



Medical Devices

**Solutions for medical and  
in-vitro medical devices**

Ensures the safe and reliable  
operation of medical applications

 **SCHAFFNER**

energy efficiency and reliability





## Schaffner GROUP

Schaffner is the international leader in the fields of electromagnetic compatibility and power quality, supplying components that support the efficient and reliable use of electric energy. Customers benefit from the technological know-how of the Schaffner Group in the development, manufacturing and marketing of high-performance products that offer optimized and fault-free operation and compliance with all major quality and performance standards. With its products and services, the Schaffner Group plays a key role in promoting technologies that support renewable energies, ensures the reliable functioning of electronic equipment and systems and meets the requirements for greater energy efficiency.

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- PCB filters
- IEC inlet filters / Power entry modules
- Single-phase filters
- Three-phase filters
- Three-phase + neutral line filters
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#### EMC/EMI chokes

#### Feedthrough filters and capacitors

#### Automotive components

#### Customized solutions

#### Power Quality

- Line reactors
- dv/dt reactors and filters
- Sine wave filters
- Harmonic filters
- Regen reactors and filters
- Transformers

#### Customized solutions

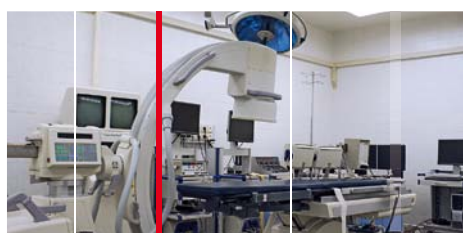


## EMC and power quality for electrical medical devices

In our modern world an increasing number of innovative medical devices are being developed and manufactured for use in the international markets with the goal of ensuring or improving the well-being and health of people. Product safety already takes up a significant importance in development to ensure patients' and operators' safety later on. International standards and national laws govern these requirements.

**Medical devices and in-vitro medical devices.** In the European Union, permission for electrical medical devices, which are operated on public power distribution networks, is regulated by the guideline for medical products (Medical Device Directive MDD 93/42/EEC and 2007/47/EC) and the guideline for in-vitro diagnostics (In-Vitro Diagnostic Medical Device IVDD 98/79/EC). In America it is regulated by the US Federal Office for Food and Drug Administration (FDA). Other countries have similar requirements or follow international standards.

In medical technology, a variety of medical devices are used in various environments for different purposes. Devices for use in hospitals, in doctors' practices or in home treatment for diagnosis, therapy or monitoring must not have a negative influence upon each other. Disturbances or accidents that lead to damages of the devices or can endanger the health and the life of patients must be prevented under all circumstances.



Therefore, tough requirements are placed on medical devices for safety and electromagnetic compatibility (EMC) to guarantee safe and reliable operation. Electromagnetic compatibility is mandatory, so medical devices emit interferences equal to or lower than the limits, and neighboring devices are not disturbed (emission). They must also offer a defined amount of immunity, so they can tolerate some interference generated by neighboring devices. In addition to electromagnetic compatibility, electric safety plays a major role. To take this into account, isolation and separation measures are defined during the design phase, which set the requirements for components.



## Electric safety: which standard is applicable?

**IEC/EN 60601, IEC/EN 60950, IEC/EN 61010.** National and international guidelines apply for the electric safety of medical devices, for example, IEC/EN 60601-1, IEC/EN 60950 or IEC/EN 61010. What standard is applicable depends upon the purpose of the medical device, according to the category of the used medical standard as well as of the countries where the final equipment is brought into use.

Electrical medical products, which are operated on public power network, fall in one of the following categories:

- Medical Devices (MD)
- In-Vitro Diagnostic Medical Devices (IVD)

This means that not all medical products are treated equally, but instead depend on the guideline used to approve and market the medical product in question. Depending upon the category, other international safety norms may also apply.

### Medical devices.

Products such as syringe pumps, artificial respirators, surgical lasers and patient monitors, etc., which are used on patients or directly in the vicinity of patients, are defined as medical devices.

Many of these medical devices and systems are operated on the public power network and must be designed according to the specifications of IEC/EN 60950. In addition, medical devices must fulfill the conditions of IEC/EN 60601-1, e.g.:

- EN 60601-1 in Europe
- UL 60601-1 in USA
- CSA 60601-1 in Canada
- GB 9706.1-2007 in China

This norm, for example, requires substantially lower leakage current from the network for protective earthing, a better separation of primary to secondary voltage through larger creepage and clearance distances and higher isolation test voltage. The norm IEC/EN 60601-1 in its 3rd version further differentiates between devices that do not come directly in contact with the patients and those that do. Schaffner offers special medical components, which meet these requirements. EMC norm IEC/EN 60601-1-2 is applied with respect to electromagnetic compatibility for medical devices.







