XP Power

TECHNICAL ARTICLE

POWER SYSTEMS FOR PATIENT-CONNECTED EQUIPMENT

This paper discusses two approaches for power systems within medical equipment for patient-connected applications. The part of the equipment that comes into contact with the patient is known as the 'applied part'. The applied part is defined as the part of a medical device which, to enable the overall device to perform its function, deliberately comes into direct contact with a patient. This also applies to parts likely to come into contact with the patient.

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Applied parts are classified in the 60601-1 suite of standards, according to the type of patient contact and the type or nature of the medical device. The latest version of 60601-1 is the third edition, first published in December 2005. The standard has been adopted in the major countries and regions of the world and published as the following latest versions:

IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012
Europe: EN 60601-1:2006/A1:2013/A12:2014
USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
Canada: CSA CAN/CSA-C22.2 No. 60601-1:14

Each classification has differing requirements for protection against electric shock. The classifications are outlined below, from the least to the most stringent:

Type B (Body). Type-B classification is given to applied parts that are generally not conductive and may be connected to Earth.

Type BF (Body Floating). Type-BF classification is given to applied parts that are electrically connected to the patient and must be floating and separated from Earth. This classification does not include applied parts that are in direct contact with the heart.

Type CF (Cardiac Floating). Type-CF classification is given to applied parts suitable for direct cardiac connection (connection to the heart of the patient, including intravenous). These parts must be floating and separated from Earth.

Power systems for type-BF and type-CF medical devices are designed to provide additional isolation from the secondary output to Earth, normally rated at 1 x means of patient protection (MOPP) at the AC line voltage. Insulation test voltages based on 250 VAC working voltage.
MOP = Means of protection
MOOP = Means of operation protection
MOPP = Means of patient protection

Insulation	MOOP			MOPP		
	Air Clearence	Creepage Distance	Test Voltage	Air Clearence	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

Additionally, these power systems must limit the Earth leakage current, enclosure leakage current and particularly the patient leakage current, as defined in the table below.

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

NC = Normal conditions
SFC = Single-fault conditions
*Patient care equipment maximum Earth and enclosure leakage current for the USA is 300 µA
Figures quoted are for portable equipment.

Earth leakage current = Current flowing in the Earth conductor
Enclosure leakage current = Current flowing to Earth via the patient from the enclosure
Patient leakage current = Current flowing to Earth via the patient from an applied part
Patient auxiliary current = Current flowing between two applied parts

The challenge for the power-system designer in patient contact equipment, where an electrical connection is required, is to ensure the system minimises the leakage currents under normal operation and protects under fault conditions by isolating the patient from ground. In these systems, the power system is the critical factor in meeting these important requirements.

The majority of medically approved standard power supplies are not suitable for direct connection to the patient. This is because they do not have the required isolation from output to ground, nor do they meet the requirements for patient leakage current. While they may offer the required 2 x MOPP from input to output and 1 x MOPP from input to ground, most of these units employ operational isolation from output to ground, often rated around 500 VAC/VDC. Patient connect applications require a minimum of basic insulation at mains voltage, where the test voltage required is 1500 VAC and the creepage and clearance distances must be adhered to. Additionally, the isolation capacitance from input to output is too high, allowing excessive leakage current from output to ground.

A simple and low-cost solution for lower-power systems is to employ a second isolation stage, in the form of a medically approved DC/DC converter that provides basic isolation at mains voltage and minimal input-to-output capacitance (20 – 50 pF), reducing the potential patient leakage current to single-digit µA. This solution also accounts for system input and output signals that may be connected to uncontrolled external equipment, such as a computer or monitor.

