POLYMERIC EMI SHIELDING: PROVIDING A MORE SECURE FUTURE FOR PATIENTS

In this article, Marnik Vaes, Business Development Manager; Leen-Pieter Deurloo, Senior Business Development Manager; and Martin Sas, PhD, Lead Scientist, all of SABIC, discuss the role of polymeric electromagnetic interference shielding in providing a more secure future for patients in a connected world.

Driven by the need to reduce costs, healthcare systems around the world are currently undergoing a paradigm shift – from treating acute and chronic conditions in hospital and intensive care settings to a remote point-of-care approach. This transformation requires medical device manufacturers to integrate data recording functions into their products that enable remote patient monitoring and ultimately improve patient outcomes at lower treatment costs. This is the promise of connected devices.

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Of course, medical devices must also be demonstrably safe when used as designed, in combination with other therapies and in a range of environments – from home to hospital. Devices that require direct contact with patients – even simple skin contact – must also be biocompatible and function without interfering with, or impairing, basic immunological functions or causing injurious, negative physiological, allergic or toxic reactions.

Connected devices are challenged with an additional safety consideration – interference with the main content stream of the radio signals produced can potentially adversely affect device performance. This is caused by the phenomenon known as electromagnetic interference (EMI) or radio frequency interference (RFI). EMI is caused by the tendency of electronic devices to generate strong electromagnetic "noise" during operations. EMI has been a challenge in radio-based communications since the work of Guglielmo Marconi approximately 150 years ago. It remains a challenge for electronics, packaging and compliance engineers to this day.

The principal area of concern – and the focus of this article – is EMI caused by non-ionising radiation. ElectroMagnetic Compatibility (EMC) standards and testing ensure that electrical devices are able to operate safely in close proximity with a minimum level of RFI. The solution to managing EMI is shielding, which can isolate the devices from their surroundings and from the signals of other devices. In simple terms, shielding involves creating a form of Faraday cage around sensitive components within the device, usually using a metal encasement or similar solution.

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However, shielding can be a complex issue to solve, as the majority of connected medical devices interact directly with wireless infrastructure or via a consumer device – for example, a smartphone or other handheld device. They rely on a range of radio frequency (RF) bands with differing of signal power levels and operate in a range of communication modes. These include short-range wireless communication technologies such as near-field communications (NFC), Bluetooth, WiFi, ZigBee and the low-power version of these wireless communication protocols from industrial, scientific and medical (ISM) and short-range device (SRD) licence-free bands. All create a need for shielding against EMI. Figure 1 identifies the power performance for common wireless devices.

In general, RFI becomes significant at frequencies above 30 MHz, with typical levels of radiated emissions in units of electric field strength. Consumer electronics and healthcare-related EMC standards classify corresponding devices into a number of categories, according to their intended use environment. They also define immunity levels and limits to radiated RFI across a wide frequency range. Figure 2 summarises some of these limits in comparison with the radiated power levels of certain wireless technologies.

RF Device	Radiated power	Power level	Medical devices and adjacent	Electric Field strength	Electric Field strength level
BT Class2	2 mW	3 dBm	body-worn devices and implants	0.3 V/m	110 dBµV/m
BLE					
laptop WiFi module	10 mW	10 dBm		0.7 V/m	117 dBµV/m
BT Class1	100 mW	20 dBm	low power wireless devices – wearables and monitoring devices	2.2 V/m	110 dBµV/m
WiFi router					
cellular phone	250 mW	24 dBm	WiFi and cellular network based devices	3.5 V/m	130 dBµV/m
5G small cell	500 mW	27 dBm		5.0 V/m	134 dBµV/m
4G base station	20 W	43 dBm	4G base station devices (not applicable)	30 V/m	150 dBµV/m
5G MIMO base station	100 W	50 dBm	not applicable	70 V/m	157 dBµV/m

Figure 1: Typical RF power performance for common wireless devices expected to interfere with healthcare environments.

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Shielding effectiveness (SE) indicates the capacity of the material to act as a shield against internal or external EMIs, providing protection from damaging electrical devices. It is determined by the material's overall conductivity level, wall thickness and target frequency range.