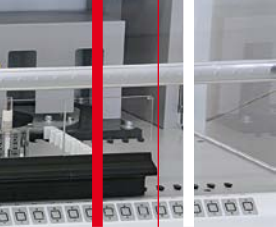
#### **In-vitro diagnostic medical devices.**

In-vitro diagnostic medical devices define a series of products, which are used for the preparation and performance of analyses of body fluids and tissues. Although centrifuges, hematology analyzers, blood/gas analyzers and other laboratory equipments are classified as medical products, they are not electrical medical devices in the sense of integrated standard guidelines series IEC/EN 60601 (“Medical Electrical Devices”), because IVD devices are not as a rule used in or on the body. Consequently, the series of norms IEC/EN 60601 is applicable on IVD devices only as exception, for example, when used in the direct vicinity of patients.



IVD medical products, which do not show any particular risk, are subject to the norms IEC/EN 61010-1 and IEC/EN 61010-2-101, which have the same significance for these products as IEC/EN 60601 and associated norms for medical products. Regarding electromagnetic compatibility, the norm IEC 61010-1 refers to the integrated standard IEC/EN 61326 (“Electrical equipment for measurement, control and laboratory use”). IEC/EN 60601-1-2 is not applicable for IVD devices. Additional standards or regulations may be applicable depending on the equipment and country.





## Distinctive features of and differences between IEC/EN 60601-1, IEC/EN 60950, IEC/EN 61010-1

**Leakage current.** Substantially stricter requirements are applicable for the leakage current for medical devices according to IEC/EN 60601-1 than for devices that are not used medically. Although IEC/EN 60601-1 is divided into three different classes (non direct patient contact, direct patient contact, direct patient contact with the heart) the requirements on the leakage current are the same for all:

Current	Normal operation	Failure mode 1
Earth discharge current	0.5mA	1.0mA
Cabinet discharge current	0.1mA	0.5mA

Designers must take into consideration the target market of the device already in development phase. In Europe, 0.5mA leakage current is permissible, while in North America only 0.3mA is allowed according to UL 60601-1.

**Air clearance and creepage distances.** Different limit values apply to air clearance and creepage according to the type of isolation.

Basic isolation	IEC/EN 60601-1	IEC/EN 60950	IEC/EN 61010
Air clearance distance	2.5mm	2.0mm	1.5mm
Creepage distance	4.0mm	3.2mm	*3.0mm

\* Degree of pollution II, material group III

Based on an input voltage of 250VAC for medical devices according to IEC/EN 60601-1, IVD devices according to IEC/EN 61010 and non-medical devices according to IEC/EN 60950. Higher values apply for double or stronger isolation.

**Isolation test voltage.** To protect patients and staff workers against the consequences of an electric shock, the medical devices must be able to withstand a higher test voltage.

Isolation type	IEC/EN 60601-1	IEC/EN 60950	IEC/EN 61010-1
Basic isolation	1500V	1500V	1500V
Complementary isolation	2500V	1500V	1500V
Double or stronger isolation	4000V	3000V	2400V

Based on an input voltage of 250VAC.

IEC/EN 60601-1 permits separating the capacitors between the isolation (e.g., EMC/EMI filter capacitors) during the test if these are allowed by IEC/EN 60584-14. This practice serves to protect the capacitors, because they can age or be destroyed in a production test due to the higher test voltage. IEC/EN 61010-1 allows an impulse voltage test of 1.2/50\_s according to IEC/EN 60060.

The new IEC/EN 60601-1 now differentiates between operator protection (MOOP, Means of Operator Protection) and patient protection (MOPP, Means of Patient Protection). Lower protection requirements apply to MOOP if there is certainty that the patient cannot come into contact with the device.





## Interference sources in medical devices

Different load behavior, e.g., of motors or valves and steep voltage rise times in switches or PWM signals, result in electromagnetic interference. It can be reduced with EMC/EMI filters to keep the interference level below the required limits. The reduction of leakage current requires that none or very small filter capacitors of Class Y are used between phase/neutral and earth (PE), which in turn has influence upon the attenuation performance of the filter. Schaffner EMC/EMI filters for medical requirements avoid filter capacitors to ground and thus guarantee minimum leakage current. Attention must be paid to the earthing concept during the device development in order to keep the required stray capacitance to a minimum. In addition to an EMC/EMI filter, suitable shielding measures and small filter capacitors can be used to further increase noise attenuation while maintaining low leakage currents.

