EMI SHIELDING DESIGN CONSIDERATIONS IN MEDICAL APPLICATIONS

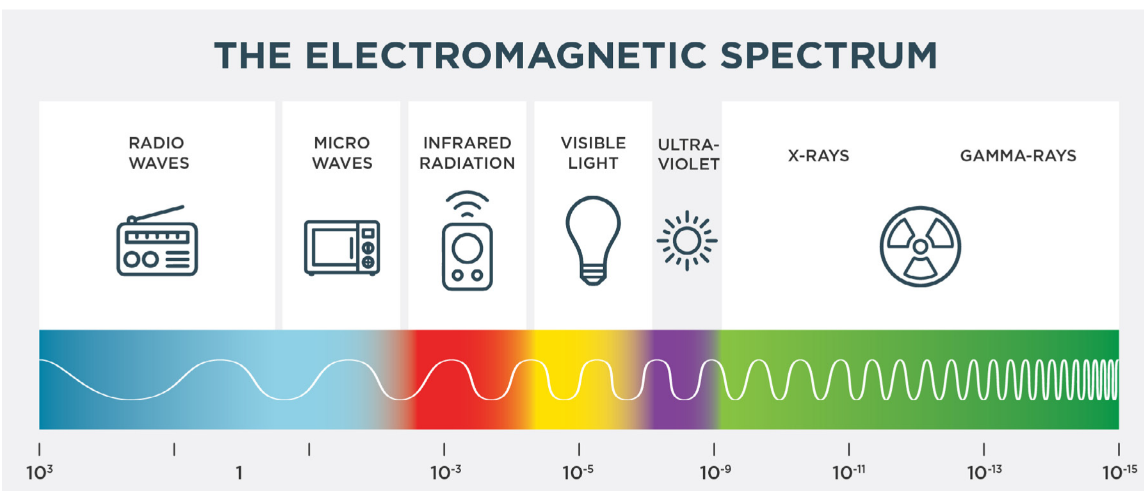
INTRODUCTION

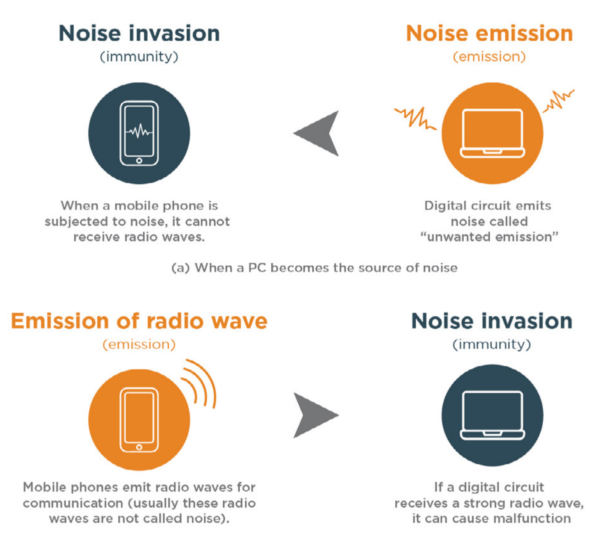
Electromagnetic interference (EMI), also known as radio frequency interference (RFI), is when an outside source causes noise or interference in an electrical path or circuit. Shielding is necessary to help prevent EMI from causing electronic devices to malfunction. Such malfunctions can range from the innocuous — an odd noise on a car radio — to the serious — an accident related to failing safety equipment.

The significant advancement in electronic devices, particularly in communication and wireless technology, has led to a substantial increase in electromagnetic interference (EMI). These unwanted signals not only compromise the efficiency of equipment but also can disrupt the operation of communication systems. One example is microprocessors, which use high-frequency signals in their operation and can cause nearby equipment to malfunction if these high-frequency signals are allowed to escape and impact other components inside or in close proximity to the device.

This paper aims to give engineers a look at what technological advances will challenge current approaches to EMI shielding and provides a detailed overview of the materials currently on the market.

The Electromagnetic Spectrum





Signal Integrity And Electromagnetic Compatibility

Signal integrity and electromagnetic compatibility (EMC) can be considered two separate yet related components of engineering design, each warranting a unique set of requirements. Signal integrity is a measurement of quality between a transmitter and a receiver. To maintain signal integrity, one must ensure that timing margins are met and that signals remain within voltage thresholds so that sending and receiving devices are not damaged. Unlike with EMC, there are no standards governing signal integrity. The main requirement for proper signal integrity is that the final product functions correctly in its intended application.

Use of simulation tools is important in developing products with good signal integrity. Inexpensive and easy to execute, signal integrity simulation can reduce the risk of failure, can enable what-if analysis in early design stages, and can provide information that justifies later stage design changes. In essence, simulation can help verify the effectiveness of design changes and can reduce time to market.

