MOUSER ELECTRONICS

How AC Powerline Filtering Can Assist Medical Devices In Meeting EMI/EMC Requirements

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TABLE OF CONTENTS

HOW AC POWERLINE FILTERING CAN ASSIST MEDICAL DEVICES IN MEETING EMI/EMC REQUIREMENTS

Today, medical devices can be found in the forefront of incorporating new technologies. This includes the ever-increasing use of sensitive analog electronics, wireless/RF/RFID, and microprocessors in all kinds of devices ranging from a relatively simple one like an electrical nerve stimulator to the more advanced device such as the magnetic resonance imaging (MRI) system. There is also a tendency toward more automation and ease of use in monitoring patients to perform diagnosis. At the same time, there is an increase of incorporating new communications technologies such Bluetooth, Wi-Fi, RFID and other various wireless computer links.

All types of wireless technologies face the challenge of coexisting in the same physical space. For example, devices operating under FCC Part 15 rules must accept any interference from primary users of the frequency band (Note: FCC Part 15 is applicable to certain types of low-power, non-licensed radio transmitters and certain types of electronic equipment that emit RF energy unintentionally).

With all of these advances, there can be some unforeseen problems such as the interactions between the products emitting electromagnetic (EM) energy and other sensitive medical devices (intersystem interference). Even the medical devices themselves can emit EM energy which can react with themselves (intra-system interference).

Electromagnetic compatibility, or EMC, means that a device is compatible with its electromagnetic (EM) environment including itself (i.e., no interference is caused) and does not cause electromagnetic interference (EMI) in other devices in the vicinity. A medical device can be vulnerable to EMI if the levels of EM energy in its environment exceed the EM immunity of itself or any nearby device. The different forms of EM energy that can cause EMI are conducted, radiated, and electrostatic discharge (ESD). This is why the Food and Drug Administration (FDA) is concerned with the need to assure electromagnetic compatibility (EMC) between devices and the myriad of other devices both medical and non-medical. It is this concern that the electromagnetic compatibility requirements of IEC/EN 60601-1-2: International Electrotechnical Commission – Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests which includes the recently published updates to the 4th edition is used to show compliance to the Medical Device Directive 93/42/EEC.

The manufacturers can design and test for emissions and immunity, but they do not have any control over the environment in which it will be used. The environment can change to one that is not anticipated by manufacturers. This is why manufacturers must design their device with adequate protection against possible interfering emissions and immunity.

Requirements

The consequence of electromagnetic interference (EMI) with medical devices may be only a transient "blip" on a monitor, or it could be as serious as preventing an alarm from sounding or inappropriate device movement leading to patient injury or death. While the number of reports with possible links to EMI have been steady, these numbers are generally not indicative of the actual occurrence of incidents. Indeed, in investigating possible EMI-related problems it is usually the case that the EM energy which caused the issue may have simply been shut off or removed from the area. Only through careful measurement and testing can the true nature of EMI immunity be determined. The Center for Devices and Radiological Health (CDRH) has regulatory authority over medical devices. Because of its concern for the public health and safety, the CDRH part of FDA has been the leader in the US of examining medical device EMI (electromagnetic interference). Extensive laboratory testing by CDRH, and others, has revealed that many devices can have immunity problems caused by EMI. Because of these concerns, the difference for medical devices is that the frequency ranges, emission limits, and immunity levels are typically higher than for "normal" generic electronic/electrical equipment.

As was mentioned earlier, the concept of EMC can be divided into emissions and immunity threats. Emissions can be further divided into conducted emissions and radiated emissions. The primary immunity threats are radiated immunity, power disturbances and electrostatic discharge (ESD). Emissions need to be controlled so that the energy generated by the device in question does not cause a problem to any nearby equipment. Radiated immunity deals not only from its own emissions, but more to intentionally transmitted electromagnetic energy due to RF from commercial, broadcast, and military or aircraft communications. Power disturbances can be continuous or transitory in nature caused by nearby "noisy" equipment. Electrostatic discharge (ESD) is due to a gradual buildup of charges, but creates an issue when the charge buildup reaches a level to create a discharge generating a conductive current surge and localized radiated transient field. Don't forget that EMC includes self-compatibility meaning that your equipment should not generate a powerful enough field to interfere with its own operation. Some of the individual testing standards include the following:

IEC 61000-4-2 ESD
IEC 61000-4-3 Radiated Susceptibility
IEC 61000-4-4 Transients
IEC 61000-4-5 Surge
IEC 61000-4-6 Conducted Susceptibility
IEC 61000-4-8 Magnetic field

It is up to the manufacturer to ensure that their product meets all the requirements of the Medical Device Directive, in order to bear the CE Mark in the EU and meet the FDA requirements in the US, UL 60601-1 for US safety, and access other global markets.

