

Isolation Level and EMC Considerations for Medical Power Supplies

The healthcare equipment market has grown significantly in recent years owing in part to the global ageing population, increased early-stage detection and screening with advanced diagnostic systems and technical advances in medical devices (for example imaging systems and, surgical robots). Medical power supplies approved to IEC60601 play a crucial role in safely powering critical medical equipment.

Regulatory bodies, such as the US Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC), have established rigorous guidelines for the design, manufacturing, and testing of medical power supplies. IEC 60601 is a widely accepted series of standards for the basic safety and essential performance of medical electrical equipment and systems. The U.S., Europe and Asia require medical devices to comply to this standard before manufacturers can place their products onto the market.

The 3rd Edition of the general standard IEC 60601-1 was first introduced in 2005 with Amendment A1 in 2012 and Amendment A2 in 2020. It is commonly known as IEC60601-1 (Edition 3.2) and represented a shift in philosophy from the 2nd Edition, including a greater emphasis on risk management and essential performance for which compliance with ISO14971:2019 'Application of risk management to medical devices' is required.

MOOPS and MOPPS

The 3rd Edition standard defines two levels of Means of Protection (MOP) from electrical hazards: MOOP (means of operator protection) and the more stringent MOPP (means of patient protection). Minimum isolation voltage levels and creepage/clearance distances are specified. (see figure 1 below).

Compliance with 2xMOOP is sufficient for equipment that is operated away from the patient vicinity, but 2xMOPP is essential for equipment in contact with or in close proximity to patients who, otherwise, may be more vulnerable to electric shock.

MOP	Isolation (VAC)	Creepage (mm)	Clearance (mm)	Insulation
1xMOOP	1500	2.5	2.0	Basic
2xMOOP	3000	5.0	4.0	Double/Reinforced
1xMOPP	1500	4.0	2.5	Basic
2xMOPP	4000	8.0	5.0	Double/Reinforced

Figure 1: MOP Isolation Table

Note: Up to 250Vrms working voltage. Distances increase at higher voltages.

Creepage is the spacing between two conductive parts measured along surface insulation. Clearance is measured through the air. These distances guard against the possibility of short circuits or arcing occurring caused by contamination due to dust or moisture for example. (see figure 2 below)

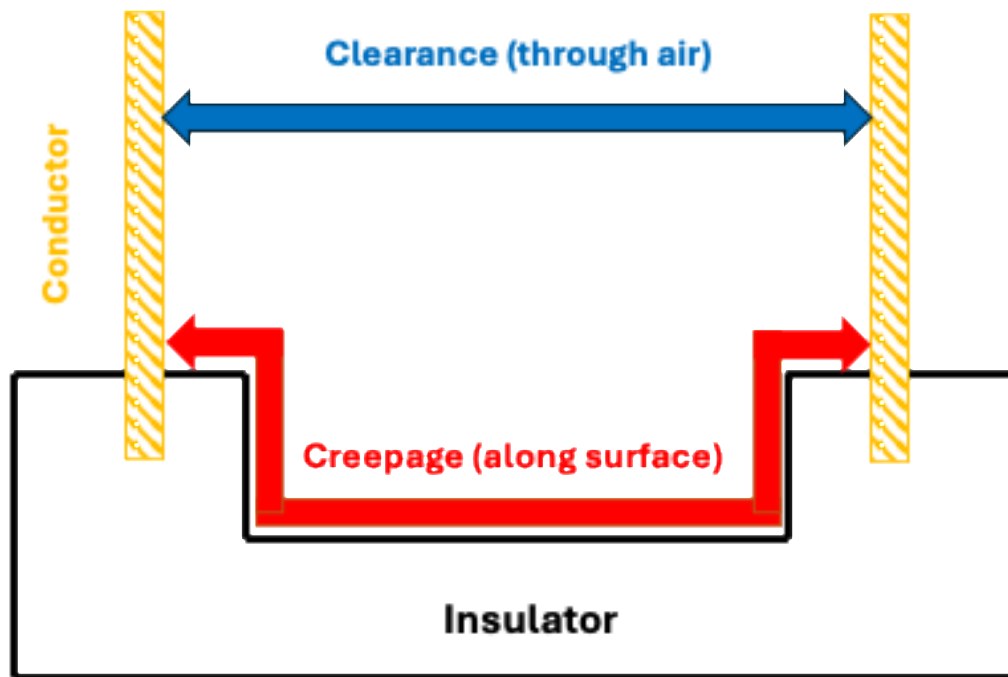


Figure 2: Creepage and clearance distance.

B, BF and CF categories

Medical power supplies are defined as suitable for types B, BF and CF body contact categories.