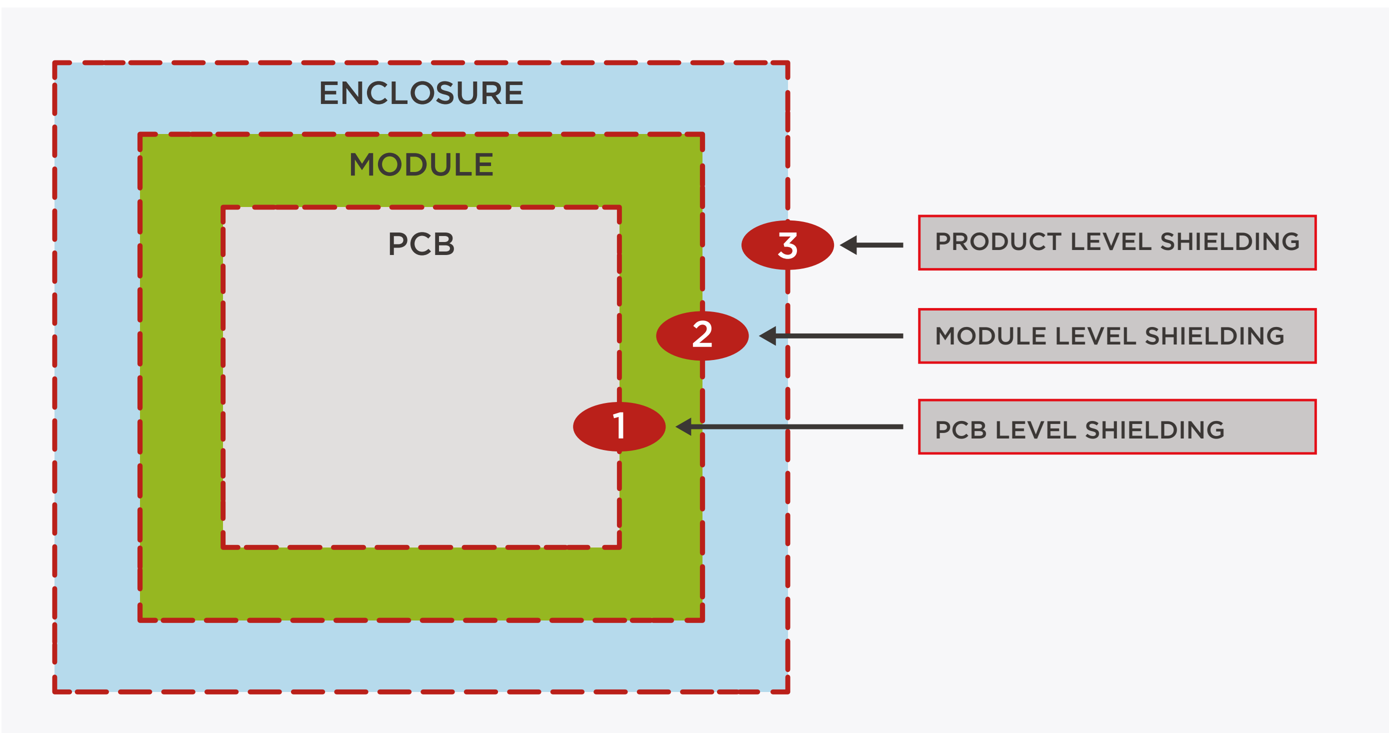
EMC, by definition, means that equipment can function satisfactorily within its electromagnetic environment without creating intolerable electromagnetic disturbances for other equipment in the environment. To resolve EMI at its source, electronics engineers will consider good board layout, filtering, grounding, and signal integrity in their design. EMC mandates that products are designed using criteria established within government standards or market-driven emissions and immunity standards. To meet EMC, circuit board layouts must be printed properly to limit the flow of unwanted common mode current to wires connected to the product. Sophisticated testing is utilized to ensure that these currents meet established limits.

Compared to simulation for signal integrity, simulation for EMC can be expensive and difficult to perform. Rather than using simulation to test for adequate EMC, engineers are better served by designing with EMC in mind and laying out circuit boards to achieve EMC. Other techniques to reduce EMI include use of proper grounding and EMI filtering or shielding. Testing products under the electromagnetic environments cited in relevant EMC standards is also important.

Levels of EMI Shielding

From a design engineering perspective, EMI shielding should be considered at all levels — from the enclosure to the module to the PCB. For radiated emissions and immunity, a Faraday cage, or a protective structure that prevents electromagnetic radiation from entering or exiting an area, can be an important component in EMI shielding at these different levels.

- **Enclosure level**: EMI shielding of enclosures effectively involves a Faraday cage to attenuate signals from within the enclosure. This minimizes signals escaping and causing interference to other equipment within the environment and can prevent outside interference from penetratingthe enclosure.
- **Module level**: Module-level shielding is the shielding of active components, such as drives, displays,etc., within the electronics enclosure to protect those components from internal interference.
- **PCB level**: Shielding at the PCB level consists of shielding of individual components, such as integrated circuits, with shielding cans, for example, making a small Faraday cage for those components.



EMI/EMC Standards for Medical Devices

The primary standard governing electromagnetic interference (EMI) and electromagnetic compatibility (EMC) in the realm of electronic medical equipment and systems is IEC 60601-1-2. This standard comprises a set of general regulations formulated to delineate the fundamental performance and safety criteria for medical electronic equipment when subjected to EMI. To meet the submission prerequisites of the U.S. Food & Drug Administration (FDA), it is imperative to subject your equipment to testing in accordance with the stipulations outlined in IEC 60601-1-2, conducted by an accredited laboratory.