Some New and Potentially New Requirements

The FDA has established compliance criteria for electromagnetic compatibility that now includes protection against exposure to RFID devices. This recent requirement is related to potential risks due to the increase of RFID equipped devices to a level that the FDA has determined warrants inclusion on current FDA applications. AIM 7351731, an FDA recognized standard for the healthcare industry, has been established to determine safe limits for medical devices with respect to RFID exposure. RFID protection compliance testing is over and above testing requirements found in the IEC 60601-1-2, and is being mandated by the FDA on their most recent acceptance criteria for medical devices and equipment. Tests included for RFID are standardized by ISO, include LF, HF, and UHF RFID as well as both active and passive ISO RFID are covered.

There is another new standard that has been listed which is EN 61000-4-31 Electromagnetic compatibility (EMC) - Part 4-31: Testing and measurement techniques - AC mains ports broadband conducted disturbance immunity test (IEC 61000-4-31:2016) published in the Official Journal (OJ) standard in 7-28-2016. This new basic standard relates to the conducted immunity of electrical and electronic equipment to electromagnetic disturbances coming from intended and/or unintended broadband signal sources (i.e. RF signals). The IEC 61000-4-31 can be considered as an addition to the common mode testing as per IEC 61000-4-6 since it covers the same frequency range, but it addresses the differential mode nature of the disturbance. Another key difference is the broadband signal which makes the test very fast, like multi tone with an infinite number of tones.

What Can We Do? How Can an AC Powerline EMI Filter Help?

Unfortunately, EMC is typically the last step in a design. When all the other product features have been implemented and the functionality is established, any EMC problems are then solved. At this point, EMC becomes expensive, time-consuming and difficult to handle. Manufacturers should therefore always start thinking about EMC in the early stages of product design. This thought process pertains to the EMI power input filter as well. Designers often forget that an EMI filter can assist not only with conducted emissions, but also in meeting immunity and fast transients requirements along with radiated emissions too. A power line or mains EMI filter is placed at the power entry point of the equipment it is being installed in to prevent EM noise from exiting or entering the equipment. Refer to Figure 1 to see how the AC mains power cable (on the left side of the diagrams) is a common element in the potential path for the device's electromagnetic emission and immunity paths.

