



# Engineering a safer future for MedTech

**The state of UK MedTech**

**The healthcare trends changing MedTech**

**The role of engineering**





The medical and healthcare industries are central to our society, whether it's in maintaining the health of the population or driving economic value. This importance often puts the industry at the heart of political and social conversations, but these discussions frequently overlook the role of design and electrical engineers in improving the health of the sector. With that in mind, what does the UK medical and healthcare industry really look like and how can engineers help?

## The state of UK MedTech

There are several factors that are used to determine the state of the industry, from its economic value and allocated governmental budgets to the development of technologies reshaping treatment. Based on these areas, we can view UK medical technology (MedTech) as a steadily growing industry.

However, these areas should be considered the drivers of change and growth in the industry rather than an accurate reflection of how the sector is implementing or facilitating these changes. In this regard, these factors mask an industry that is struggling with market uncertainty, cost-saving challenges versus increased service demand and a range of electrical issues introduced by new technologies.

Looking at the drivers and challenges side by side paints a different picture of the UK healthcare industry. According to statistics provided by the Department for International Trade's Exporting is GREAT scheme, the UK has the third largest MedTech market in Europe with a value of £7.6bn and a turnover of £21bn.

Despite this, the UK Government's healthcare budget has seen investment in health research and development (R&D) decrease in recent years, from £2.2bn in 2016 to an estimated £1.8bn in 2018 — 8.5 per cent of the UK's MedTech turnover. It's currently uncertain how the R&D investment plans outlined in the UK Government's industrial strategy, unveiled in November 2017, will tie into MedTech R&D.

The relatively small medical R&D investment from the Government may lead to a restricted rate of market growth in the years to come. While the £1.8bn figure is just a projection and does not account for private investment, it can be perceived as indicative of the Government's confidence in the industry.

Likewise, market uncertainty is shaking the confidence of medical equipment manufacturers. The medical industry is subject to strict regulation, but the Brexit process has created uncertainty about how effectively the UK will be equipped to conduct conformity tests for CE certification of products after Brexit.



CE certification is required for all medical equipment in Europe. In its Medical devices and CE marking: the impact of Brexit report, the Institution of Mechanical Engineers (IMechE) warns that failure to secure a new cooperation agreement with the European Union (EU) will mean one of two things for the UK: increased compliance costs due to outsourcing conformity testing to EU companies, or a bilateral agreement that means “having to comply with directives the UK no longer had any influence in shaping”.

This threatens to shake confidence in the industry from manufacturers themselves. In an interview with Cambridge News, Cambridge Medical Robotics CEO Martin Frost said that “certainty around safety marking and potential export tariffs are critical for the medical device sector that works on multi-year development times and significant financial investment.

“Despite the NHS being one of the largest and most respected healthcare purchasers in Europe, the UK is home to only one of the world’s top 50 medical device companies. If we are to change this position, we require certainty and confidence to continue to attract the right long-term investors.”

The financial challenge of market uncertainty is compounded by the cost crisis that has proven an ongoing challenge for UK healthcare in recent years. The NHS has been set targets by the UK Government to reduce its spend by £22bn, while still providing adequate care for its reported 60+ million service users. This in turn means maintaining well-worn medical equipment with minimal budgets for system modernisation or replacements.

Besides investment and cost, the MedTech industry is being shaped by an accelerating amount of technological advancement and adoption. As with many industries, the two core concepts driving MedTech change are the Internet of Things (IoT) and digitalisation. These technologies present a wealth of new possibilities for the sector, but bring with them the challenges of equipment safety, power quality and system continuity.



This makes the role of design and electrical engineers critical. By building in components that help overcome the challenges presented by new technologies, design engineers can make the investment in new devices and equipment more appealing to healthcare procurement managers.

Likewise, electrical engineers can reduce the problems faced by existing systems through the installation of effective electrical equipment such as efficient isolated transformers, isolation monitors and network isolators. These products reduce operating costs and power quality problems to strengthen system continuity and reliability.

Despite the market uncertainty, design and electrical engineers together have the potential to bring the MedTech industry closer to overcoming its challenges. By making new equipment yield a clear return on investment, reducing the operating expenses of existing devices and making healthcare environments safer, engineers can lead the industry safely through the trends and challenges to shape a safer future for the sector.

# The healthcare trends changing MedTech

UK MedTech is in a transformative period, driven by several technological and social trends. These range from changes in the population to the rise of digital healthcare technology, the latter of which has manifested itself in numerous forms and been the catalyst for many changes in the sector.

