

Safety in medical electrical equipment starts with the power input

Power connectors and power entry modules built to IEC standards for medical applications

Electrical equipment used in medical technology must not place patients or medical staff in danger. This, in turn, requires that designing safe equipment starts at the point where the power is supplied. Power connectors and power entry modules with or without a power-line filter must fulfill the requirements of the base standard for medical electrical equipment, IEC/UL 60601-1.

Medical technology uses a wide range of electrical equipment. During normal operation and in the event of a malfunction, it is imperative that the equipment does not pose any danger to patients or medical staff. A piece of equipment that causes a short circuit or residual current can trigger a protective system upstream and in doing so shut down other, possibly life-sustaining, equipment. Thus, it is necessary to pay special attention to how each unit is supplied with power. Connectors and power entry modules used in the equipment are tested to component standards and if in compliance with these standards can generally be used in most equipment without additional testing. This is especially true for medical equipment, where extensive requirements regarding safety are in effect, as defined in the base standard for medical electrical equipment, IEC/UL 60601-1. In addition, there are a wide range of specific requirements for each category of equipment according to IEC 60601-x-xx. The IEC standards for medical electrical equipment are harmonized with UL so that the same requirements are also in effect for equipment in North America.

Power feed



V-Lock system with hospital grade plug

Medical devices can be connected directly to the mains or with a detachable power cord. Such plug connections must meet the requirements of Standard IEC 60320. Depending on the application, it is recommended to include a

mechanism to protect against any unintentional removal of the plug from the equipment's power socket. The most common type of protection against inadvertent disconnection is a cord-retaining bracket. Depending on the type of equipment and because of the many types and shapes of power sockets, it is important to select the correct bracket shape. SCHURTER offers cord-retaining brackets for most power sockets.

In addition, SCHURTER offers the V-Lock cord retaining solution, a simple, attractive and alternative system to using brackets. With the V-Lock solution, the power socket is equipped with a notch that interlocks with a special latch on the connector on the power cord. The system prevents the cord from being pulled out of the socket unintentionally. The advantage of this solution is that no cord-retaining system specific to a unit's power socket or retaining bracket must be adapted and attached. SCHURTER offers a wide range of power cords with or without V-Lock for various countries. As part of the assortment, a «hospital grade» cord set is available for medical applications in North America.

Fuse holders

Permanently installed medical electrical equipment comes with its own fuses. If there is a failure in a piece of equipment, a fuse prevents that unit from tripping the circuit breaker and disconnecting other, sometimes life-critical devices, from the mains. Equipment manufacturers must ensure that energized supply leads are protected by a fuse. A few power distribution networks, however, are not polarized. That means that the power plug can be inserted in such a way that the energized conductor can be on either the plug's left or right pole (e.g. Schuko plugs in Germany). As a result, the equipment fuse could be protecting the neutral conductor, which results in no protection against a short circuit to earth. Therefore, it is recommended that all medical electrical equipment be equipped with a double-pole fuse holder. It must further be ensured that only authorized personnel can remove or replace fuses. The basic standard for medical electrical equipment, IEC/UL 60601-1, specifies fuse holders that can only be opened up with the help of a tool. For this, SCHURTER

offers the «Extra-Safe» fuse drawers. (See IEC 60601-1: 5.9.2.1, 8.11.5.)



PEM DD12 for safe power feeds

Switches

The line switch at the power feed has an important function. Just as with fuse holders, it must be ensured that the equipment is completely disconnected from the power network after being turned off. If only one pole in a non-polarized power distribution network is interrupted, the equipment could still be live. Thus, it is preferable to use a switch that disconnects the power feed on two poles. (See IEC 60601-1: 8.11.1.)

Power-line filters



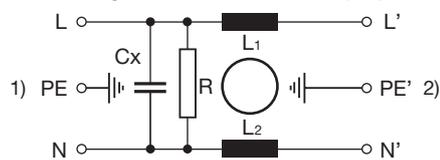
FMBB NEO universal single-phase line filter

The power-line filter is a central protective element. It protects the equipment from external HF interference and reduces the HF interference radiated by the equipment. A power-line filter is often necessary in order to fulfill the EMC standards for CE declaration of conformity. Because power-line filters can be under constant voltage, they are subject to strict requirements:

1. Leakage currents

Capacitors wired between the power supply lines and earth within the power-line filter are known as Y capacitors. They produce a leakage current to earth whose value depends on the component's capacitance and the power-line frequency. This fault current can, if too large, trigger the fault interrupter whereby the power supply is shut off. Thus, touch leakage current for medical electrical equipment may not exceed 100 μ A under normal conditions, and for devices with direct patient contact, it even drops down to just 10 μ A. As a result, power-line filters for medical electric equipment do not have any Y capacitors, which results in a maximum leakage current of 5 μ A, or they have only very small Y capacitors such as of 470 pF, which results in a peak leakage current of 80 μ A. Here it is important to note that additional components in the equipment can cause leakage currents, so the leakage current for the entire unit must always be measured. (See IEC 60601-1: 8.7.3.)