In addition, it is advisable for manufacturers of medical equipment to incorporate EMI emission and immunity requirements designed for automotive and ambulance applications into their product designs. Depending on the intended usage, manufacturers should also take into account EMI standards applicable to general aviation, medical helicopters, and railway environments. These specific requirements can be found in the following standards:

- CISPR 25
- ISO 7637-2
- ISO 7137
- RTCA DO-160
- EUROCAE ED-14

Another relevant standard that medical equipment manufacturers should consider during their design process is ANSI C63.27, which addresses the coexistence of wireless systems equipment. This standard governs the proper functioning of medical devices equipped with RF transmitters when operating in proximity to other wireless devices like cell phones, Wi-Fi equipment, and biotelemetry systems.

The objective when adhering to these standards is to prepare your medical equipment's printed circuit boards to successfully meet the requirements of IEC 60601-1-2 testing, a crucial step for FDA submission. To achieve this, it's essential to ensure the integration of effective electromagnetic compatibility (EMC) practices into your design process.

EMC Testing

EMC must be addressed before any electronics product comes to market, regardless of industry or application. EMC testing measures a product's RF emission levels and its immunity to RF emissions. Results from the testing environment will give engineers an indication of whether the product will produce EMI in the real world. There are three main steps to EMC testing:

- **Identify the appropriate standards**: As previously stated, applicable standards vary across products, applications, and geography. It is desirable to either contact an established test house and ask which standards apply or fully research the standards yourself before beginning any testing activities.
- **Perform pre-compliance testing**: To ensure that your product is fully immune to EMI and meets standards for energy emissions before formal testing, you will ideally want to test within an anechoic chamber or an RFI shield enclosure. Fully EMC-compliant testing equipment, such as EMI receivers, can be rented for these purposes. Detailed instructions for setting up pre-compliance testing in-house, an overview of the necessary equipment, and a supplier guide are available at https://learn.interferencetechnology.com/2022-emc-testing-guide/.
- **Select an EMC test lab**: Make sure that the lab you select is accredited by the American Association for Laboratory Accreditation (A2LA) for ISO/IEC 17025. Crucial when placing your product in market, this accreditation can validate your testing. Expect a lag of at least several months when booking the lab and plan your pre-compliance testing accordingly.

Several basic tests are performed to assess a product's EMC. These include radiated immunity and missions and conducted immunity and emissions. Testing for radiated immunity gauges the product's performance when it is exposed to electromagnetic energy within its environment. Testing for radiated emissions evaluates the amount of electromagnetic disturbance caused by the product. Conducted immunity testing measures the test product's response to electromagnetic energy that originates with another product and is conducted via a cable or conductor to the test product. Conducted emissions testing analyzes the electromagnetic energy that travels from the test product along a conductor to another product. A variety of specialized equipment is available for the in-house performance of each of these tests. Conducting these tests in-house before sending a product to a lab for EMC certification can allow for the fine-tuning that may prevent a product from failing on the first attempt at certification.

Shielding Materials to Address EMC In Medical Devices

Regrettably, a significant number of these devices feature non-conductive plastic components that do not provide protection against electromagnetic interference/radio frequency interference (EMI/RFI) emissions or susceptibility to interference from other devices. This necessitates the inclusion of shielding systems in their design and production to guarantee dependable performance. According to medical device engineers, these devices have historically posed challenges in terms of EMI/RFI shielding due to their design and functionality.

To mitigate electromagnetic emissions, a variety of shielding materials are employed. It has been determined that materials with high conductivity and dielectric permittivity are effective at shielding against electromagnetic interference, with metals being the conventional choice for EMI shielding materials. Aluminum is a common choice for EMI shielding, although it has the drawback of having relatively low impact resistance.

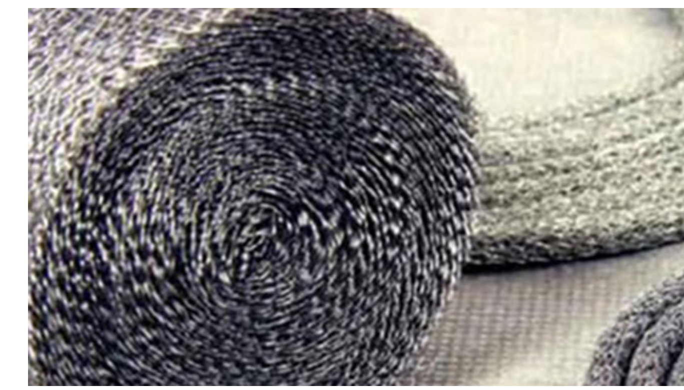
Shielding Options

EMI shielding gaskets and components are available in a variety of materials to meet a broad range of needs across applications and industries. Different types of materials address different challenges to achieving an effective EMI shield. The main types of EMI shielding materials include the following:

- Knitted wire mesh
- Electrically conductive elastomers
- Form in place
- Oriented wire
- Conductive fabric over foam
- Metal fingers, typically beryllium copper or stainless steel
- Shielded windows