Conventional approaches to providing EMI shielding have relied on metal enclosures, usually using aluminium alloys; this method currently accounts for more than half the market. However, increasing miniaturisation and the growing engineering complexity of connected devices, along with the demand to make them lighter and less intrusive, is posing challenges and highlighting design limits. Weight becomes a greater consideration, with even the lightest aluminium alloys likely to be unsuitable – not to mention costly. In addition, the increasing complexity and sensitivity of these devices, combined with reductions in design space, could render them more susceptible to interference. Clearly, other solutions are needed to meet these evolving demands.

Some manufacturers have explored alternative approaches for providing shielding, such as metal coatings, vacuum metallisation and conductive paints on plastic enclosures. While these methods can be effective, they are less so than metal

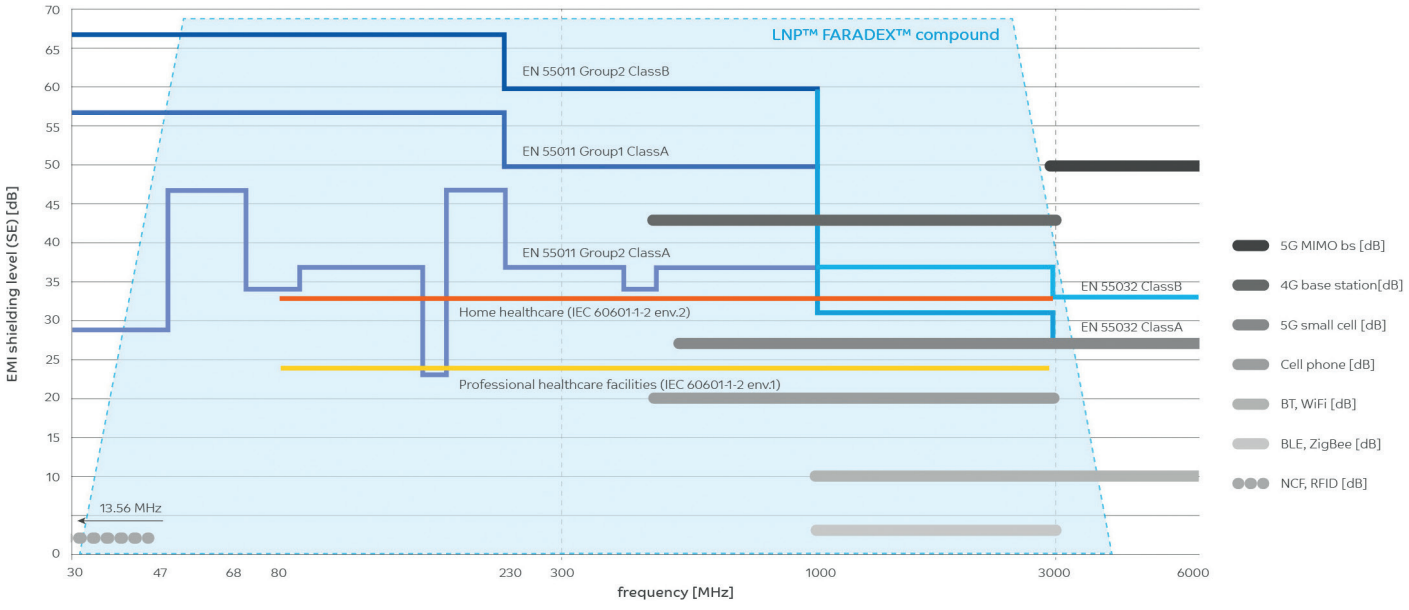
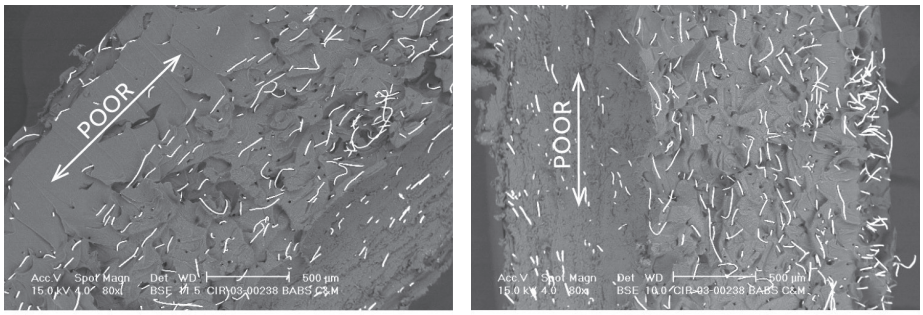


Figure 2: EMC-radiated emissions limits in terms of SE in dB based on EN 55011:2016, EN 55032:2015 and IEC EN 60601-1-2:2015 with examples of wireless technologies radiating RF power levels. Range of LNP FARADEX compound shielding effectiveness is highlighted.



