment
- The more rigorous IEC60601-1 standard for equipment used in patient vicinity
- The requirement for an additional isolation barrier in equipment which is in intentional physical contact with patients

We now consider each of these requirements in more detail.

EN60950 and Levels of Protection (LOP)

'Levels of Protection', or LOPs, are used to define safety specifications for all electronic equipment. An LOP is provided by insulation or by a protective earth and fuse. Insulation is defined as one of five types (See Table 1) with varying LOP ratings. Similarly, an earth can be classified as functional or protective, with no protection provided by a functional earth and one level of protection by a protective, or fused, earth. The basic principle is to provide two LOPs against electric shock.

Reference	Earth type	LOP
FE	Functional	0
PE	Protective	1
Reference	Insulation Type	LOP
OP	Operational	0
B	Basic	1
S	Supplementary	1
D	Double	2
R	Reinforced	2

Table 1. How Levels of Protection can be provided within electronic equipment

Each of the insulation types is defined in terms of air clearance and creepage distances. Creepage limits include specifying the minimum spacing of components on the printed circuit board for a given AC and DC applied voltage. Leakage current specifications are also a key part of safety regulations, as discussed later.

Where IEC60601-1 differs from EN60950

The main differences between IEC60601-1 specifications, the standards for equipment used in the patient vicinity, and those of EN60950 relate to increased air clearance, creepage distances and test voltages, as shown in Tables 2 and 3. In addition, the allowable leakage current is also much lower.

Insulation	EN60950		IEC60601-1	
	Air clearance	Creepage distance	Air clearance	Creepage distance
Basic or supplementary	2.0	3.2	2.5	4.0
Double or reinforced	4.0	6.0	5.0	8.0

* All distances in mm.

Table 2. EN60950 and IEC60601-1 compared: based on power supply with 250 VAC input

In addition, the test voltages applied to insulation are greater for IEC60601-1 than for EN60950, as shown in table 3.

Insulation Type	EN60950	IEC60601-1	Test voltage	Test Voltage
Basic	1500	1500		
Supplementary	1500	2500		
Double or reinforced	3000	4000		

Table 3. Insulation test voltages based on 250 VAC input

A 25% - 33% increase in component clearances and more substantial insulation requirements means that IEC60601-1 approved power supplies are often larger than their non-approved counterparts.

Leakage Current Considerations

Leakage current specifications for all IEC60601-1 approved power supplies are more stringent than for non-medical units. The specifications define several different kinds of leakage current, but the most important with respect to power supply design are:

- Earth leakage current: the current flowing along the earth conductor
- Enclosure leakage current: the current flowing from the enclosure to earth via the patient

Maximum leakage current is defined for three main types of application with respect to IEC60601-1 approved power supplies:

- Type B: equipment where there is no physical contact with the patient e.g, laser treatment systems
- Type BF: equipment where there is intentional physical contact with the patient e.g. ultrasound, monitors of various kinds including ECG equipment, and operating tables
- Type CF: equipment where there is intentional cardiac physical contact with the patient e.g. invasive heart monitors

A common misunderstanding is that leakage current specifications vary within these types of application. In fact, in all of these classes of application, the allowable leakage current is the same. Table 4 shows the permissible leakage current levels for EN60601-1, the European implementation of IEC60601-1. North American specifications are tighter. For example, where 0.5mA is allowable in Europe, just 0.3mA is permissible in the US and Canada, hence the need for medical equipment designers to appreciate where the systems they develop may be sold.

Current	Type B		Type BF		Type CF	
	NC	SFC	NC	SFC	NC	SFC
Earth leakage	0.5	1.0	0.5	1.0	0.5	1.0
Enclosure leakage	0.1	0.5	0.1	0.5	0.1	0.5