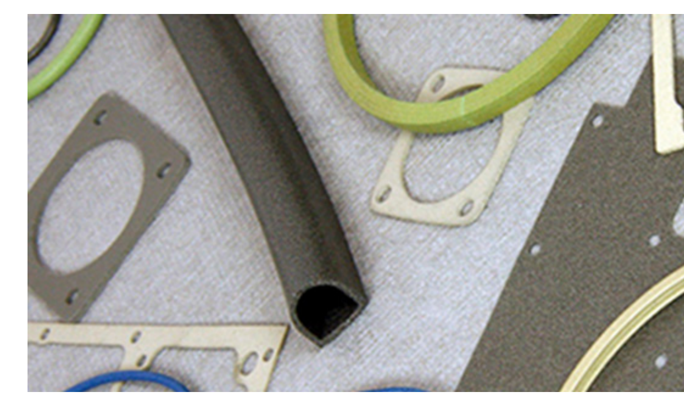
Knitted wire mesh

Knitted wire mesh represents a cost-effective solution for EMI shielding. This type of shielding consists of multiple layers of wire, commonly an alloy of nickel and copper (such as Monel alloy), tin-plated copper clad steel, stainless steel, or aluminum, knitted over a core. Core materials range from silicone sponges and solid silicone to closed cell neoprene sponges. The availability of different wire mesh materials allows for galvanic compatibility with mating flanges, reducing the likelihood of corrosion. Knitted wire mesh can be fabricated in complex shapes and can be fitted to grooves as an O-ring. When bonded to a carrier, knitted wire mesh also can be mounted to a surface and will provide a dust and moisture seal.
This type of shielding is well-suited for cabinet doors, lids, and removable cover plates. The shielding effectiveness of knitted wire mesh begins to decrease beyond 1 GHz, necessitating the addition of more wire mesh layers.

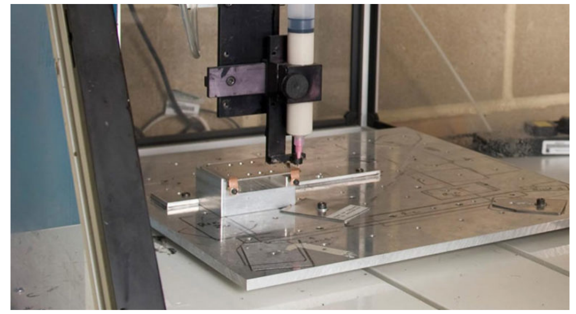


Electrically conductive elastomers

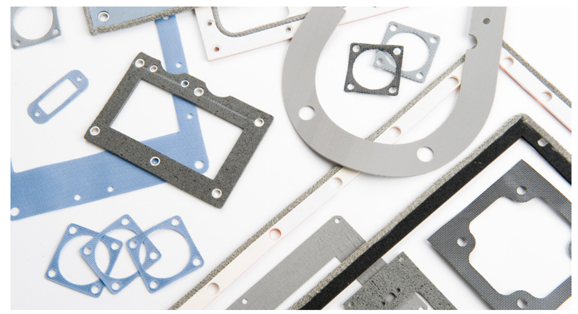
Another cost-effective choice in EMI shielding, electrically conductive elastomers come in a range of materials for various applications. These materials include silver-plated aluminum, or silver-plated copper, in silicone or fluorosilicone and nickel-coated graphite or nickel-plated aluminium in silicone or fluorosilicone. Each of these materials offers high performance at all frequencies. Representing the most popular materials, nickel-coated graphite and silver-plated aluminum feature a low specific gravity, which make them more cost effective than copper or nickel-based fillers. However, nickel-coated graphite is three to five times less expensive than silver-plated aluminum. Like knitted wire mesh, electrically conductive elastomers also provide galvanic compatibility through the diversity of conductive fillers. Conductive elastomers are available in sheets, flat gaskets, or O-rings. The fluorosilicones are fuel and oil resistant, making them an ideal choice for harsh environments. The nickel-coated graphite in silicone product is also available in a flame-retardant version approved to UL 94 V-0 rating, file number E344902.



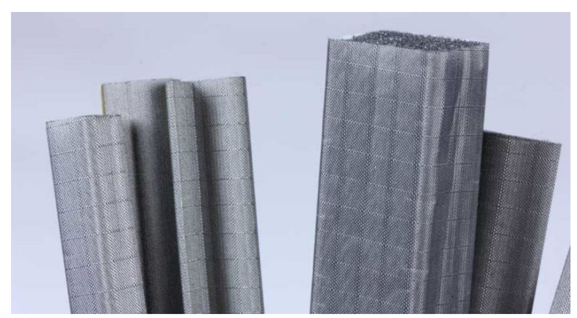
Form in Place
Form in place conductive elastomers consist of a conductive silicone in liquid form that can be dispensed directly into enclosure hardware. Materials include nickel-coated graphite in silicone and silver-plated aluminum, copper, or nickel in silicone. Form in place conductive elastomers also are available in nonconductive silicone. Form in place conductive elastomers can be well suited for small enclosures with minimum gasket land area and provide a dust and moisture seal



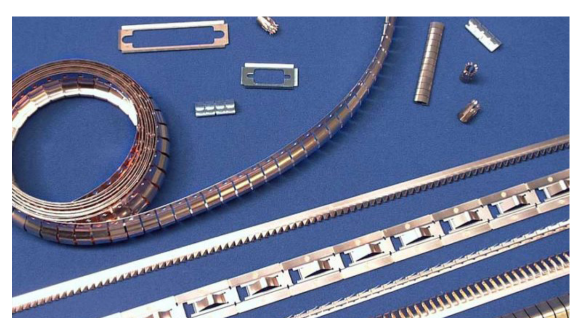
Oriented Wires
Oriented wire in silicone is a flat, silicone sheet material embedded with vertically oriented nickel-copper alloy or aluminum wires. Oriented wire in silicone is a great shielding option for electromagnetic pulse and provides an environmental seal. Variants include solid closed cell silicone, soft solid silicone, sponge silicone, and solid fluorosilicone and different wire counts.