Near gating area | Near end of flow path

Figure 3a: SEM analysis conducted by SABIC illustrates inferior dispersal of conductive fibres in moulded parts (PC resin).

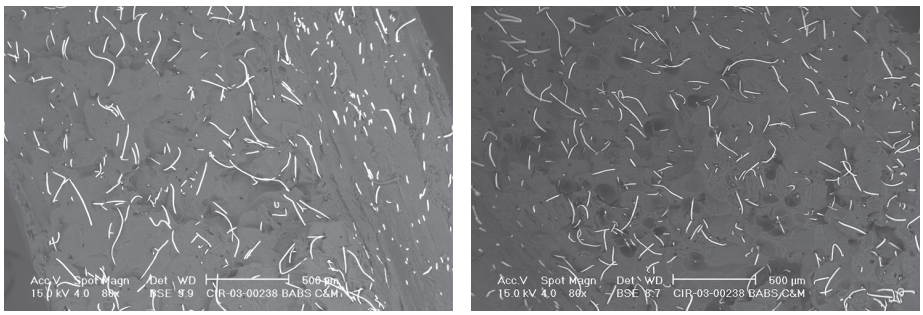


Figure 3b: SEM analysis conducted by SABIC illustrates good dispersion of conductive fibres in moulded parts (PC resin).

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enclosures and rely on secondary processes to the plastics following initial production. These steps add to the system cost and complexity – and increase the overall environmental footprint of the products. In addition, not all thermoplastics may be suitable for such secondary treatments.

The ideal solution, therefore, is to use a polymer that can provide EMI shielding as an integral property of the resin. This ensures a high degree of shielding and, by reducing the need to accommodate secondary treatments, allows greater flexibility in design. LNP FARADEX compounds, developed by SABIC's Specialties business, provide EMI shielding performance as an embedded, intrinsic property of the resin and the moulded part.

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The optimal dispersion of conductive fibres in the moulded part is critical to achieving maximum shielding performance. SABIC has conducted extensive moulding studies to optimise fibre dispersion by selecting appropriate injection moulding conditions. Figures 3a and 3b demonstrate how SABIC's processing expertise can provide insights into material performance. Figure 3a shows poor dispersal of the fibres; the left-hand side of both images show a resin-rich part. Figure 3b shows the optimised fibre versus resin concentration after taking advantage of SABIC's processing knowledge to maximise the Faraday cage effect.

As well as simplifying the process of providing shielding, LNP FARADEX compounds offer a number of additional benefits, as summarised in Figure 4. Without the need for secondary processes, the material offers manufacturers considerably wider design freedom. Medical devices can be manufactured using more complex 3D shapes, offering greater comfort and convenience for patients. The material performance properties may also help to improve device development efficiency,

Bulk Shielding method	Weight reduction	Relative cost	Shielding effectiveness	Recyclability	Waste generation	Design flexibility	Comments
Conductive Compounds LNP™ FARADEX™ Compounds	●	▲	▲	▲	●	●	Design sensitive, limited shielding ability around apertures and joints, part thickness dependent.
Plating methods Electroless & electroplating	●	■	▲	■	■	▲	Masking limitations, waste disposal, EHS issues, tooling and fixture costs.
Conductive spray coats Paints, zinc arc	●	▲	▲	■	▲	▲	Masking limitations, adhesion to plastics.
Metalization Vacuum, cathode sputtering	●	■	▲	■	▲	▲	Tooling, fixtures, masking limitations, EHS, waste disposal.
Metal enclosures Die cast, foils, stamped sheet metal	■	●	●	●	●	■	Weight, size & lack of design freedom for complex geometries.

