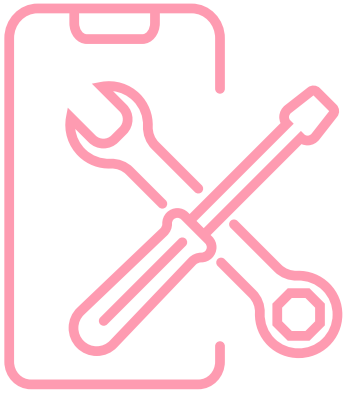
IPEM
Institute of Physics and Engineering in Medicine

IPEM Position Statement:

Formal Arrangements for Right to Repair Medical Devices in the UK



The members of the Institute of Physics and Engineering in Medicine (IPEM) propose the creation and adoption of a formal framework specifying requirements for a 'Right to Repair' medical devices within the UK.

A well-structured 'Right to Repair' framework could have significant benefits for the healthcare system, while maintaining high standards of safety and compliance, including:

- **Enabling faster repairs of medical devices[1] by using local in-house facilities.**
- **Reducing costs by using local in-house service and maintenance.**
- **Enhancing sustainability by reducing emissions from transport (both engineers and devices).**
- **Meeting social value model targets by employing more local resources.**

POSITION STATEMENT

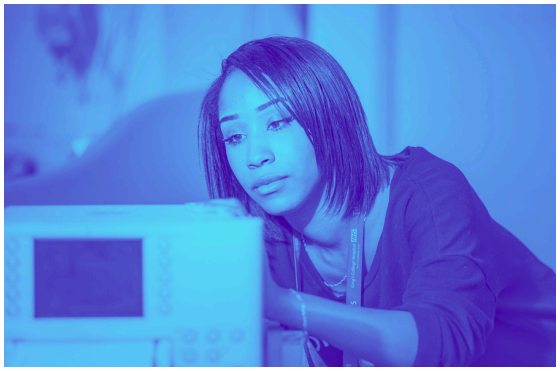
RIGHT TO REPAIR: BENEFITS FOR UK HEALTHCARE

Currently, manufacturers are the primary medical device repair and maintenance provider within the NHS and other healthcare facilities. Issues can occur when some manufacturers limit access to the tools, parts, information, and the training required to enable third-party repairs.

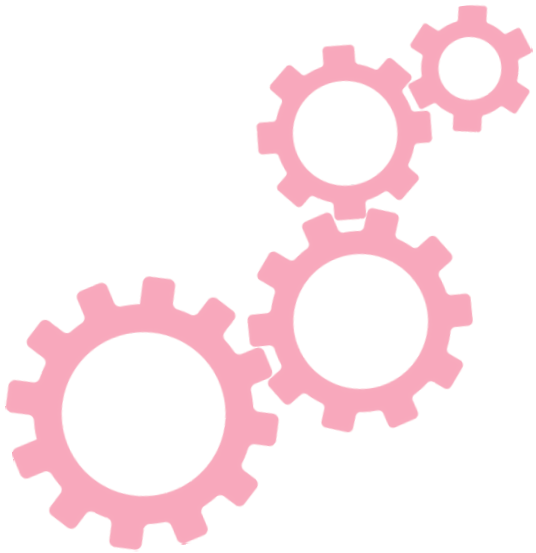
In some cases, the sole dependency on manufacturers can be financially burdensome and could delay repairs, such as when having to send equipment away. This may necessitate stocking additional medical devices to cover these periods or limit the availability of service for patients if no replacements are available.

As the social value model, sustainability, and associated carbon reduction plans, are key NHS policies, providing local repair and maintenance facilities presents a viable way to achieve these targets. Development of in-house capability will contribute to better equipment availability, reduced downtime, and control over assets/equipment records. The provision of local service reduces the need to transport medical devices to and from a manufacturers facility or may remove the travel need for their field service engineers, both of which will result in carbon reduction and potentially cost saving.

"Development of in-house capability will contribute to better equipment availability, reduced downtime, and control over assets/equipment records"



Adopting a Right to Repair framework at either a regulatory or procurement level will help address the challenges of providing repair and maintenance services within NHS healthcare facilities or those provided by other third-party companies. This framework can enhance the access of clinical engineering teams and certified third-party providers to necessary repair tools, information, and training, thereby expanding the potential for:



- Providing faster repairs of medical devices by using local in-house facilities.
- Reducing costs by using local in-house service and maintenance.
- Enhancing sustainability by employing local resources and reducing emissions from transport.

However, to ensure the success of this initiative, it is crucial that all stakeholders across the healthcare sector and medical device industry collaborate and contribute to developing a suitable model.

KEY CONSIDERATIONS FOR IMPLEMENTING RIGHT TO REPAIR

To ensure the practicality, safety, and long-term viability of a Right to Repair approach in healthcare, IPEM proposes the following guiding principles:

Access to Genuine Parts and Software: Healthcare organisations and certified third-party service providers require access to manufacturer-approved parts, diagnostic tools, and software updates to enable safe and effective repairs.