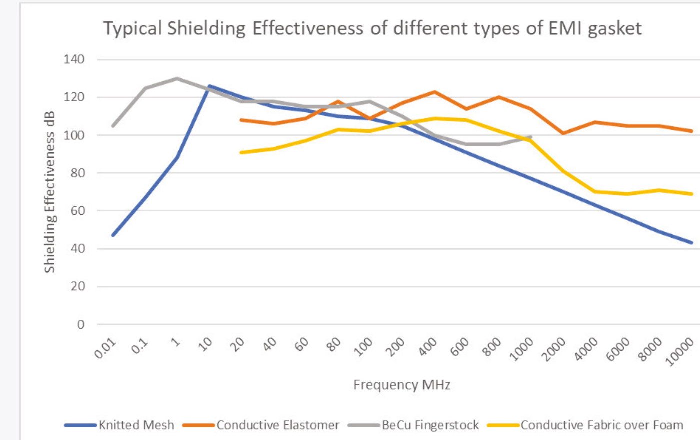
Conductive fabric over foam
This type of EMI shielding consists of conductive nickel/copper or silverplated polyester or nylon fabric over a soft polyether polyurethane foam core. Conductive fabric over foam is available in many different forms, making it useful for a wide range of applications, including commercial uses. Conductive fabric over foam offers effective shielding up to 10 GHz. While this type of shielding provides no water seal, it does offer a limited dust seal.



Finger stocks
With mechanical spring characteristics and high electrical conductivity, finger stock, most often made of beryllium copper, represents a useful EMI shielding choice for cabinets and doors or other areas that are frequently accessed. Various plating finishes are available to address galvanic compatibility. Finger stock is available in a wide range of solderable and unsolderable finishes with gold, silver, bright tin, bright nickel, zinc, and electroless nickel options.



SHIELDING EFFECTIVENESS



KNITTED WIRE MESH
H field (magnetic) shielding 62dB @ 10Khz achievable. SE falls off after 1GHz

CONDUCTIVE ELASTOMERS
Shielding with wide frequencyr ange, >100dB upto 10GHz E field.

FABRIC OVER FOAM
Shielding with wide frequency range, >100dB upto 10GHz E field.

BERYLLIUM COPPER FINGERS
Shielding with wide frequencyr ange, >100dB upto 10GHz E field.

EMI shielded optical windows
EMI shielded windows provide a high-performance EMI shield for an enclosure while maintaining optimum optical transparency. EMI shielded windows provide an EMI screen as part of a shielded enclosure that will provide protection against radiated emissions and susceptibility. Shielded windows provide good transparency for viewing display devices, such as LED and LCD, and they also can form the front panel of an enclosure to provide impact protection, contrast enhancement of displays, display color matching, anti-reflection, and anti-glare surfaces. Shielded windows can be used to provide EMI shielding on a wide range of applications, such as laptops and small display screens. In addition, large windows can provide transparent EMI shielding for architectural use, such as computer rooms, shielded rooms, MRI rooms, and secure communication cabins.

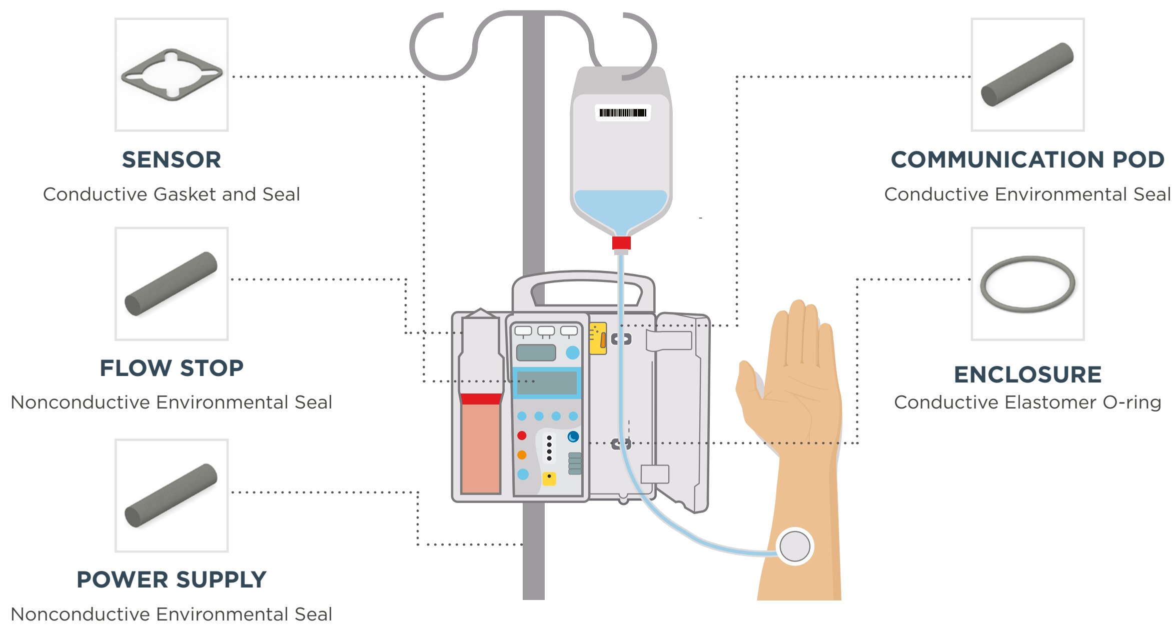
These optical windows come in two configurations:

- **Laminated window**: A very fine woven wire mesh trapped between two layers of optical substrate, which are laminated together using a polyurethane interlayer.
- **Cast window**: A very fine woven wire mesh embedded in a cast substrate.