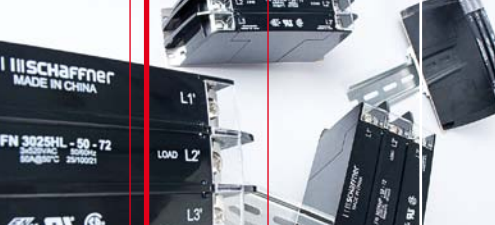
	Patient monitoring equipment	Medical imaging equipment	X-ray equipment	Ultrasonic equipment	Surgical equipment	Therapeutic equipment	Life-support equipment	Diagnostic equipment	Laboratory equipment
Linear power supply	■	■	■		■	■	■	■	■
Switch-mode power supply	■	■	■	■	■	■	■	■	■
Flyback converter	■				■			■	■
High voltage DC power supply	■	■	■		■		■		
RF power supply		■			■	■			
SCR controlled heater			■			■			■
SCR controlled motor					■		■		■
DC servo/stepper drive			■		■	■	■	■	■
DC motor control		■	■		■			■	■
Internal battery charger	■					■	■	■	



## Electrical medical devices

### Schaffner solutions for medical and in-vitro diagnostic medical devices

	Application and features	Products
<b>IEC inlet filters</b> 	<b>IEC inlet filters for medical and IVD devices. Medical type (B type) filters fulfill the requirements of patient coupled devices according to IEC/EN 60601-1.</b> <ul style="list-style-type: none"> <li>■ Suppression of high interference levels</li> <li>■ Fulfillment of required EMC standards</li> <li>■ International power cord configuration</li> <li>■ Improvement of safety and reliability</li> <li>■ Various mounting options</li> <li>■ Selectable attenuation performance levels</li> </ul>	<b>FN 9222(B), FN 9233(B), FN 9244(B), and FN 9246(B) standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 250VAC</li> <li>■ Current: 1 to 20A</li> <li>■ Low leakage current (B types)</li> <li>■ Surge pulse protection</li> <li>■ High test voltage</li> <li>■ Approvals: ENEC, UL, CSA, CQC</li> </ul>
<b>Power entry modules with fuses, switch and/or voltage selector</b> 	<ul style="list-style-type: none"> <li>■ Multiple options: fuse holder, voltage selector, mains switch</li> <li>■ Multiple functions in one compact device</li> <li>■ Suppression of high interference levels</li> <li>■ Fulfillment of required EMC standards</li> <li>■ International power cord configuration</li> </ul>	<b>FN 9260(B), FN 280(B), FN 370(B), FN 380(B), and FN 390 standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 250VAC</li> <li>■ Current: 1 to 10A</li> <li>■ Low leakage current (B types)</li> <li>■ Single or dual-fuse EU/USA</li> <li>■ High test voltage</li> <li>■ Approvals: ENEC, UL, CSA, CQC</li> </ul>
<b>Single-phase EMC/EMI filters</b> 	<b>Small and compact EMC/EMI chassis filters for higher power medical and IVD devices.</b> <ul style="list-style-type: none"> <li>■ High attenuation performance</li> <li>■ Single or dual-stage filter</li> <li>■ Selectable attenuation performance levels</li> </ul>	<b>FN 2010(B), FN 2030(B), FN 2070(B), and FN 2090(B) standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 250VAC</li> <li>■ Current: 1 to 60A</li> <li>■ Low leakage current (B types)</li> <li>■ Approvals: ENEC, UL, CSA, CQC</li> </ul>
<b>Three-phase EMC/EMI filters</b> 	<b>Compact and light weight three-phase EMC/EMI filters for IVD devices.</b> <ul style="list-style-type: none"> <li>■ Light weight plastic enclosure for extra safety</li> <li>■ Protective safety covers</li> <li>■ Time-saving chassis or DIN-rail mounting</li> </ul>	<b>FN 3025, FN 3026, and FN 3258 standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 3x 520/500V</li> <li>■ Current: 10 to 180A</li> <li>■ Minimized leakage current</li> <li>■ Approvals: ENEC, UL, CSA</li> </ul>







Solutions beyond medical devices

# Building and energy management for hospitals

Harmonics are a serious problem in modern hospital buildings. Harmonics reduce system efficiency and waste precious energy. The energy-rich noise generated through harmonics influences other equipment and can result in malfunctions. Many systems have to work safely together in a hospital without disturbing each other due to harmonics or EMI noise caused by elevators, air conditioning, office equipment, industry cooking equipment, UPS systems, diagnostic equipment, surgery equipment, intensive care equipment, illumination and others.