Circuit diagram of a medical filter (M5)



2. Capacitors

The capacitors used in power-line filters must meet strict criteria. They are wired directly between the energized conductors (X capacitors) or between the energized conductors and earth (Y capacitors). In addition, they are constantly under line voltage without any additional protection. Common equipment standards such as IEC 60950 (IT equipment) require that capacitors between a phase conductor and the neutral conductor be at least Class X2, and capacitors between phases/neutral and the earth conductor be at least Class Y2.

For medical electrical equipment without direct patient contact (MOOP), Class Y2 capacitors to earth are sufficient; for equipment with direct patient contact (MOPP), Y1 capacitors are required. (See IEC 60601-1: 8.5.1.)

Capacitors store energy corresponding to their value of capacitance. If you pull a power cable out of a power socket, the stored voltage from the X capacitors is still present on the power pins. If touched, they can result in an electrical shock. Thus, medical electrical equipment with detachable power connectors may only have a maximum of 60V on the touchable plug pins one second after the plug has been pulled. To achieve this, a bleeder resistor is switched in between the phase and neutral conductors, and it discharges the capacitor in a very short time. (See IEC 60601-1: 8.4.3.)

3. Dielectric strength



5008: compact C8 power socket with EMC power-line filter for Protection Class II

Increased dielectric strength is required for medical applications. An important safety aspect for achieving high dielectric strength consists of the distances between voltages. The base standard for medical electrical equipment, IEC/UL 60601-1, specifies air and creepage distances of at least 3 mm between energized parts of different polarities and 4 mm between energized conductors and earth. Care is required here because various UL standards allow a smaller separation in these distances than does the IEC standards. A power socket compliant with IEC 60320 fulfills medical requirements, while sockets compliant with UL 498 do not have sufficient air and creepage distances to meet the requirements of IEC. The UL 498 standard for plugs and sockets specifies only a 1.2 mm separation between energized parts of different polarities at a rated voltage of 250 VAC max. In contrast, for the same components, IEC 60320 requires 3 mm as does the base standard for medical electrical equipment IEC/UL 60601-1. Power sockets as well as power entry modules with and without a filter from SCHURTER fulfill the IEC/UL 60601-1 requirements, making them qualified for use in medical applications; this means that by meeting the requirements of the standards, the components can generally be used without any additional testing.

In the case of power-line filters, voltage separations inside the devices must also be observed. Here, too, the base standard for medical electrical devices specifies 3 mm between the energized phase conductor (L) and the neutral conductor (N), and it must be 4 mm to earth. According to base standards for medical electrical equipment, these air and creepage distances can be reduced to some extent if the filter is potted. (See IEC 60601-1: 8.9.3.1.)

Minimum air and creepage distance requirements from applicable standards

Application	Standard	Between L - N		Between L+N - PE	
		Air [mm]	Creepage [mm]	Air [mm]	Creepage [mm]
Socket ≤ 250 VAC	IEC 60320	3.0	3.0	4.0	4.0
	UL 498	1.2	1.2	1.2	1.2
Filter ≤ 250 VA	IEC 60939	2.5	3.0	3.0	4.0
	UL 1283	2.4	2.4	2.4	2.4
Medical*)	IEC/UL 60601-1	1.6	3.0	2.5	4.0

*) Larger distance depending on application

As a safety test, the base standard for medical electrical equipment specifies a high-voltage test of 1.5 kVAC between L and N as well as between L/N and earth (PE). To PE, the 1.5 kVAC corresponds to the values of the filter standard and can be met without any problem. However, a filter between L and N should not be tested with 1.5 kVAC because its capacitors could be damaged. Therefore, here IEC/UL 60601-1 makes an exception for interference-suppression capacitors, which can be removed for a high-voltage test if they have been tested to IEC 60384-14. All X and Y capacitors used in SCHURTER power-line filters are tested to IEC 60384-14, so no additional high-voltage testing is necessary. (See IEC 60601-1: 8.8.3.)

Furthermore, following fabrication, all SCHURTER power-line filters are subjected to a rigorous high-voltage test of at least 1.5 kVAC between L/N and PE; filters of Protection Class 2 are even tested to levels of 4 kVDC between the energized conductors L/N and the housing. Such filters and connectors can be found in medical electrical equipment intended for home use that have power cables without an earth conductor, such as is specified in IEC 60601-1-11. SCHURTER offers a variety of Class 2 power-line filters for medical equipment designed for home use.

Conclusion

Electrical equipment used in medical technology must fulfill high requirements in terms of safety. This protects both the patient and medical staff. This protection begins with the safe supply of electric power. SCHURTER offers a wide range of power sockets and power entry modules with and without power-line filters as well as filters for use in a broad range of equipment.

Company

SCHURTER continues to be a progressive innovator and manufacturer of electronic and electrical components worldwide. Our products ensure safe and clean supply of power, while making equipment easy to use. We offer a broad range of standard products including circuit protection, connectors, switches, EMC products and input systems, as well as electronic manufacturing services. Moreover, SCHURTER is ready to work with our customers to meet their application specific requirements, not covered in our standard range. You can rely on SCHURTER's global network of companies and partners to guarantee a high level of local service and product delivery.

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