Here, we'll explore the five key trends that are reshaping the industry.

## Home healthcare and mobile health

With the rise of digital healthcare technology has come the increased use of healthcare apps and devices in the home. According to a 2014 study by Deloitte for the UK Government Office for Life Sciences, the UK's digital health market is expected to be valued at £2.9bn by the end of 2018.

Much of the home healthcare or mobile health (mHealth) trend is being driven by the development of smart phone technology allowing health apps to provide more comprehensive analysis of user conditions, as well as the advancement and popularity of consumer wearable electronics.

These applications currently offer limited insight into user health, but there is a belief among those in the industry that there is scope for this to develop. As Deloitte's 2014 report explicitly states, "the potential lies in supporting higher-impact clinical decision-making and developing the interaction between clinicians and patients".

Rather than signalling the commoditisation of healthcare, the rise of mHealth has triggered a shift in how the UK's healthcare industry operates. In 2015, the NHS announced proposals to develop the capability for mHealth applications and wearables to sync directly with NHS patient records.

Following on from this, the NHS shared its digital apps library in early 2017. This is a directory of NHS-certified healthcare applications that, along with a companion site to help app developers meet NHS guidelines, helps patients identify and use trustworthy apps.

A significant factor in the development of mHealth technology has been the financial pressures and time constraints faced by healthcare practitioners. This has been an ongoing issue for UK healthcare over the past decade and digital healthcare has the potential to ease the pressure.

At the time of the NHS announcing its digital proposal

in 2015, Tim Kelsey, then-national director for patients and information of the NHS, stated that "better use of technology can save money. Letting people rebook online will help tackle the estimated £160 million that missed appointments cost the NHS each year".

The NHS also announced in 2017 that it was set to trial the use of apps for patient care in four NHS trusts by early 2018. Clinical trials of the apps showed a reduction in hospital admissions and GP appointments, which Lionel Tassarenko, of the Oxford University Institute of Biomedical Engineering, believes shows that, by using the app, "patients are much more confident about managing themselves and are getting into trouble far less often".

The start of these trials is a sign that the use of mHealth technology will continue to increase in coming years, in both home and hospital environments.

# The ageing population

While financial constraints create pressures for medical practitioners, so too does a growing population with increasing lifespans.

Based on data from the Office for National Statistics (ONS), the life expectancy increased by nine years for males and six years for females between 1980 and 2016. Alongside this, UK birth rates have been fairly consistent during the same time period, with more than 665,000 live births each year on average.

*“statisticians from the ONS estimated that life expectancy in 2041 would be 86.2 years and 83.4 years for women and men respectively”*

Excluding periods of conflict such as world wars, the average life expectancy has consistently increased for most of the past century. However, recent findings indicate that this might be set to change.

In October 2017, statisticians from the ONS estimated that life expectancy in 2041 would be 86.2 years and 83.4 years for women and men respectively. This was one year less than the ONS projected two years previously. A similar trend is appearing in the US, where life expectancy has declined in recent years.

Despite this, today we are living longer than the public in 1948 when the NHS was established. As we age, we become more susceptible to illness and infection. As such, an ageing population inevitably increases the volume of hospital admissions and practitioner appointments, placing significant pressure on healthcare systems.



This is one of the biggest challenges for design engineers of medical devices and equipment. New MedTech must be able to operate reliably and safely, both functionally and practically. For example, many pieces of equipment must be washed down properly between uses to reduce the risk of infection to elderly patients, so devices must be designed accordingly.

Wearable MedTech has contributed to addressing the issues that come with an ageing population, allowing home healthcare devices to monitor patients and ensure medical staff are notified if anything requires urgent attention.

The ageing and less mobile population seemingly drives a need for devices that are mobile. With this comes a paradigm shift for the healthcare sector, from reactive care of illness to proactive maintenance of health. Digital MedTech manufacturers will have to find ways of designing this approach into their products, as well as ensuring any reactive elements — such as emergency staff responding to sudden changes in a patient at home — are acted on promptly.





# Medical data security

The rise of medical devices that monitor, record and process patient data might mean better and more comprehensive care, but it also exposes the patient to greater risk than ever before.

Few things exemplify this like 2017's WannaCry ransomware attack on NHS systems. The ransomware encrypted patient data and resulted in, according to the National Audit Office (NAO), at least one third of NHS trusts in England being disrupted. The attack cost the NHS an undetermined amount including costs such as paying the ransom, cancelled appointments, IT support and the cost of system restoration.