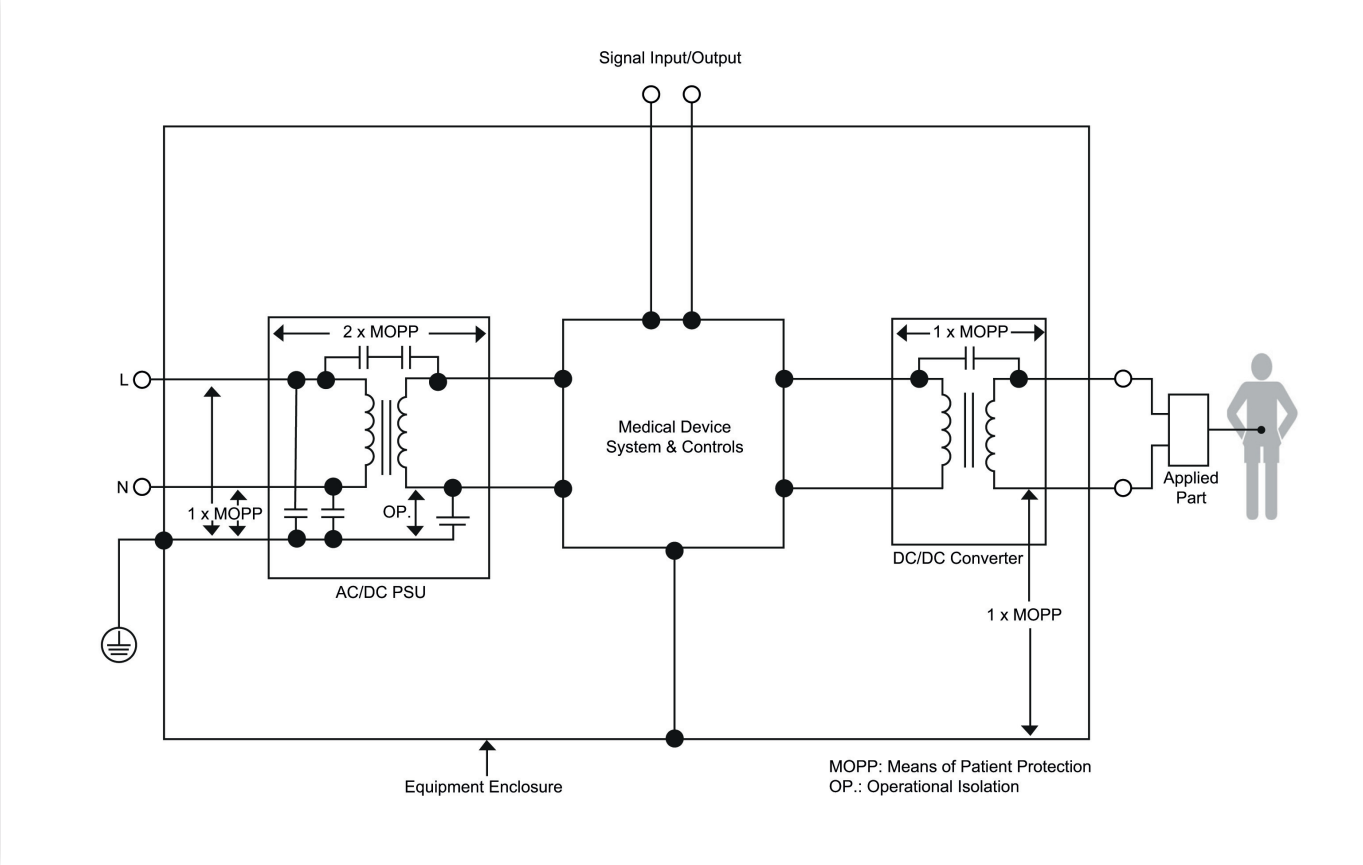

Figure 1: Medical power system with secondary DC/DC isolation.

DC/DC converters from 1 W up to 20 W are readily available, with the required input-to-output isolation and very low internal capacitance, designed specifically for these applications at a competitive cost. When used in conjunction with a standard medically approved mains input power supply, they can reduce patient leakage current to levels as low as 2 µA, suitable for use in both BF and CF applications.

Where the supply to the DC/DC converter is from a regulated AC/DC power supply, a fixed-input, semi-regulated output device can be used, making it a very cost-effective solution. Wide-range input DC/DC products, offering a tightly controlled output over a wide DC input and output load range, with up to 2 x MOPP isolation and equally low internal capacitance, are also readily available for DC input or battery-powered portable devices.

Figure 2: XP Power's JHL and JHM series

In higher-power applications, such as surgical equipment or motor-driven devices, it is undesirable to employ an additional isolation stage. This is due to the poor availability of suitably isolated DC/DC devices with high power ratings, and the inefficiency of dual-conversion of the power. In these applications, a power supply designed with the necessary isolation, spacing and patient leakage current is required.

As these are typically BF rather than CF applications, the patient leakage current requirement is less severe (100 uA rather than 10 uA) and there are increasing numbers of standard products available that allow patient contact in BF-rated applications. XP Power's new 250 W, BF-rated, CMP250 series is a good example, with the isolation and leakage current requirements catered for. It has the added benefits of convection cooling (to eliminate noisy system fans) and up to 2x peak power for up to one minute for motor-driven applications, such as bone-shavers, surgical tools and electrically powered tables, beds and chairs.

Figure 3: XP Power's CMP250

This combination of high isolation and low leakage currents presents its own design challenges in an AC/DC supply. The internal spacing requirement on the secondary side is greatly increased, and must be implemented with system integration in mind. The requirements for low emissions and low leakage current are in conflict, requiring a low-noise topology and care in minimising differential and common mode noise throughout the product. At the same time, there's a need to minimise the line-frequency ripple in primary circuits, to reduce patient leakage current for the same input-to-output capacitance.

The requirements for patient-connected medical equipment are challenging for the medical device power-system designer. Using standard, approved, suitably rated products or combinations of products with proven EMC performance, such as those discussed above, provides the best value, lowest risk and fastest time-to-market for the end equipment, simplifying both safety and EMC compliance of the end medical device.