



Protecting medical devices and reducing patient risk from electromagnetic interference

As the number of wireless devices in healthcare facilities rise, it's important to consider the issue of electromagnetic interference.

The rise of the device

Innovative technologies continue to appear in the healthcare sector that enable more advanced care. Having undergone vigorous testing prior to release, the latest medical equipment is not only saving countless lives but also improving patient care. These benefits have of course led to a growth in the number of medical devices now used within hospitals.

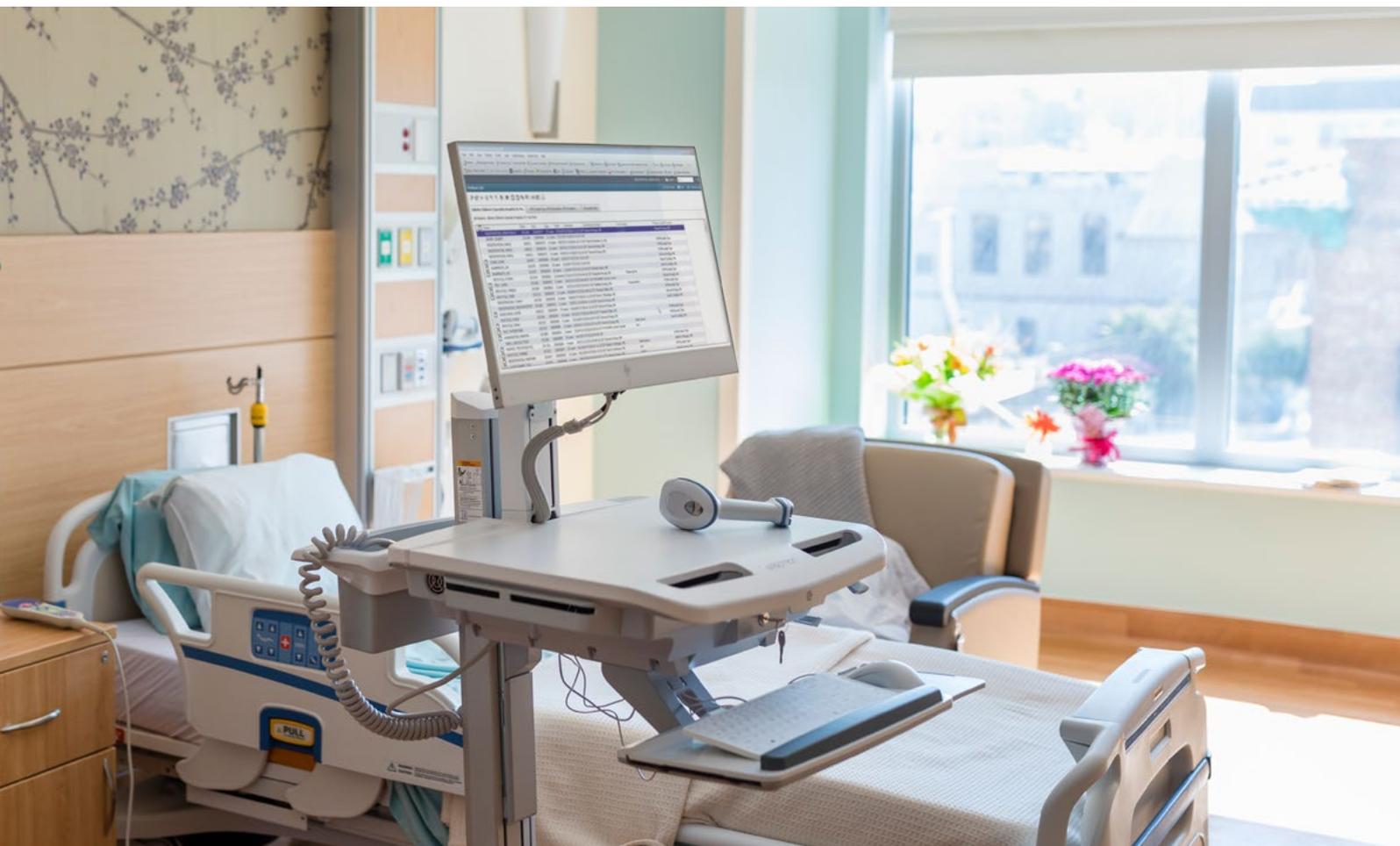
The increasing amount of wireless technology in healthcare is exposing environments to increasing levels of electromagnetic radiation. Driving this market is the concept of the 'connected hospital', where devices are used to provide better care to patients by sharing real-time information. As well as improving care, this kind of technology provides actionable insights that help clinicians save time and money, which unsurprisingly is supporting the uptake of medical devices.

