

Safe Power For Medical Devices Used At Home

Multi-functional Connectors According to IEC 60601-1-11 with Protection Class II

An aging population and the rising cost of healthcare around the world are a matter of concern to the general public these days. This is especially true in the USA, where keeping costs under control becomes more and more challenging. In order to reduce the cost of overhead, while offering increased levels of care by way of technology, we are seeing a trend towards medical care at home. Along with this trend is increasing demand for smaller, more portable and efficient medical equipment. While the shorter stay in overcrowded hospitals is saving costs in the health industry, manufacturers of medical devices are being presented with new challenges to minimize the safety risks associated with the use of medical devices. Medical devices used at home are being operated by laypersons with no medical training, instead of trained personnel in a controlled hospital environment. Regulatory requirements have been established to provide safety measures specifically for these users.

As an important addition to the basic standard IEC 60601-1 for medical devices, IEC 60601-1-11 describes requirements about medical equipment used in the home. The developers of such devices or components have to observe additional requirements as it relates to safety in addition to specifications about marking (simple operation) and documentation (for example, understandable operating instructions). The utmost care has to be exercised when it comes to powering the device. The safety requirements according to IEC 60601-1-11 can be summarized as follows:

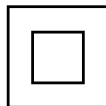
- Altered ambient conditions (domestic environment)
- Protection Class II
- Minimum IP 21 degree of water and dust protection
- Stricter shock and vibration tests

A key criteria is most certainly the responsibility to provide Protection Class II safety, as well as equipment immunity to electromagnetic interference.

Safe power supply for medical equipment used at home

Domestic power supply systems, unlike installations in hospitals, are not always reliable or may be insufficiently grounded. A medical device used at home has to compensate for this potential. It is therefore imperative that it be designed with Protection Class II safety. Protection Class is defined in safety standards that offer protection against dangerous contact voltages. Devices in Protection Class II have

double insulation between the mains circuit and the output voltage or metal enclosure. Even if they do have electrically conductive surfaces, they are protected against any contact with other live parts through the double insulation.



Icon for Protection Class II

The icon for Protection Class II symbolizes two insulation layers and is affixed to all Protection Class II devices.

The protective insulation has to be reinforced according to the general standard IEC 61140 for protection against electric shocks or be double that of Protection Class I. A second insulation for the power feed is a common solution. Doubling the clearance and creepage distances for all live contacts also has the same effect as a double insulation. This ensures that the two conductors, consisting of the phase and neutral conductor, are sufficiently insulated against all other surfaces that can be touched. If the surfaces that can be touched are electrically conductive, the gaps and insulations also have to be doubled. The clearance and creepage gaps for Protection Class I are 4 mm between live conductors and metal enclosures or ground conductors. This value is doubled in Protection Class II, corresponding to a gap of 8 mm between live conductors and a metal enclosure.



5008: C8 appliance inlet with filter

A C8 style IEC connector with a maximum rated current of 2.5 A is suitable for all devices with outputs up to approx 500 W. Matching connecting cables are available with 2-pin Euro and National Electrical Manufacturing Association (NEMA) plugs.



C8

C18

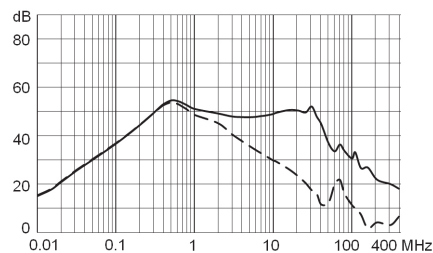
The C18 connector, with a rated current up to 10 A VDE and 15 A UL is available for medical devices with higher outputs.