Use Cases

Infusion Pump

Infusion pumps coordinate the delivery of nutrients and medications directly into the body, requiring precise control of fluids. Managing the ability of equipment to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to other equipment in that environment is crucial. Shielding of the enclosure is just as important and helps solve the problem of radiated emissions and susceptibility. There are many types of EMI shielding capable to protect critical components and increase performance, reliability and value to medical professionals.



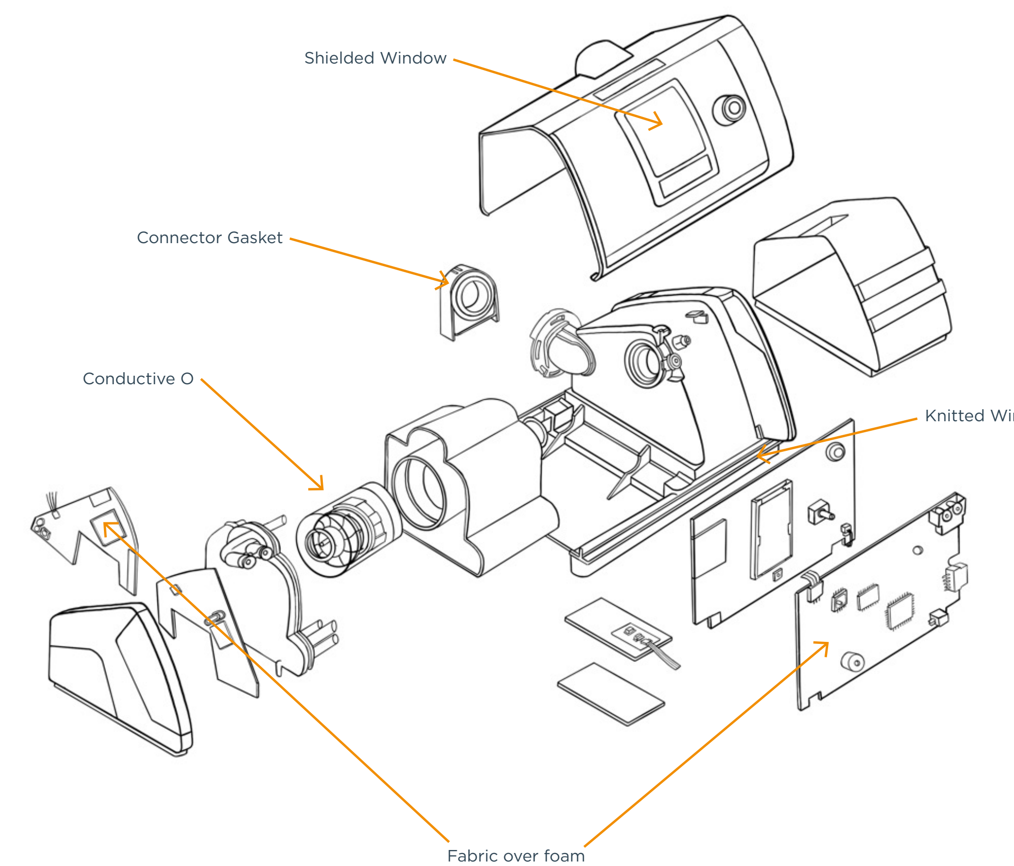
EMI Solution	Application	Key Product Features	Benefits
Conductive Elastomer O-Ring	• Enclosure • Communication Pod	• Conductive elastomers can provide great EMI shielding performance at a relatively low cost • Range of different materials and profiles available to suit the application including a UL94-V0 material"	• Material options to provide required EMI performance and galvanic compatibility • Provide low contact resistance between connector and enclosure
Conductive Gasket	• Sensor • Power Supply	-	• Ensures additional electrical bonding between the surfaces with a very low contact resistance
Non-conductive Environmental Seal O-Ring	• Housing Flow stop	• The groove also forms a compression stop for the O-Ring gasket	• Provides an environmental seal by achieving metal to metal contact Moisture or pressure sealing
Conductive Elastomer	• Communication Pod	• Fully cured silicones or fluorosilicone loaded with a variety of highly conductive particles providing superior EMI/RFI shielding performance combined with excellent environmental sealing	• Ensure complete electrical conductivity is maintained across the joint • Ensure galvanic compatibility whilst providing low contact resistance between mating surfaces

Ventilator

Interruption in medical device performance such as ventilator can be the difference between life and death. Without proper EMI shielding, medical devices, including life-support systems and essential monitoring equipment are vulnerable to signal noise, damage, or total functional impairment.