Data Bridge reported that the global medical device connectivity market was worth \$5.7 billion in 2016 and is expected to reach \$46.4 billion by 2024, growing at a CAGR of 30.1%¹.

Medical equipment is being used for diagnostics, surgery and ongoing treatment. In addition hardware throughout the hospital is being used for administration, security and the monitoring of patients and staff.

And this is without even considering the technology that patients and visitors may bring with them. Perhaps they wear a fitness tracker, or have brought along an e-reader, tablet or laptop to keep them entertained during their stay. Then, of course, there's the ubiquitous mobile phone. In the US smartphone penetration has hit 77%, while in the UK its 82.2%², so most people inside a healthcare facility are likely to have one with them.

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The risks related to EMI

One study highlighted that you'll frequently see smartphones, tablets, computers, monitors and peripherals all operating within six feet of a patient's bedside or exam table.³ This growth in the use of devices in wards and patient rooms has brought up an important technology industry discussion – that of electromagnetic interference (EMI) and its risk to patient health.

"Given that more and more products are being designed for wireless use, the radio spectrum is becoming very congested, increasing the probability of interference," says Steve Hayes, Technical Director at Element Materials Technology. "Bluetooth, Wi-Fi, ZigBee and ANT+ are all technologies that use the 2.4GHz ISM band and must coexist with one another to ensure they work as intended."⁴

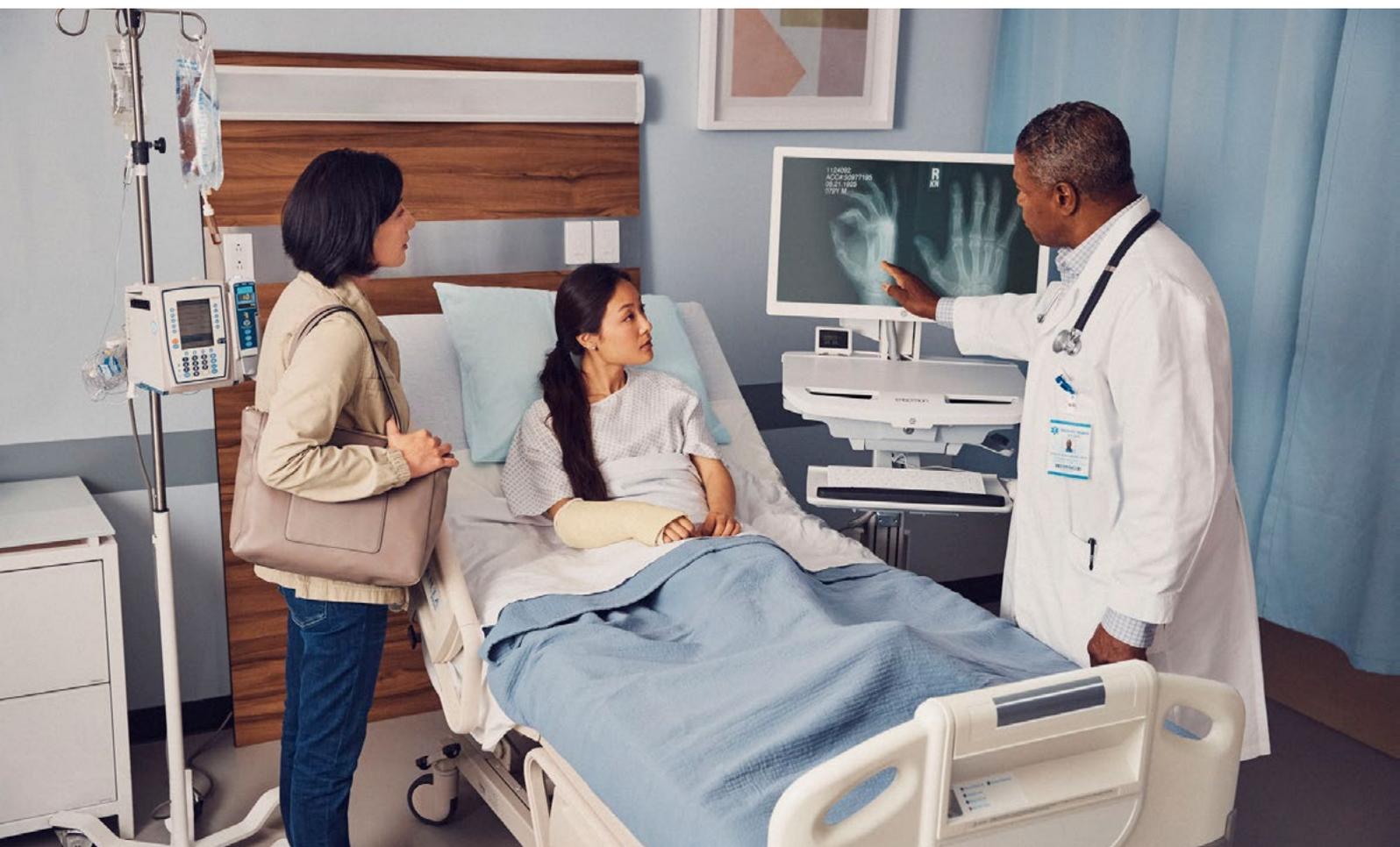
Simple machine errors caused by EMI could have catastrophic results. For example, if the performance of life-saving equipment such as defibrillators or ventilators is affected by EMI, it could cause irreparable damage to patients' health.