Type B (Body) are usually connected to earth ground and can be used to power medical devices that are not intended for direct conductive patient connection and, if circumstances require it, must be able to be immediately released from the patient. Examples of equipment include MRI scanners, X-ray machines and medical lasers.

Type BF (Body Floating) cannot have an earth ground connection and are therefore “floating”. They are used to power medical devices that have conductive contact with the patient through a suitable applied part. The output-to-ground isolation levels are more stringent than Type B. (see Figure 3 below) Examples of equipment include electrically powered hospital beds, ultrasound scanners, blood pressure monitors and incubators.

Type CF (Cardiac Floating) also cannot have an earth ground connection. This type of power supply is suitable for medical devices that may have contact with the heart -either directly or through the bloodstream. Patient leakage current limits are 10x lower than B and BF levels. Examples include Electro surgery instruments, dialysis machines and blood warmers.

Type	I/P to O/P	I/P to PE	O/P to PE
B rated	4000Vac (2xMOPP)	1500Vac (1xMOPP)	500Vac
BF/CF rated	4000Vac (2xMOPP)	1500Vac (1xMOPP)	1500Vac (1xMOPP)

Figure 3: Body (B), Body Floating (BF) and Cardiac Floating (CF) Isolation levels. I/P is input. O/P is output. PE is protective earth(ground)

The simplest choice-to use with patients is a certified medical power supply that meets the 2xMOPP standard. Using a power supply rated to 1xMOPP plus an isolation transformer is feasible; however, transformers can be bulky and add expense. Using a power supply rated to 2xMOPP is a smaller, lower cost solution.

For medical products and equipment intended for use in a household environment (which includes non-hospital clinics and care homes in EU) a related collateral standard IEC60601-1-11:2015 applies.

EMC requirements for medical devices

Also relevant to medical power supplies is an additional collateral standard IEC 60601-1-2:2014 4th Edition which addresses electromagnetic compatibility (EMC) requirements. The growing deployment of medical equipment outside of a relatively controlled hospital environment e.g. home /care home and the presence of mobile communication devices e.g. phones /tablets means that medical devices can be exposed to electromagnetic interference (EMI) from another electronic device and to electrostatic discharge (ESD) from humans or objects potentially causing malfunctions. This poses a risk to patients relying on medical devices keeping them alive or monitoring vital signs. Medical power supplies need to demonstrate compliance with strict limits of emissions and immunity.

In summary, to ensure patient and operator safety, medical power supplies are required to comply with the stringent isolation and electromagnetic disturbance levels detailed in IEC60601.

Delta Electronics Medical-Grade Power Supplies

Known for lower leakage currents, superior EMI performance and exceptional reliability, Delta's medical power supply solutions set the industry standard. Features such as low acoustic noise, high power density, reinforced isolation with two means of patient protection (2 x MOPP), and low leakage highlight Delta's commitment to adaptable and patient-safe technology. The portfolio includes power supplies with capacities exceeding 1000 W and lower capacities for small and portable devices, engineered to ensure medical equipment operates with efficiency and safety.

Delta's medical power supplies are IEC 60601-1 certified and offer solutions that reduce design time, simplify end-user certification, and provide fast time to market. The range includes AC adapters, open frame, enclosed, and configurable models,

The MEP-600A24J BRA is an example of Delta's open frame medical power supplies in the MEP series. The compact model, with a 3" x 5" footprint (7.62 x 12.7 cm), delivers up to 600 W with fan cooling or up to 450 W with natural convection cooling. Leveraging Gallium Nitride (GaN) technology, the MEP-600A24J BRA has higher power with reduced size, achieving up to 26.67 W/inch³ power density. In addition, GaN adoption allows it to reach higher efficiency and improved thermal performance, making it well-suited for medical applications such as ultrasound, anesthesia ventilators, endoscopes, and in vitro diagnostics (IVD). It also has additional features, including a 5V / 2A standby output, built-in remote on/off, current sharing, and up to 80°C operating temperature, ensuring stable and safe performance.



Figure 4: The GaN based technology MEP-600A supports up to 600 W output power in a wide operating temperature range (Source: Delta Electronics)

The GaN based technology MEP-600A offers high power density in a 3" x 5" footprint. It supports up to 600 W output power in a wide operating temperature ranging from -20°C to +80°C. With 5V/2A standby power and electric shock protection (complying with 2 x MOPP) it ensures protection against electrical shock even in patient-contact applications. The MEP-600A offers reliable power supply for type BF medical equipment (body floating, a classification for medical equipment that has electrical contact with a patient, but not near the heart).

In addition, the MEP-600A24J BRA is certified to the IEC/EN/UL safety standards for medical, IT, and household use as well as EN 55032 Class B standard for minimal electromagnetic interference.

For local purchase and service of industrial and medical power supplies, please contact our authorized distributors.

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