A ventilator that doesn't meet prescribed emission limits can lead to various unfavorable consequences for other medical devices:

- **Potential Equipment Shutdown**: Potential Equipment Shutdown: In the worst-case scenario, the non-compliant ventilator might unexpectedly shut down, a critical issue when it's supposed to operate continuously.
- **Intermittent Failures**: Such non-compliance can result in intermittent failures, disrupting normal device operation. Identifying and troubleshooting the source of electromagnetic interference (EMI) disturbances can be time-consuming and challenging. These intermittent failures could lead to the malfunction of essential features like alarms, lights, motors, displays, and LED indicators during crucial moments.
- **Metastable Logic**: Another consequence could be the occurrence of metastable logic, typically caused by a logic gate getting stuck between states 0 and 1. This can trigger a firmware error, necessitating a manual restart of the machine.

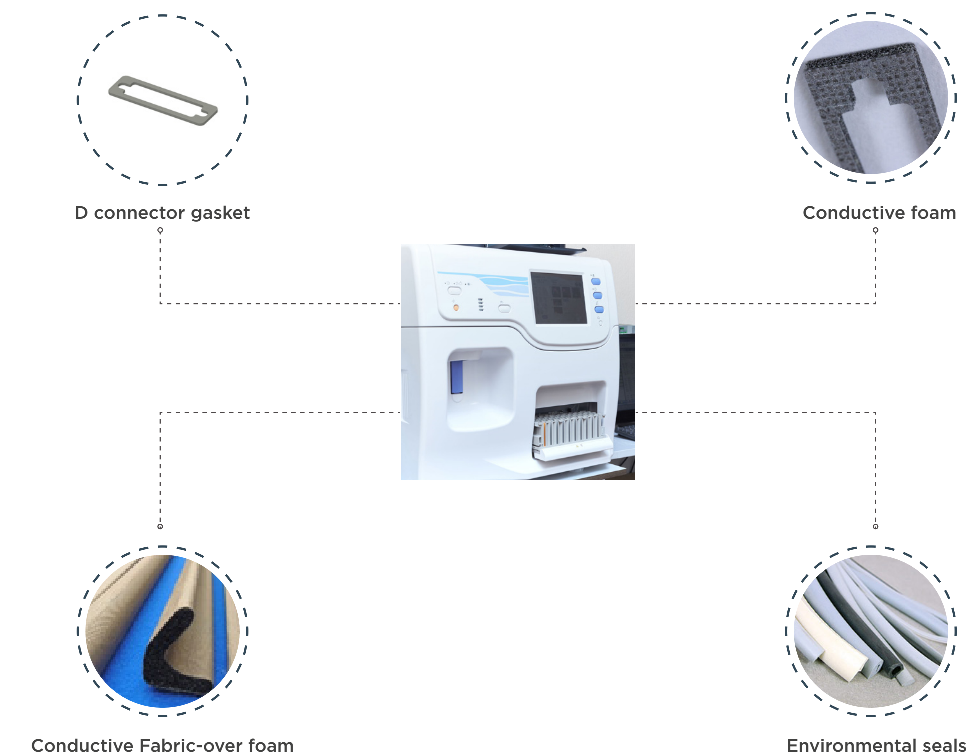


Application	Shielding Type	Features	Benefits
Air Filter Cover	Connector Gasket	• Offering a wide range of standard MIL connector gaskets • Different materials are available to meet the demands of EMI shielding, environmental sealing, galvanic compatibility and fuel / oil resistance	• The compression stop also ensures additional electrical bonding between the surfaces with a very low contact resistance • Surface mounted gaskets are to be used where groove mounted gaskets such as O-Rings cannot be accommodated
LCD Display	Shielded Window	• Termination of the EMI Shield windows to the enclosures is achieved with a continuous low resistance conductive edge around the window	• Providing optimum transparency and EMI shielding
PCB	Fabric over foam	• Soft and conformable	• Grounding
Enclosure	Knitted Wire Mesh	• The mono-filament interlocking loop construction gives strength while allowing it to confirm to almost any size or shape • A selection of elastomer cores are available to meet conditions such as temperature range, compression set, compression force.	• Delivers good galvanic match with mating flanges, thereby limiting the possibility of corrosion between gasket and flange • Excellent radio frequency interference (RFI)/electromagnetic interference (EMI) shield between two metallic surfaces
Fan	Conductive o ring	• Conductive elastomers can provide great EMI shielding performace at a relatively low cost • Range of different materials and profiles available to suit the application including a UL94-V0 material	• Material options to provide required EMI performance and galvanic compatibility • Provide low contact resistance between connector and enclosure

Mass Spectrometry

Mass spectrometry instrumentation enables you to separate compounds by mass, charge, shape, and size. These world-class instruments allow for structural elucidation of proteins and peptides – with confidence and reproducibility.

- Lab equipment and systems must meet the required EMC standards to ensure that the equipment will no introduce intolerable electromagnetic interference into its environment and to ensure that it will not be susceptible to electromagnetic interference in that environment
- Due to the high sensitivity of the equipment, EMI shielding is necessary to ensure the performance and accuracy of the equipment.