Note: NC = normal conditions; SFC = single fault condition

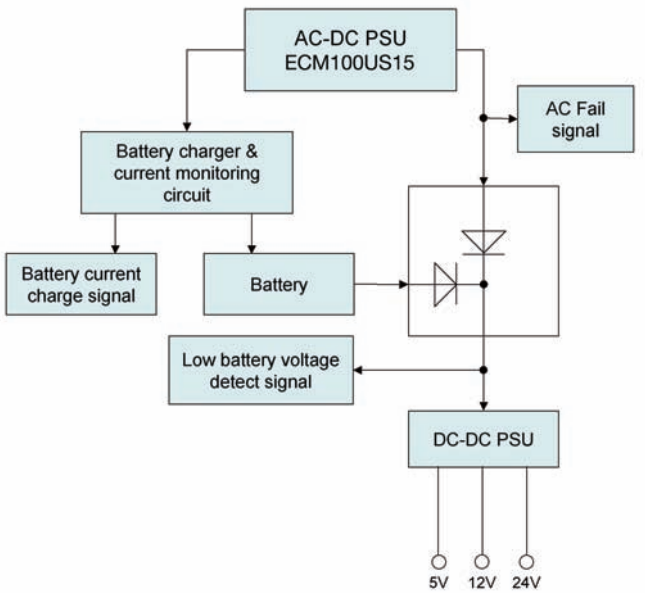
Table 4. Allowable values of continuous leakage current in different application types

Reducing leakage current within a power supply usually means eliminating or limiting the value of Class Y filter capacitors from live-to-earth and neutral-to-earth. It also demands that stray capacitance to earth is minimised through careful design. Unfortunately, the overall effect of these measures tends to compromise EMC performance, although minimising stray capacitance can reduce common mode noise. As a result, IEC60601-1 approved power supplies often meet EN55022/11 Class A instead of the more demanding Class B EMC specifications. They can be designed to meet Class B, but only through the addition of more complex filtering and screening arrangements, leading to increased power supply size and cost.
In applications falling into the BF or CF classifications, often termed 'patient connect', an additional level of isolation is required to isolate the patient from earth, signal ports and power supply output. This is needed to protect the patient against single fault conditions and to maintain the level of patient leakage current within the limits outlined in the standard. This isolation may be provided by other items that form part of the end equipment, for example plastic probes or tubing that have sufficient insulation. Where an electrical connection to the patient is needed one approach is to use an IEC60601-1 approved AC/DC power supply to feed one or more isolated DC/DC converters to provide the secondary isolation. Careful selection of the DC/DC converter is needed to ensure the isolation requirements are met.

Case Study: A Power Supply for a Ventilator

A manufacturer of medical ventilators recently had a Type BF application requiring a power supply. They approached XP to provide a solution tailored to the application but without using a full-custom design due to the delays and costs involved.
The mains-connected power supply clearly had to meet IEC60601-1 but in this instance XP advised the customer that there was no requirement for secondary isolation within the power circuit because protection was provided by the ventilator tubing and its associated connection to the equipment housing. In other words, there was no electrical connection to the patient.

An ECM Series AC/DC medical power supply a single output formed the basis of the power supply system. A 13.8VDC output feeds a back-up battery charging and current monitoring circuit and a DC/DC converter made up of discrete components. The three final outputs are 5, 12 and 24VDC. Signals for AC failure, battery charging and low battery voltage protection were incorporated into the design. Figure 1 shows the block diagram of the final unit.



Earth leakage current was limited to 0.27mA in this application at 264VAC, 60Hz. The power supply meets EN60601-1, UL60601, and CSA-C22.2 No 60601.1 safety specifications and EN55011 Class A with respect to conducted emissions. It also complies with EN60601-1-2 (clause 36.22) and EN61000-3-2 with respect to EMC immunity.
Most importantly, samples of the power supply were available within eight weeks of the agreed specification and the typical time to full production release for this type of solution is just three months. Because the AC/DC element of the power supply was already IEC60601-1 approved, there was no need for the ventilator manufacturer to seek further detailed safety approvals with respect to the power system. As custom medical power supplies can often take between one and two years to develop and approve, this 'semi-custom' approach is very attractive to medical equipment makers.

Summary

In 2005 the 3rd edition, IEC60601-1 :2005 was introduced. This standard is more comprehensive and has aligned many areas with IEC60950. It now makes distinction between circuits that provide Means Of Operator Protection (MOOP) and circuits providing Mean Of Patient Protection (MOPP). The more relaxed requirements of MOOP can be used if, through a risk assessment process, the patient will not make contact with the medical device. This will over time provide more flexibility of the type of power supply used within specific types of equipment. Medical device manufacture are beginning to use this new standard although it will be some time before it is universally used and the previous edition withdrawn.

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