And these concerns aren't unfounded. Every year the USA's Food and Drug Administration receives hundreds, and sometimes thousands, of reports of malfunctioning medical devices involving EMI.⁵ The majority of these involve active implanted devices such as defibrillators, pacemakers, neurostimulators and infusion pumps, but a wide variety of equipment can be affected. Reports have included the airway pressure of a high-frequency oscillatory ventilator changing when a group of staff used their smartphones

nearby, an apnea alarm failing to sound due to a local source of EMI and a smartphone ring affecting the rate of an infusion pump.⁶

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"There are implications, particularly for any kind of local, portable types of radio signal emitters that could be brought in the vicinity of any potentially susceptible medical devices or systems," says Don Witters from the FDA's Center for Devices and Radiological Health (CDRH)⁷. "If there's a failure – even a momentary failure or effect – they could have very serious consequences for the patient. Obviously the goal is to minimize or eliminate this as much as possible."





The introduction of 60601-1-2

In response to the rise of more complex wireless devices within hospitals, which include high frequency WiFi®, Bluetooth® and smartphone signals, an updated International Electrotechnical Commission (IEC) standard, the IEC 60601-1-2, has been developed.

This, the fourth edition of the standard, has been revised to ensure that all medical devices comply with new requirements for electromagnetic compatibility and immunity. These include electromagnetic capability (EMC) risk analysis of devices to determine the test levels needed to ensure safety, new and increased test levels for EMI immunity, and new requirements for operating instructions information.

“The most notable changes to the immunity standard are the increased electrostatic discharge level; raised from 6KV/8KV to 8KV/15KV, contact and air discharge respectively, radiated RFE fields and proximity fields from RF wireless communication equipment,” says Lorenzo Cividino, Director, Global Applications and Support at SL Power Electronics.⁸

In addition, it’s worth noting that the updated standard places greater emphasis on the intended environment of use, as more wireless devices are ‘going home’ with patients to administer treatment and monitor health when they are ready to leave the hospital. With the FDA reporting one patient’s neurostimulator turning on and off during use of their electric razor⁷, it’s imperative that all medical devices are immune to electromagnetic interference wherever they are being used.

The importance of proactive risk management

From January 1st 2019, all medical devices, whether new releases or existing models, have had to comply with the requirements of the IEC 60601-1-2 standard. However, this does not cover wireless-enabled IT devices such as computers, smartphones and tablets.

Inferior devices can possibly interfere with critical equipment; therefore it’s imperative that clinicians and hospital administrators take a proactive approach to risk management when it comes to all equipment used within a medical environment.

Experts advise healthcare professionals to take the time to proactively weigh the risk of EMI in their current equipment infrastructure, assess purchasing plans and guidelines, investigate potential equipment purchases thoroughly and work closely with vendors.⁹

There is also a plethora of advice available to healthcare facilities from organizations working in this area, such as the Center for Devices and Radiological Health (CDRH), which is the branch of the FDA responsible for the premarket approval of all medical devices.

The CDRH offers the following recommendations:¹⁰

- **Make use of available resources** Make use of available resources such as EMC professionals, publications and websites on the subject of medical device EMC;
- **Assess** the electromagnetic environment of the facility – for example identify radio transmitters in and around the facility – and identify areas where critical medical devices are used such as the emergency room, accident and emergency or intensive care;
- **Manage** the electromagnetic environment, RF transmitters and all electrical and electronic equipment, including medical devices, to reduce the risk of medical device EMI and achieve EMC;
- **Coordinate** the purchase, installation, service, and management of all electrical and electronic equipment used in the facility to achieve EMC;
- **Educate** healthcare facility staff, contractors, visitors, and patients about EMC and EMI and how they can recognize medical device EMI and help minimize EMI risks;
- **Establish and implement written policies and procedures** that document the intentions and methods of the healthcare institution for reducing the risk of medical device EMI and achieving EMC;
- **Report** problems and communicate experiences to colleagues in open forums such as medical/technical publications and conferences.