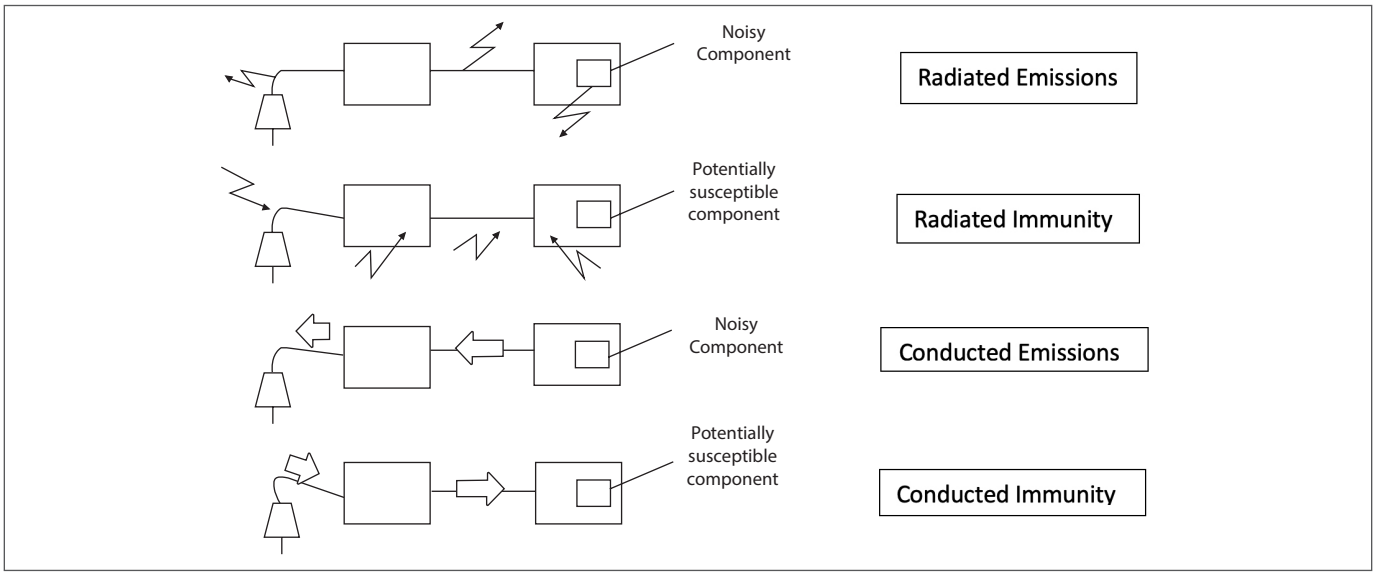

Figure 1. Noise Paths.

So, the AC main power filter could become a key component to resolving or preventing both emissions or immunity electromagnetic noise issues especially with the future addition of differential mode noise requirement (EN 61000-4-31 Electromagnetic compatibility (EMC) - Part 4-31: Testing and measurement techniques - AC mains ports broadband conducted disturbance immunity test. The design parameters for selecting an appropriate EMI filter include the attenuation or insertion loss, rated current, rated voltage, and regulatory approval requirements specified by the user. However, there are many other parameters that should be or must be considered to get the most efficiency, reliability, and proper operation from the filter.

Electrical Design Parameters

Essentially, an AC power or mains EMI filter is a low pass filter that blocks the flow of "noise" while passing the desired input 50/60 Hertz power frequency. An ideal EMI filter will reduce the amplitude of all frequency signals greater than the filter cut-off frequency.

The cut-off frequency is the frequency between the signal's passband and the reject bands at 3 dB attenuation below the acceptance line. The measure of a filter's ability to reduce a given signal level is insertion loss or attenuation.

Filters are not only for conducted emissions, but also help in meeting radiated emissions levels and also helps in immunity issues and fast transients like electrical fast transients (EFT) as shown in the previous *Figure 1*. In all circuits, both common-mode (CM) and differential-mode (DM) currents are present. There is a difference between the two types of noise and filtering configuration.

Given a pair of transmission lines and a return path, one or the other mode will exist, usually both. Differential-mode signals carry data or a signal of interest (information). Common-mode is an undesired side effect from differential-mode transmission and is most troublesome for EMC. Common-mode filtering involves capacitors to ground and/or a common mode inductor in series with both side of the line or lines (Reference *Figure 2*).

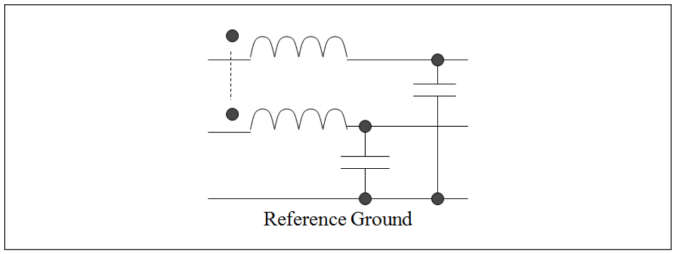

Figure 2. Common Mode Filtering.

Differential-mode filtering involves placing capacitors between lines and/or an inductor in series with either the high or low side of the line (Reference *Figure 3*).

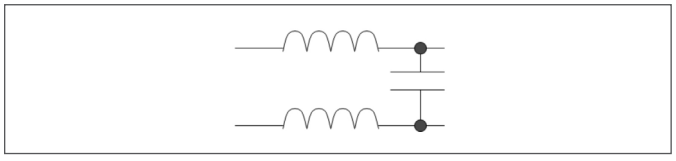

Figure 3. Differential Mode Filtering.

Safety Design Parameters

LEAKAGE CURRENT

During normal operation of electrical equipment, some cur-

rent flows to earth. Such currents, called leakage currents, pose a potential safety risk to the user and are therefore limited by most current product safety standards. IEC/EN60601 for medical equipment has very stringent leakage levels. For EMI filters it is common to calculate the leakage currents based on the capacitor values against earth and other parasitic components. This leakage current is limited by the international safety agencies to prevent a danger to personal safety.