The NHS was widely criticised following the security breach. According to Amyas Morse, head of the NAO, "it was a relatively unsophisticated attack and could have been prevented by the NHS following basic IT security best practice. There are more sophisticated cyber threats out there than WannaCry, so the Department and the NHS need to get their act together to ensure the NHS is better protected against future attacks".

Many, including the NHS's deputy chief executive Rob Shaw, believe these attacks will almost certainly continue into the future. Shaw has stressed that "the threats we have seen

during 2017 are unlikely to be going anywhere, with low-effort, high reward ransomware continuing to be prevalent along with more sophisticated command and control structures, making it more difficult to employ traditional mitigation and remediation methods". While WannaCry was the most high profile cybersecurity breach on the NHS in recent years, it is not the only threat to NHS systems or patient data. In addition to cybersecurity concerns, there is a general threat to system continuity through the reliability of IT hardware.

Many IT systems used by NHS hospitals are outdated, which was a contributing factor in the WannaCry infiltration. These systems will also have inefficient hardware that can contribute to poor electrical conditions, such as electromagnetic interference (EMI), that create problems elsewhere in electrical systems. This can therefore make medical equipment unreliable, or negatively impact IT system continuity.

The trend for improving data security will only become more prevalent in the coming years, but it is essential that healthcare organisations don't just improve their cybersecurity procedures and neglect the performance of the hardware used to access the data in the process.



# Portable devices and complex setups

Particularly since the advent of the Internet of Things (IoT) in healthcare environments, the number of devices in a typical hospital has significantly increased in recent years. The increased use of portable and handheld devices, including vital patient monitoring and analysis devices as well as endoscopy equipment and tablet computers, has changed the face of healthcare.

Likewise, even mainstays of healthcare environments have been replaced with a digital or electronic alternative. Notepads have been replaced with iPads, mechanical beds with electrically adjustable beds and traditional film imaging has been substituted for the latest digital picture archiving and communication system (PACS).

The increasing electrification of devices creates problems on the mains power supply. AC to DC power conversion by the device's power supply introduces issues such as voltage distortion, current harmonics, electrostatic discharge, power surges and EMI into the supply.

These power quality problems can affect the calibration and sensitivity of diagnostic devices used by doctors and healthcare professionals. Erroneous test results can result in misdiagnosis and potentially harmful treatment plans for patients.

That comes without considering the consumer devices that are increasingly common in hospitals. Commercial off-the-shelf (COTS) equipment is often used in hospitals alongside medical equipment. This equipment, such as commercial PCs, can result in electrical interference and subsequently have serious effects on medical equipment functionality.

For example, there have been reports of cases where critical medical equipment such as defibrillators failed to work because of interference from secondary equipment, such as ambulance radios.

As digitalisation brings new benefits to healthcare, engineers must be primed to eliminate the problematic by-products of these developments. Design engineers must ensure their devices are designed to comply with electrical standards, such as electromagnetic compatibility (EMC) directives to minimise EMI, while electrical engineers must ensure systems are kept safe from power quality problems.



