

○ TECHNICAL ARTICLE

POWER SYSTEMS FOR MEDICAL EQUIPMENT MUST ENSURE PATIENT SAFETY

A fundamental tenet of medical electrical equipment that comes into contact with patients is that it must be safe to use, both for the patient and the operator. Consequently, there are rigorous standards that apply to such medical equipment, which entail a detailed risk assessment during its design to ensure not just basic safety, but also the essential performance required for effective use in its intended environment.

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Specifically the IEC 60601-1 standard – and its equivalent EN, ANSI/AMMI, and CSA standards in Europe, the USA, and Canada respectively – mandates what is defined as the ‘General requirements for basic safety and essential performance’ for medical electrical equipment used within the vicinity of a patient, including requirements where part of the equipment deliberately comes into contact with a patient – known as the ‘applied part’.

The IEC 60601-1 primary standard includes many subsidiary requirements defined by ‘collateral’ standards for more specific aspects of device performance, and ‘particular’ standards that relate to specific use cases. The standard has evolved through several editions but the 3rd edition, first published in December 2005, is currently in effect in most regions and countries around the world. Some countries, notably the US and Canada, require compliance with Edition 3.1, an amendment that was introduced in 2012 to update certain requirements to take account of evolving medical equipment technology. On the horizon, and requiring compliance from January 2019, is a more rigorous treatment of EMC – strictly this is an update to collateral standard IEC 60601-1-2, but is more broadly being referred to as the 4th edition.

Of particular relevance to power systems, the 2nd edition established patient-focused requirements for protection against electric shock that depended on increasingly stringent equipment use classifications:

- Type B (Body) – relates to applied parts that are generally not conductive, can be immediately released from the patient, and can be connected to earth.
- Type BF (Body Floating) – covers applied parts that are electrically connected to the patient and are floating, so not connected to earth.
- Type CF (Cardiac Floating) – is the most stringent classification for applied parts that are intended to make physical contact with the heart, i.e. direct cardiac connection, so must be floating and not connected to earth.

To meet these requirements, power systems must achieve defined levels of insulation and isolation, including specified creepage & clearance distances and leakage currents.

This ‘means of protection’ (MOP) approach was further developed in the 3rd edition of IEC 60601-1 to distinguish between ‘means of operator protection’ (MOOP) and ‘means of patient protection’ (MOPP). Type BF and CF medical devices need to provide additional isolation from the secondary output of a power supply to earth. This normally requires a 1 x MOPP rating for the AC-line voltage connection, but CF-type devices require further isolation between the supply and the applied part, which may be achieved either with an isolation transformer or using a 2 x MOPP supply that meets the double insulation requirements detailed in table 1.

Insulation	MOOP			MOPP		
	Air Clearance	Creepage Distance	Test Voltage	Air Clearance	Creepage Distance	Test Voltage
Basic (1 x MOP)	2.0 mm	3.2 mm	1500 VAC	2.5 mm	4.0 mm	1500 VAC
Double or Reinforced (2 x MOP)	4.0 mm	6.4 mm	3000 VAC	5.0 mm	8.0 mm	4000 VAC

Table 1. Means of protection (MOP) requirements based on 250 VAC working voltage

Other requirements that power supplies must comply with are limits on earth leakage current, enclosure leakage current and, most importantly, patient leakage current. These are defined for portable equipment in table 2 under both normal conditions (NC) and single-fault conditions (SFC), noting that in the USA the maximum earth and enclosure leakage current for patient care equipment is 300 µA.

Leakage Current	Type B		Type BF		Type CF	
	NC	SFC	NC	SFC	NC	SFC
Earth Leakage Current*	500 µA	1 mA	500 µA	1 mA	500 µA	1 mA
Enclosure Leakage Current*	100 µA	500 µA	100 µA	500 µA	100 µA	500 µA
Patient Leakage Current	100 µA	500 µA	100 µA	500 µA	10 µA	50 µA

Table 2. Leakage current limits under normal and single-fault conditions

Designing power systems for medical equipment where there is electrical contact with the patient has to address the dual challenge of minimising leakage currents under normal conditions and providing the isolation from ground that will protect a patient under fault conditions. Most standard power supplies, including those that are medically approved, do not meet the output-to-ground isolation or patient leakage current requirements. While they may meet the 2 x MOPP input-to-output and 1 x MOPP input-to-ground isolation, most units employ operational isolation from output to ground that typically only achieves a 500 VAC/VDC rating. This is insufficient to meet the basic 1 x MOP insulation test voltage of 1500 VAC even before considering creepage and clearance distances, and the excessive leakage current from output to ground that results from an input-to-output isolation capacitance that is too high.

Fortunately, the problem can be readily and inexpensively solved for lower-power systems by using a medically approved DC/DC converter as a second isolation stage (see figure 1). This will provide isolation at mains voltage with minimal input-to-output capacitance (20–50 pF), limiting any patient leakage current to no more than a few μA . This approach also allows for signal connections to other equipment not subject to medical safety requirements, e.g. a computer.