**International requirements.** International Power Quality standards such as IEEE 519-1992, EN 61000-3-12, EN 50160, EN 12015, G5/4 or AS 2279 define – among many other things – distortion limits and recommend harmonics mitigation practices. IEEE 519-1992 is probably the most widely accepted set of recommendations that defines maximum permissible current and voltage distortion percentages at the point of common coupling (PCC) under full load conditions. The applicable limit depends upon the system loading parameters, i.e. the relation between the maximum short circuit current ( $I_{sc}$ ) and the maximum demand load current ( $I_L$ ) at the PCC.

**IEEE 519-1992 current distortion limits [%]**

$I_{sc}/I_L$	TDD	Harmonic order (odd harmonics)				
		<11	11≤h<17	17≤h<23	23≤h<35	35≤h
<20	5.0	4.0	2.0	1.5	0.6	0.3
20<50	8.0	7.0	3.5	2.5	1.0	0.5
50<100	12.0	10.0	4.5	4.0	1.5	0.7
100<1000	15.0	12.0	5.5	5.0	2.0	1.0
>1000	20.0	15.0	7.0	6.0	2.5	1.4

Maximum harmonic current distortion in percent of  $I_L$  (even harmonics are limited to 25% of the odd harmonic limits above).





**IEEE 519-1992 voltage distortion limits [%]**

Special applications (hospitals, airports)	3
General systems applications	5
Dedicated systems (100% non-linear loads)	10

In hospitals, the consideration of harmonics at the PCC is often not sufficient. The mitigation of harmonic currents may be necessary right at the individual non-linear consumer to ensure the voltage quality throughout the building.



## Schaffner solutions for building and energy management for hospitals

	Application and features	Products
<b>Three-phase EMC/EMI filters</b>  	<b>Three-phase EMC/EMI filters should be used in central air conditioners and elevators to protect nearby systems against electromagnetic malfunction.</b> <ul style="list-style-type: none"> <li>■ Reduction of EMI noise</li> <li>■ Fulfillment of required EMC standard</li> <li>■ Improvement of reliability</li> </ul>	<b>FN 3270 and FN 3258 standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 3x 520 VAC</li> <li>■ FN 3270: 10 to 1000A</li> <li>■ FN 3258: 7 to 180A</li> <li>■ Ambient temp: 50°C</li> <li>■ Approvals: ENEC, UL, CSA</li> </ul>
<b>Three-phase and neutral line EMC/EMI filters</b>  	<b>For three-phase installations with neutral line.</b> <ul style="list-style-type: none"> <li>■ Reduction of EMI noise additional on neutral line</li> <li>■ Very low leakage current</li> <li>■ Suitable for installations with a residual-current-operated protective device</li> </ul>	<b>FN 3256 and FN 3280 standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 3x 520VAC</li> <li>■ Current: 8 to 600A</li> <li>■ Ambient temp: 50°C</li> <li>■ Approvals: ENEC, UL, CSA</li> </ul>
<b>Passive harmonic filters</b>  	<b>ECOSine™ harmonic filters mitigate current harmonics of AC motor drives.</b> <ul style="list-style-type: none"> <li>■ Efficient use of power</li> <li>■ Reduce installation cost</li> <li>■ Compliance with IEEE 519, EN 61000-3-12</li> <li>■ Better voltage quality in the building</li> </ul>	<b>ECOSine™ FN 3410 and FN 3412 standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: Up to 3x 500VAC</li> <li>■ 50Hz filters: Up to 200kW</li> <li>■ 60Hz filters: Up to 250HP</li> <li>■ Higher power range in preparation</li> <li>■ THID: &lt;5%</li> <li>■ Approvals: CE, UL</li> </ul>
<b>Active harmonic filters</b>  	<b>ECOSine™ Active harmonic filters make power quality easy.</b> <ul style="list-style-type: none"> <li>■ Harmonics mitigation</li> <li>■ Power factor correction</li> <li>■ Load balancing</li> <li>■ Response time &lt;300µs</li> </ul>	<b>ECOSine™ Active FN 3420 and FN 3430 standard filters.</b> <ul style="list-style-type: none"> <li>■ 3x 480V three-wire filters</li> <li>■ 3x 400V four-wire filters</li> <li>■ 50/60Hz</li> <li>■ 50 to 300A corrective current</li> <li>■ Approvals: CE, UL</li> </ul>
<b>LC sine wave filters</b>  	<b>Sine wave filters to protect the motor against voltage overshoot caused by long motor cable length.</b> <ul style="list-style-type: none"> <li>■ Smoothing of motor drive output voltage</li> <li>■ Efficient motor protection</li> <li>■ Reduce acoustic noise</li> <li>■ Protect from bearing damage</li> <li>■ Suitable for multi-motor (fan) application</li> </ul>	<b>FN 5010 standard filters.</b> <ul style="list-style-type: none"> <li>■ Voltage: 3x 400VAC</li> <li>■ 0.75 to 355kW</li> <li>■ Ripple voltage &lt;5%</li> <li>■ Up to 400m motor cable length</li> <li>■ 1.5 times overload</li> </ul>