# Surgical robots

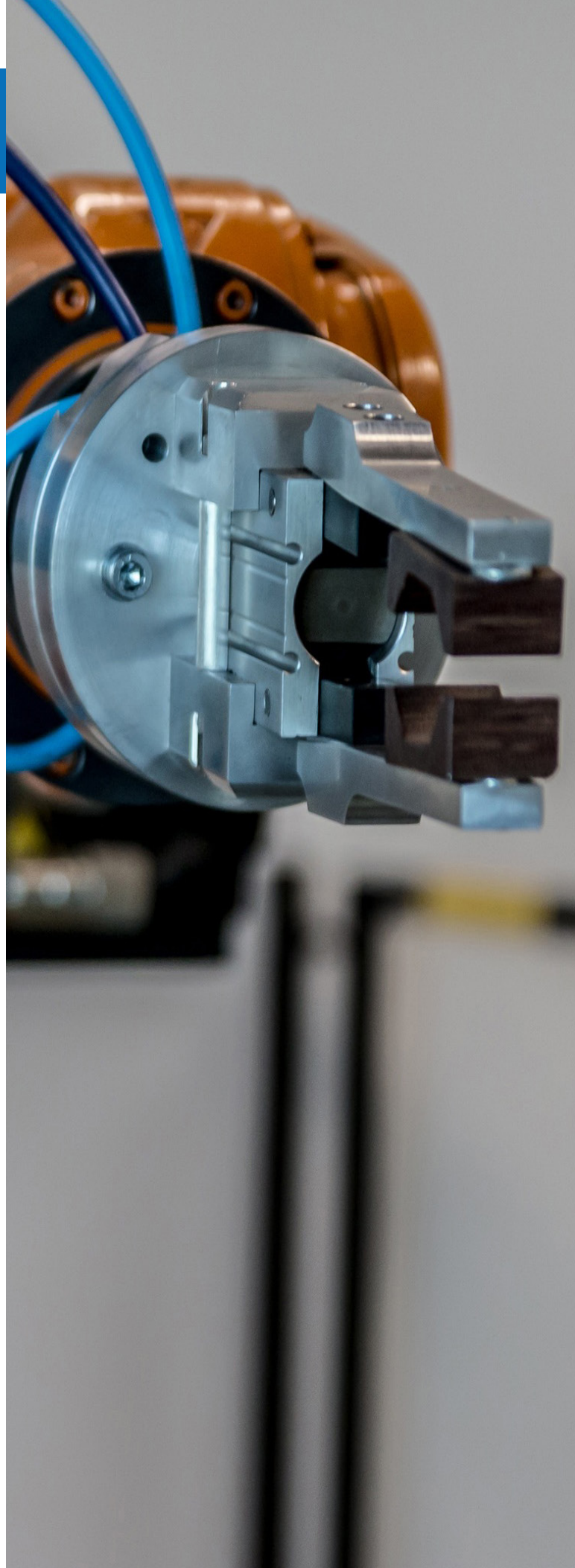
According to a report from market research firm Allied Market Research, the global surgical robotics market will be valued at \$28.8bn by 2020. The surgical robotics industry has been growing for more than a decade, but it's only in recent years that we've started to see the technology gain traction in the UK.

It has been reported that the number of NHS prostate cancer centres offering robotic surgery more than tripled between 2010 and 2017, with more than three quarters now offering the surgery. This, along with UK scientists developing the world's smallest surgical robot in 2017, indicates that a change is occurring in the UK's healthcare and robotics industries.

There are several reasons why surgical robots are becoming increasingly prevalent. One of the biggest is that collaborative robotics allows surgeons to work for longer without the health issues that are traditionally associated with surgeries, such as back pain during long surgeries that create longer-term issues as surgeons age.

The other argument for surgical robots is that they greatly enhance accuracy during keyhole surgery. According to Graham Mackrell, managing director of robot gear manufacturer Harmonic Drive UK,

*“Surgical robots used for keyhole surgery allow surgeons to be more precise in their incisions as the system handles the multiple apparatus required. Instead of a surgeon effectively juggling the laparoscope and surgical tools, the robot can handle both simultaneously for a quicker and more efficient operation”.*





# The role of engineering



With UK MedTech undergoing such significant change but facing equally significant challenges, engineers are pivotal in supporting a safer future for the sector. But what could this involve?

## Powering healthcare: a designer's dilemma

Safety is critical when designing medical equipment and every design engineer understands this. The importance of this consideration is underlined by the wide range of regulations and directives that medical equipment is subject to, such as the European EN60601-1 standard for electrical MedTech. This standard governs the safety, essential performance and EMC of equipment.

The directives classify devices into three areas based on how closely they are used to the patient's body. Type B devices operate within a six-foot vicinity of the patient without bodily contact. Type BF makes physical contact with the body and Type CF makes physical contact with the heart. Each of the categories outlines the level of isolation, insulation, creepage, clearance and leakage allowed.

The EU has introduced several new regulations and directives in the past few years that affect how medical devices are designed, developed and manufactured. The medical devices regulation (MDR 2017/745) was published in mid-2017 and will be in effect from mid-2020 onwards.

The MDR details an increased focus on product lifecycle requirements rather than solely pre-approval processes, with the aim to make medical devices consistently safer from cradle to grave. In addition to this, EN ISO 13485:2016 is mandatory as of 2019 and will put even greater focus on quality management and risk management as part of product development.

More regulation means more headaches for design engineers, but the greater focus on safety and reliability across the entire product lifecycle offers an opportunity for design engineers to positively impact the wider industry. By keeping power considerations in mind during the design stages and being mindful of EMC directives, design engineers can keep devices compliant while maintaining clean power in healthcare environments.

For example, REO UK manufactures resistive and inductive wound components that ensure a higher standard of power quality. These components are used in the REOMED range of isolating medical transformers, which can be integrated into medical devices to comply with EMC directives as well as EN60601.

The transformers allow safe galvanic separation between the primary and secondary electrical circuits, which limits the electrical leakage and, as such, the interference to other devices. Likewise, it keeps the equipment safe from poor power quality introduced to a network by mains-connected consumer devices — ensuring optimum performance.