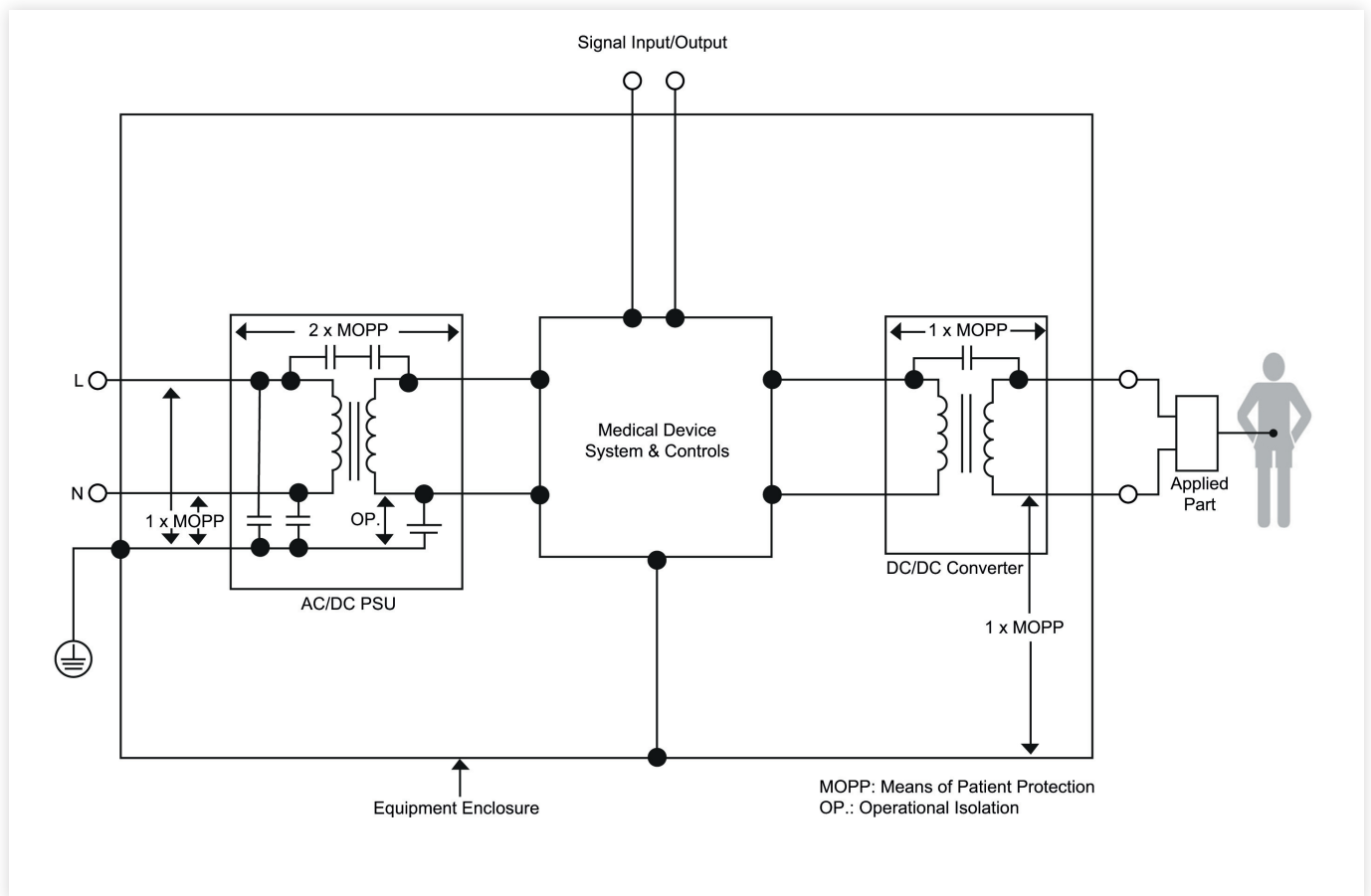


Figure 1: Medical power system with secondary DC/DC isolation

Combined with a standard medically approved mains input power supply, readily available DC/DC converters capable of supplying from 1 W to 20 W provide a cost-effective solution that can reduce patient leakage currents to as little as 2 μA , well within the limits required for BF and CF applications. And, where the mains input supply is already regulated, a fixed-input, semi-regulated DC/DC converter can be used, further saving cost. Or, for battery-powered and other DC input equipment, there are DC/DC converters with up to 2 x MOPP isolation and low I/O capacitance that will handle a wide input voltage range and provide a well-regulated output across a range of loads.



Figure 2: XP Power's JHL and JHM series

Surgical equipment and equipment that includes motor drives, such as bone-shavers and electrically powered beds, do not lend themselves to the approach of using an additional isolation stage. This is because of limited availability of sufficiently high-power, isolated DC/DC converters and the inefficiency that can result from two stages of conversion. However, the problem is less severe than it first appears, since most of these applications are Type BF, for which the patient leakage current limit is 100 μ A rather than the more demanding 10 μ A maximum required for Type CF, allowing BF-rated supplies like XP Power's new 250 W CMP250 series to be used directly.

This unit features convection cooling, which eliminates noisy fans, and can supply a peak power double its nominal rating for up to one minute, to assist motor drive applications that have to overcome an initial torque.



Figure 3: XP Power's CMP250 complies with BF-type medical requirements

Achieving BF rating with a higher power supply comes with its own challenges. Aside from having to greatly increase internal component spacing on the secondary side to meet the high isolation voltages, there is also the conflict between achieving low leakage currents and ensuring low emissions. Care is needed to minimise differential and common-mode noise using a low-noise topology, and to minimise line-frequency ripple in the primary circuits. This will become increasingly challenging with the introduction of more demanding EMC requirements in the 4th edition of IEC 60601-1.

Designing power systems to meet the compliance requirements for patient-connected medical equipment is highly challenging even for experienced power system designers. A simpler, lower-risk and faster time-to-market approach is to use pre-approved, suitably rated, off-the-shelf power supplies that offer proven performance in meeting the latest safety and EMC compliance requirements for medical equipment.