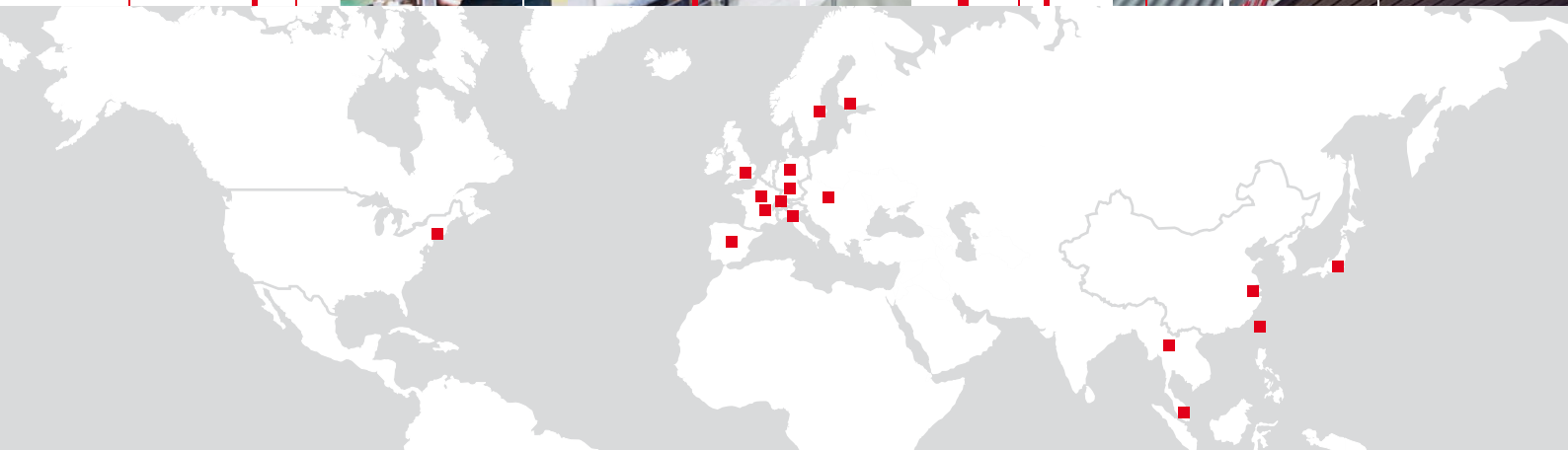
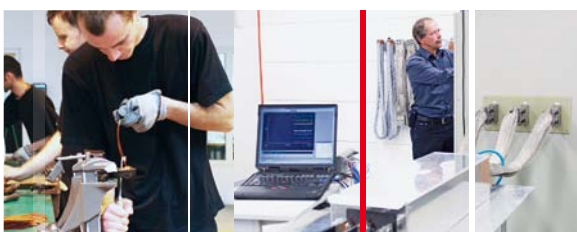


## Worldwide presence, global experience, unique proximity to customers

In addition to offering the most comprehensive range of EMC/EMI filters, Power Quality products, and magnetic components, Schaffner supports design and application engineers with engineering advice, testing, trouble-shooting, and custom product design.

With 16 customer service and application centers around the world, Schaffner is always close to the customer. Our own manufacturing plants in Switzerland, Germany, Hungary, Thailand and China allow us to build both highly specialized parts as well as high volume commodities. Being the largest EMC/EMI filter manufacturer in the world, our global procurement network ensures the lowest raw material costs in times of soaring copper and steel prices, savings that we pass on to our customers.

Please feel free to contact your local Schaffner partner any time to discuss how we can support you in dealing with your individual challenges in the demanding medical device marketplace.





energy efficiency and reliability

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