Isolating transformers are often embedded in large clinical equipment, such as MRI machines and anaesthesia units, to maximise safety. However, equipment for patient environments, such as operating theatres, does not often contain an embedded transformer to isolate the unit. Introducing one into the design stages could offer greater safety over the course of the product lifecycle, complying with the increasingly stringent EU directives.

# Powering healthcare: an electrical problem

In the earlier years of the twenty-first century, mobile phones were not permitted by doctors, nurses or other medical staff in many NHS hospitals due to fear that they would interfere with medical equipment. This led to calls in 2007 from UK Government for the ban to be lifted, with then-health minister Andy Burnham saying there was “no reason for trusts to have an outright ban on mobile phones”.

We’ve progressed since then to understand that mobile phones will generally not interfere directly with equipment, but the technology does still contribute to electrical interference in hospitals. With the rise of health apps for mobile phones as part of the mHealth revolution, this interference is becoming a growing concern.

The rise in portable and handheld devices used to monitor patient vitals increases the number of devices in hospitals and, with more devices used, the risk of electrical interference rises. Such devices are susceptible to changes in power quality, which affects the quality of data received.

These changes in power quality can lead to issues like EMI, which causes surges and spikes in power. This has an impact on both the data collected by medical equipment and the way devices interact with each other, as well as staff access to patient records.

During the WannaCry attack on the NHS, hundreds of appointments had to be cancelled due to patient files being encrypted and therefore inaccessible. This is arguably one of the greatest invisible costs of the attack to the NHS. Yet a similar lack of record access, albeit on a smaller scale, could happen with poor power quality impacting healthcare IT systems.

Part of the routine in a general practitioner (GP) appointment is that the doctor reviews, and subsequently updates, a patient’s medical record to ensure the right course of treatment is prescribed and that an accurate record of the appointment is kept. If interference creates an unreliable power supply to IT systems or a damaging power surge, GPs may be unable to access these files — leading to a risk of cancelled appointments and subsequent expense.





Such events can be mitigated by using network isolators and isolation monitors. In the same way that an isolating transformer separates a piece of equipment from mains power, network isolators such as the REOMED Isonet provide effective electrical isolation of devices in copper wire-bound ethernet networks. The Isonet also protects both equipment and people from the impact of electrical voltage spikes.

In other medical environments such as surgical theatres, isolating transformers can be used to ensure critical equipment has galvanic separation from the mains to ensure a consistent and reliable performance.

Depending on the transformer used, this can also reduce operating costs. In 2017, the NHS announced during NHS Sustainability day that its use of energy efficiency systems and on-site generators had resulted in savings of more than £300m. Despite this significant saving, there are areas that are still inefficient; transformers are one such example.

Traditional medical transformers typically have quite high electrical losses, which results in higher energy costs and a greater environmental impact. However, REO UK's REOMED toroidal transformers have been tested and consistently shown to deliver significantly lower losses. Where a conventional transformer with a capacity of 2200VA might exhibit losses of 113W during use, a REOMED transformer with the same capacity would typically exhibit losses of 62.5W — a 45 per cent reduction.

But electrical engineers can go one step further than efficiency and use an electrical isolation monitor, in conjunction with the transformer, to detect any isolation breakdown and maximise safety.

Electrical engineers can use the isolation monitor to monitor dielectric resistance between the live outlets of the transformer and the earth potential. The resistance is constantly monitored to ensure it does not fall below a set value and to notify staff in the event of a fault condition.

As the growing mHealth market shows us, it is unlikely we'll see a return to the times of mobile devices being banned from hospital environments. As such, electrical engineers must ensure the electrical components are in place to protect the network from power failure and keep systems running efficiently.

**Reliable power is just as central to medical and healthcare environments as those industries are to our society. For all the challenges facing the industry, the first step to overcoming them is to ensure the equipment and networks can facilitate the future solution. Good power quality is critical in ensuring this in an efficient, safe and reliable way.**

**Whether you're an electrical or design engineer, REO UK has the products to help ensure a high standard of power quality. For more information, contact the company on +44 (0) 1588 673 411.**



REO (UK) Ltd, Units 2-4 Callow Hill Road,  
Craven Arms Business Park, Craven Arms,  
Shropshire, SY7 8NT

Tel: +44 (0)1588 673411  
Fax: +44 (0)1588 672718  
Email: [sales@reo.co.uk](mailto:sales@reo.co.uk)