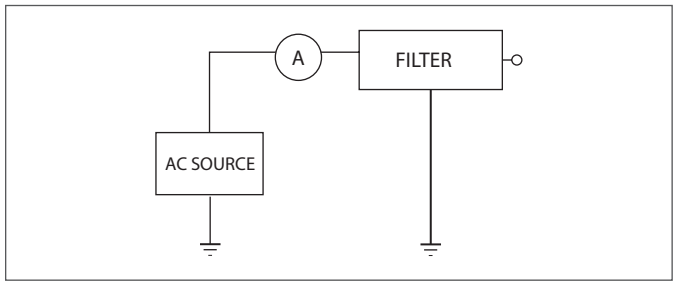

Figure 4. Leakage Current Test Circuit.

DIELECTRIC WITHSTAND (HI-POT)

Dielectric testing, sometimes referred to as Hi-Pot testing, demonstrates the ability of the filter capacitors to ensure higher than rated voltage. In filters, components are used that are connected between the phases of the supply network or between one phase and earth. It is therefore important to determine how well filters resist high voltages.

A dielectric withstand test is performed for this reason by applying a voltage between enclosure and phase or between two connectors for a defined time. The current flowing between the same points is measured. Current flow means that the insulation is broken; the equipment fails the test.

During approval procedures, the test is usually performed over a longer period (typically one minute) with a defined voltage. Many safety standards require the testing to be performed on 100 % of all units, but to save time, a test with higher voltage but reduced time is accepted. It should be noted that repeated high-voltage testing can lead to a damage of the insulation. Please note that this test is a high-stress test for the capacitors inside the filter. Each additional test stresses the capacitors again and leads to a reduction of lifetime. Schaffner recommends keeping the number of tests to a minimum and never test the filters at higher than the indicated voltages.

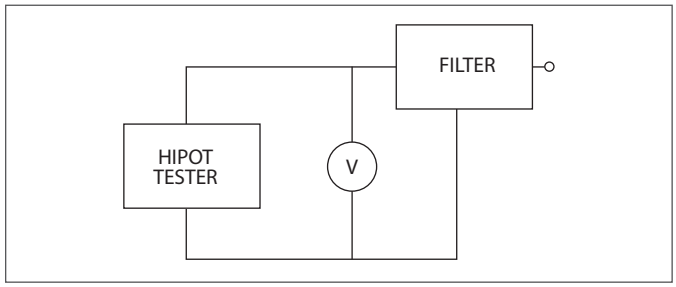

Figure 5. Typical Test Setup for Dielectric Withstand or Hi-Pot.

INSULATION RESISTANCE

Insulation resistance indicates quality of the filter capacitor construction and filter insulation system. Low insulation resistance may indicate a condition which may lead to possible deterioration over time. Sometimes this can be calculated from measurements of the DC leakage current at the specified voltage.

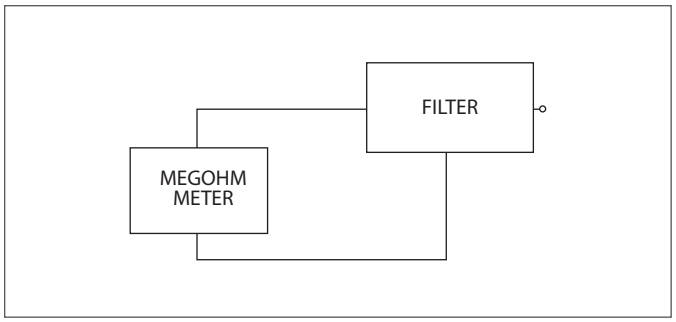

Figure 6. Setup for Insulation Resistance Test.

Conclusion

Meeting the Medical Device Directive can be a challenging effort for manufacturers with stringent EMI/EMC requirements that are typically over and beyond the normal generic requirements of ordinary electrical/electronic devices. With the potential of adding new requirements that involve differential noise immunity, the AC power main filter could easily become a key component with both its differential and common mode filtering capabilities. Schaffner not only can provide off the shelf EMC filter solutions but also support manufacturers with their EMC layout from the early stages of new product ideas or designs. Schaffner can also offer custom made solutions to help manufacturers meet any unique electrical, mechanical or EMC challenge. Contact your nearest Schaffner representative for assistance.

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MOUSER ELECTRONICS
1000 North Main St.
Mansfield, TX 76063
1-800-346-6873
sales@mouser.com
www.mouser.com

SCHAFFNER EMC INC.
52 Mayfield Avenue
Edison, New Jersey 08837
+1 800 367 5566
+1 732 225 4789
usasales@schaffner.com
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