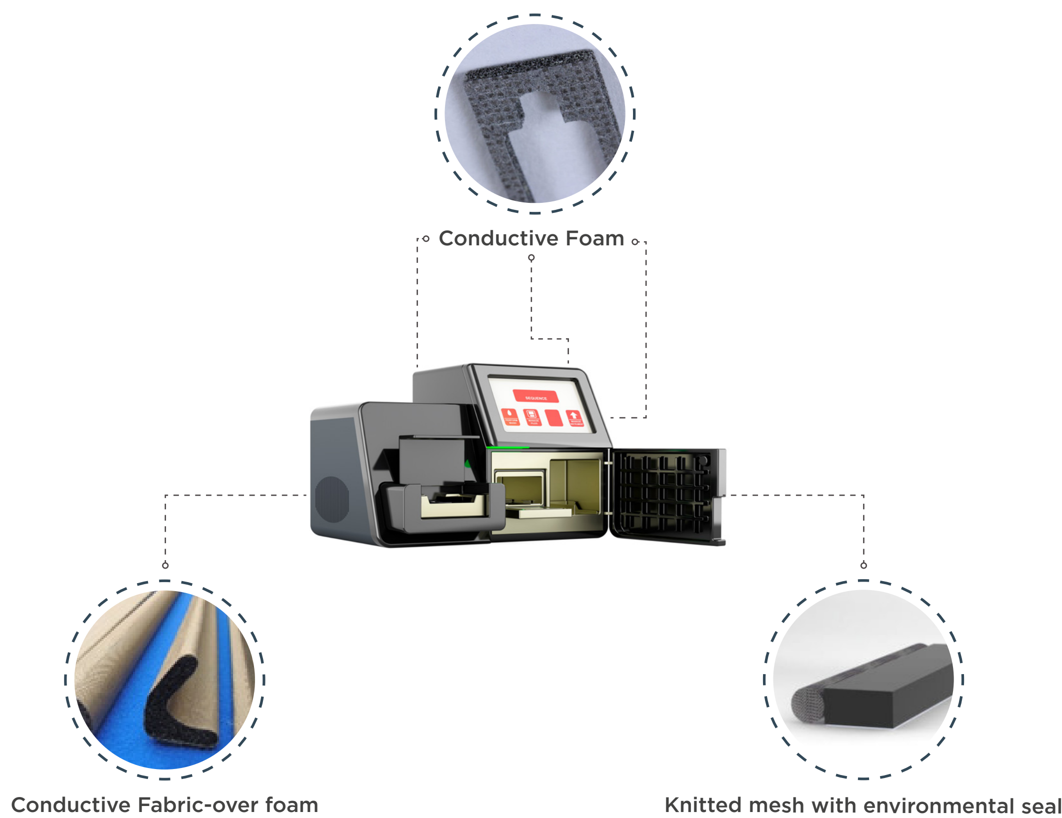


Application	Shielding Type	Features	Benefits
Connector	Oriented wire in silicone	• High EMI shielding performance • Reliable low surface contact resistance	• provides shielding on the connector interface • Supplied as cut gasket
Enclosure and access panels	Conductive fabric over foam	• Soft and conformable • Adhesive backing to aid assembly • Supplied in standard lengths and cut to length during assembly	• Low closure force • Takes up wide tolerances • Supplied as standard strip, easily cut to various lengths during assembly
Internal shielding	Conductive foam	• Soft and conformable • Provided as a cut flat gasket • Conductive adhesive backing to aid assembly	• Low closure force • Provided as cut part to fit directly into assembly • Provides internal shielding within unit
Environmental sealing	Silicone sponge	• Soft and conformable • Bespoke flat gaskets to provide sealing in key areas • Adhesive backing to aid assembly	• Low closure force • Supplied as pre-cut bespoke seals to fit directly into the assembly

Sequencing Analysis

DNA and RNA sequencing enables the analysis of RNA transcripts present in a sample from an organism of interest. The method provides a dynamic view of the cellular activity at the point of sampling, allowing characterisation of gene expression and identification of isoforms.

- Medical equipment and systems must meet the required EMC standards to ensure that the equipment will no introduce intolerable electromagnetic interference into its environment and to ensure that it will not be susceptible to electromagnetic interference in that environment
- Due to the high sensitivity of the equipment and the high data rates, EMI shielding is necessary to ensure the performance and accuracy of the equipment.



Application	Shielding Type	Features	Benefits
Module covers	Conductive foam	• Very soft and conformable • Provided in cut parts • Provided with conductive adhesive backing	• Low closure force • Adhesive backing aids assembly • Provides shielding on cover
Enclosure body seams	Knitted mesh with environmental seal	• Soft and conformable • Provides environmental and EMI seal • Adhesive backing on environmental part	• Low closure force • Combined EMI and environmental seal • Adhesive backing aids assembly
Enclosure	Conductive fabric-over-foam	• Soft and conformable • Adhesive backing • Wide range of profiles • Can be fabricated into a gasket	• Low closure force • Adhesive backing aids assembly

Key Takeaways

Advances in electronic devices and technology, including the increasing reach of the IoT, are leading to a greater need for EMI shielding. It is imperative that engineers consider EMI shielding early in the design process. From the enclosure to the module to the PCB, each level should incorporate EMI shielding. Benefits of accounting for shielding early in the process include eliminating inefficiency, avoiding costly redesign, and preventing delays in product launch. Various shielding materials are available for individual applications — each well suited for meeting different EMI challenges. TE Connectivity has a broad portfolio of EMI shielding materials and is the ideal partner can help you identify the most appropriate material for your specific project.

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