C18 PEM connector 5707 with V-Lock locking system and IP 65 protection

Complying with EMC for domestic medical equipment

Since laypersons operate medical devices at home, special attention to the equipment's ability to effectively suppress interference is needed. This also includes ensuring electromagnetic compatibility (EMC). Most devices today are supplied with power by switchedmode power supplies. These are suitable for the various mains voltages around the world and have a high efficiency, due to the fast switching capability by ICs. These switching ICs, however, cause great interferences that can be measured on the power mains. The EMC standards specify limits for conducted and radiated interfering voltages. This is a precondition for compliance with the EMC standards, which in turn is necessary for the CE conformity marking. The use of a filter is recommended because of the interferences caused by modern electronic devices. A filter can be discreetly mounted on the PC board or used as a block or in line filter in combination with the connector. Since the ground connection is usually missing with Protection Class II, the filter has to make do without grounded capacitors. These so-called Y-capacitors are very popular in most filter circuits since they offer good attenuation in the higher frequency range. The two attenuation curves for the same filter, one with (standard) and one without Y-capacitors (Protection Class II) clearly show the attenuation loss for the asymmetric attenuation in the frequency range above 1 MHz.

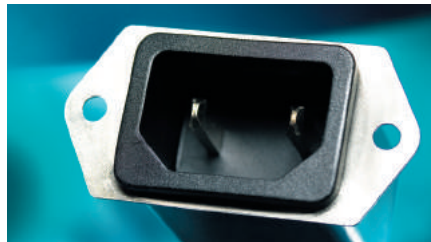


Asymmetric attenuation curves: 1-A filter with Y-capacitors (top line) and without Y-capacitors (bottom line)

The attenuation loss can be compensated by more inductivity or by attaching ferrites to the power cable. But this is not always practical and possible. This is why it is recommended that interferences in this frequency range be dealt with as close as possible to the source of the interference. Connecting capacitors to the internal ground are suitable means in a secondary circuit. Linear chokes may also be suitable, though these have only a limited frequency range.

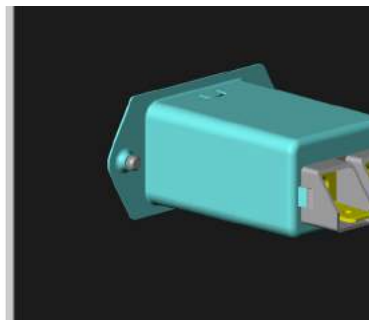
If interferences occur in a device in a frequency range above 30 MHz, shielding should also be provided in addition to the input filter. If the high-frequency source of the interference can be spatially separated from the remainder of the electronic circuits; we recommend that it

be shielded by a metal enclosure. Should this prove impossible the entire device should be shielded, though this is not always easy since Protection Class II devices do not normally have a metal enclosure. Plastic enclosures with metal coating on the inside provide an effective shielding alternative and are often used as a lower-cost alternative.



5120: IEC-C18 connector with EMC filter

If a connector with integrated filter is used, it is advisable to rear-mount it to the inside panel. The metal flange of the filter then meets with the shielding inside the plastic enclosure, thus guaranteeing the most complete shielding possible. Make sure that the electrically conductive shield is double insulated against the live conductors. An inlet filter in Protection Class II already satisfies these requirements. The inlet filter together with the enclosure shielding guarantees a very broadband attenuation. This forms the basis for successful proof of the EMC conformity.



Rear side mounting on metalized plastic

Conclusion

SCHURTER offers various combination connectors that satisfy the requirements of the standard IEC 60601-1-11 which includes Protection Class II variations. These filtered connectors in a Protection Class II design have been high-voltage tested with 4000 V. Every single one of the manufactured components is tested in the final inspection between live and tangible conductive parts. Examples of conductive parts are the filter shield or the assembly panel. The combination connectors are also protected against solid foreign bodies with a diameter above 12.5 mm, against penetration with a finger, and have an IP 40 degree of protection. Additionally, we recommend a flushmounted installation in the enclosure so as to achieve the protection against drip, in accordance with IP 21.



Headquarters in Lucerne

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, EMC products, switches 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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