● Most positive ▲ Moderate ■ Most negative

Figure 4: Comparison of key features for the different shielding methods.

by enabling the design freedom associated with the use of plastics versus other materials. Additionally, LNP FARADEX compounds provide the opportunity to reduce both the weight of the final device and its assembly costs.

In healthcare applications, patient safety remains a primary concern. Therefore, all plastics intended for use in medical devices that come into contact with the skin must be certified as biocompatible and undergo a range of tests – most notably the Biological Reactivity Testing (USP Class VI) and ISO 10993 "Biological Evaluation of Medical Devices" – to ensure that they fulfill the correct parameters.

To address demand for a biocompatible material that also provides EMI shielding, SABIC has developed a new healthcare grade LNP FARADEX NS003XXW compound, which has been pre-assessed for biocompatibility according to ISO 10933. For those manufacturers considering switching from a metal, or metallised approach, to a polymer, the LNP FARADEX NS003XXW compound also offers the benefit of SABIC's management of change policy, which provides medical device manufacturers with surety of supply and formula lock.

The demand for connected medical devices will continue to grow rapidly for the foreseeable future, driven by the pressing need to constrain spiralling healthcare costs. It will also be driven by advances in technology, both in the health parameters measured and the technology that can perform the monitoring.

In such a dynamic environment, a biocompatible plastic with inherent EMI shielding properties, such as SABIC's LNP FARADEX NS003XXW compound, can provide device manufacturers with a cost-effective material solution, enabling improved accessibility for a greater number of patients and – because the devices can be lighter and more convenient to use – can increase their acceptance. In addition to product development, SABIC also brings its in-depth materials and processing expertise to assist manufacturers throughout all stages of the product lifecycle, including design, prototyping, moulding techniques and post-production quality control.

For those device manufacturers seeking to position themselves at the forefront of the expanding connected medical device market, SABIC is interested in collaborating to address the requirements for both EMI shielding and biocompatibility in a single material – the LNP FARADEX NS003XXW compound.

ABOUT THE COMPANY

SABIC is a global leader in diversified chemicals headquartered in Riyadh, Saudi Arabia. It manufactures on a global scale in the Americas, Europe, Middle East and Asia Pacific, making chemicals, commodity and high-performance plastics, agri-nutrients and metals. SABIC supports its customers by identifying and developing opportunities in key markets such as construction, medical devices, packaging, agri-nutrients, electrical and electronics, transportation and clean energy. SABIC has more than 33,000 employees worldwide and operates in around 50 countries. It has 12,540 global patent filings, and significant research resources with innovation hubs in five key geographies – the US, Europe, Middle East, South Asia and North Asia.

ABOUT THE AUTHORS

Marnik Vaes is an experienced business development manager for SABIC's Specialties business in Europe, collaborating along the value chain to drive innovations in medical device platforms for multinational healthcare original equipment manufacturers. He has more than 20 years of experience in a range of application development and commercial roles, delivering petrochemical solutions to customers in the healthcare industry. Mr Vaes holds a Master of Industrial Science from the University of Leuven (Belgium).

Leen-Pieter Deurloo is the senior business development manager for SABIC's Specialties business in Europe. He is responsible for delivering high-performance compounds and copolymer solutions for customers in a range of sectors, including healthcare, telecoms and mass transportation. He has more than 35 years of experience in a variety of technical and commercial roles within the plastics industry and is currently specifying electrical conductive materials for applications in the petrochemical industry. Mr Deurloo holds a BSc in Chemistry from the HMLS Breda (The Netherlands).

Dr Martin Sas is a lead scientist for SABIC's Specialties business, managing projects and activities for electrical applications of high-performance polymers. He has more than 15 years of experience in a range of technical roles, including research and development lead engineer for sensor development in the automotive industry – and, in the semiconductor industry, for application design of embedded systems and micro-electromechanical systems (MEMS) sensors for automotive, healthcare and consumer electronics products. Dr Sas holds an MSc in Mechanical Engineering and a PhD in Applied Physics from Slovak Technical University (Slovakia).

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INNOVATION FOR PATIENT SAFETY

SABIC's healthcare business is driven by our passion to support our customers and improve patient experiences and outcomes.

Leveraging our global capabilities and creating new collaborations, we develop advanced materials and technologies that help drive innovation for the next generation of medical devices.