"it is crucial that all stakeholders across the healthcare sector and medical device industry collaborate and contribute"

Standardisation of Repair Protocols: Standardised repair protocols should be established for in-house and independent engineers and technicians. This will ensure that repairs meet strict safety and compliance standards. In most cases this will be achieved by following the manufacturers provided instructions for service and repair. Quality systems must be in place to demonstrate capability and competence with the engineering governance being traceable back to British Standards.

Liability and Accountability: A clear framework is required for establishing liability in the event of equipment malfunction post-repair, assuring that repairs do not compromise patient safety or device performance. Responsibility for maintaining the equipment passes to the 'Trust' at the point of sale, as the 'Trust' has insight into how the equipment is used, the operating environment, and the local risk and quality management systems — information the manufacturer does not possess.

Training and Certification: Manufacturers where possible should provide both in-house and third-party engineers and technicians initial and ongoing training opportunities and certification programs to maintain a high standard of safety and knowledge across the healthcare sector. This manufacturer training should be equivalent to that provided to their own employees, providing it is safe, practical, and without compromising intellectual property. A framework for the education and training of technicians must exist to ensure that competency can be awarded, and that competency can be maintained throughout the lifecycle of the medical device for those who maintain it. Manufacturers must respect the skills and capability of the in-house technician. When arranging training, teams should collaborate with manufacturers to facilitate this, for example, as part of the procurement process.

National Standards and Compliance: Any Right to Repair implementation must align with all applicable medical device regulations and associated product standards. Any work on the medical device should not compromise the medical device certification (e.g. CE or UKCA marking).

The Right to Repair initiative can empower healthcare providers with the ability to repair and maintain devices more efficiently, which can reduce costs, and improve medical device availability across the NHS. It also enhances organisational capability and strengthens resilience by ensuring that technical expertise is available close to the point of need.

“The Right to Repair initiative can empower healthcare providers with the ability to repair and maintain devices more efficiently”

Moreover, a Right to Repair framework would encourage environmentally sound practices to meet sustainability and social value model targets. The procurement process that must address the through life maintenance aspect of bringing a device into service based upon a robust risk/quality management systems, warranty agreements, clearly defined levels of repair responsibility, identification of all special tools and test equipment and levels of spares to effect fast repairs. This must also be part of the through life costing of the device.

INVITATION TO COLLABORATE

While IPEM are confident that Right to Repair offers real benefits to the healthcare system, we also acknowledge the importance of understanding the perspectives of all relevant stakeholders. It is recognised that manufacturers, service providers, healthcare organisations, and regulatory bodies all have valuable insights into how such a framework can be implemented.

As the next step in bringing this position to life, we would like to organise a stakeholder discussion, inviting input on best practices, risks, and potential limitations associated with Right to Repair in medical devices. This will ensure that any eventual framework reflects the realities of the sector and meets the needs of all parties involved.

We encourage you to share your thoughts and contribute to this conversation.

Please get in touch on: anna.stec@nhs.net

AUTHORS

Anna Stec, Senior Project Manager, NHS England
Michael Bernard, Engineer, Siemens healthcare Limited

EDITORS & CONTRIBUTORS

Edward Chapman, Head of service - Clinical Engineering, Cardiff and Vale UHB
Shaun Atherton, Head of Service, Med Phys and Engineering, The Christie NHS FT, Manchester
Laura Metcalfe, Head of Service, Medical Equipment Management, NHS Greater Glasgow & Clyde
Simon Townsend, Senior Engineer, Radiotherapy Physics, Poole Hospital
Richard Stubbs, Risk Manager, Aneurin Bevan University Health Board University Hospitals
Victoria Kidgell, Lead Clinical Scientist, Sheffield Teaching Hospitals NHS FT
Richard Coldrick, Senior Operations Manager, Elekta Limited
Christopher Taylor, Sustainability Lead UKI, Government & Public Affairs, Electa Limited
Peter Chase, Service Director, North Europe, Fujifilm Healthcare UK
Delcian McGregor, National Service Delivery Manager, Coventry and Warwickshire NHS Trust
Clara Ferreira, Technologist, Nuclear Medicine, Royal Victoria Hospital, Belfast Health & Social Care Trust
Mike Chan, Engineering Technologist, Clinical Engineering & Physiological Sciences

SPECIAL ACKNOWLEDGEMENTS

Special Acknowledgement to the Clinical Engineering SIG members for the provided feedback and comments

NOTES

[1] ‘Medical device’ is any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings (Moreover, a Right to Repair framework would encourage environmentally sound practices to meet sustainability and social value model targets. The procurement process that must address the through life maintenance aspect of bringing a device into service based upon a robust risk/quality management systems, warranty agreements, clearly defined levels of repair responsibility, identification of all special tools and test equipment and levels of spares to effect fast repairs. This must also be part of the through life costing of the device.), e.g. an infusion pump, a blood glucose monitor, an electrocardiogram (ECG) machine, a patient vital signs monitor.