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Forward-thinking IT vendors are working more closely than ever with clinicians and hospital IT departments to ensure their devices – including consumer and enterprise-grade technologies that are not normally expected to comply with IEC 60601-1-2’s stricter criteria – meet the more rigorous test levels around electromagnetic compatibility and immunity.

HP, for example, has introduced its Healthcare Edition portfolio of computers, displays and peripherals that, unlike most enterprise IT devices, has been tested to meet the IEC’s 60601-1-2 standard.

“PC vendors must work with their healthcare customers and regulatory agencies to assess risk and make thoughtful design choices to address it,” concludes Raja Bhadury, Head of HP’s Care Delivery Portfolio.



The HP Healthcare Edition Portfolio

HP's Healthcare Edition range of computers, displays and peripherals has been tested to meet stringent electromagnetic compatibility and immunity levels.

Its latest devices have been certified to meet IEC 60601-1-2 standards, enabling healthcare practitioners to use these devices close to patients without any risk of electromagnetic interference.

HP's goal is to streamline patient care, optimize clinical workflows, and make vital information readily accessible to authorized caregivers. The breadth and depth of HP's Healthcare portfolio, which is backed by a full suite of support services, make it easy for healthcare facilities of all sizes to get all their technological requirements from a single, reliable source.

Learn more about the [HP Healthcare Edition](#) portfolio.

CASE STUDY

HP has begun to see a growing number of proactive healthcare professionals reach out to discuss EMI risk management. Agencies and facilities around the world are looking towards ensuring all new devices they purchase for use within clinical areas are, wherever possible, IEC 60601-1-2 compliant.

Europe appears to be leading the way when it comes to EMI protection and safety testing, as the industry looks to ensure it protects patients from the risks of EMI as much as it can.

“In my experience the Nordics – Denmark, Finland, Iceland, Norway and Sweden – are focused on certification of all IT equipment used in clinical settings. Big facilities I’ve met with these last few months are putting priorities on EMI-related projects; this includes Västra Götalandsregionen (VGR) healthcare facilities in Sweden and HUS Helsinki University Hospital in Finland.”

“IEC 60601-1-2 is not just for operating theatres, but for the full patient journey as the risk of damage or interruption of implantable medical devices such as pacemakers is constant with the increasing use of IT solutions at each step of a treatment plan.”

Benjamin Philippe,
HP EMEA Healthcare Sales Specialist.

But this isn't the only region in Europe showing an interest in EMI risk management. Philippe has recently spoken with customers in the UK and in Germany who also want to make sure they are meeting the IEC 60601-1-2 standard.

And they're looking at the bigger picture. Facilities want to ensure the equipment used by patients both in the hospital and beyond, is standard compliant and immune to EMI.





1. <https://risemedia.net/2019/07/15/medical-device-connectivity-market-to-33-7b-by-2019-top-key-players-are-qualcomm-inc-lantronix-inc-ge-healthcare-ltd/>
2. https://resources.newzoo.com/hubfs/Reports/Newzoo_2018_Global_Mobile_Market_Report_Free.pdf?_hstc=133451409.5e6274e1c941f7615b3e1f5d9f5ce424.1563223040689.1563223040689.1563223040689.1&_hssc=133451409.5.1563223040689
3. <https://www.healthcareitnews.com/news/it-devices-crowd-point-care-experts-weigh-new-emi-risks> / HIMSS Media, Creating a Patient-Safe Technology Environment: A HIMSS Custom Research Report prepared for HP, October 2017
4. <https://www.element.com/nucleus/2018/08/15/16/00/emc-testing-of-medical-devices-more-than-a-single-standard>
5. <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>
6. Achieving a higher standard for patient safety – HP/HIMSS Media document
7. <https://www.nwemc.com/sites/www.nwemc.com/files/An%20FDA%20Perspective%20on%20Medical%20Device%20EMC%20and%20Wireless%20-%20Jeff%20Silberberg.pdf>
8. <https://www.mddionline.com/what-you-need-know-iec-60601-1-2-4th-edition>
9. <https://www.healthcareitnews.com/news/it-devices-crowd-point-care-experts-weigh-new-emi-risks>
10. <https://www.fda.gov/radiation-emitting-products/electromagnetic-compatibility-emc/fdacdrh-recommendations-emcemi-healthcare-facilities>

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