Planned and effective maintenance – a saving, rather than a cost

With resources at full stretch because of the pandemic – staffing costs escalating due to payment of overtime cover for sickness or essential self-isolation, plus pressure to deal with the well-documented backlog of patient treatments – it's understandable that equipment maintenance may have dropped down the priority list.

But this can be false economy – with costs not only in financial terms, but also potentially and tragically, in human life: an investigation by the HSE which concluded in 2016, led to an NHS Trust being fined £200,000 plus costs[1] for a breach of the Health and Safety at Work Act 1974, Section 3, Sub Section 1, due to its management of the use and maintenance of the medical device involved in an incident that led to the death of a patient.[2]

And fines applied by the HSE to NHS trusts under the same section since that case have amounted to £3,929,453.

The watchdog for medical equipment management and maintenance

While both the Medicines and Healthcare Products Regulatory Agency (MHRA) and Care Quality Commission (CQC) take a proactive role as healthcare regulators, the overriding regulation for medical equipment is derived from the Health and Safety Executive (HSE) through:

The Provision and Use of Work Equipment Regulations 1998 (PUWER)[3]

Health and Safety at Work etc Act 1974 (HSWA)[4]

The Management of Health and Safety at Work Regulations 1999[5]

Day-to-day responsibility for Medical Devices

The UK's annual spend on clinical and medical equipment is currently circa £4.77 billion, and a significant proportion of that equipment will require maintenance and / or calibration on a regular basis.

Given there are at least 10,000 different types of medical device from over 2,000 different suppliers available in the UK market, this creates a resource heavy demand on the 3,500 biomedical engineers employed to maintain them.

The average Trust (of which there are 223 in the UK) has around 16 biomedical engineers[6] – all required to:

- **give numerous training sessions to practitioners**
- **conduct pre-preventative maintenance, calibration, diagnostic breakdown analysis and ad hoc repairs**
- **deal with manufacturer communications**
- **provide end user support**
- **manage the component stock inventory**
- **source specialist tools or software**

The approach to this second element – conducting pre-preventative maintenance etc. – however, is the subject of specific MHRA guidance, updated as recently as January 2021.[7]

Under section 8 Maintenance and Repair of this document Managing Medical Devices Guidance for Health and Social Care Organisations, it states: ***'the healthcare organisation's medical device management policy must cover the provision of maintenance and repair of all medical devices...The healthcare organisation is responsible for ensuring their medical devices are maintained appropriately.'***

It also states ***'The frequency and type of planned preventative maintenance should be specified, in line with the manufacturer's instructions…'***

In carrying out their risk / benefit analyses before finalising the specification of any maintenance and repair service provision for a medical device type, healthcare organisations need to look at many factors.

Taking cost alone into account can be deceptive: an approach that dictates 'only repair when needed' could actually turn out to be more expensive than pre-preventative maintenance if a breakdown means that a certain treatment can't take place with all the ramifications of lost theatre time and wasted staff resources.

Using only in-house staff to conduct repairs and maintenance may also be false economy: a Trust's own biomedical engineer may take longer to troubleshoot or service a piece of equipment they deal with only occasionally than a specialist repair and maintenance engineer, who deals with the complexities of the piece of kit on a daily basis.

So, a healthcare organisation looking to find the best balance of in-house / outsourced support in this area can explore three possible options:

- **Manufacturer's service organisation**
- **Manufacturer's appointed service agent**
- **Generic third-party service provider**

Each of the above should provide evidence of accreditation with BS EN ISO 13485 or BS EN ISO 9001 to ensure their work is compliant with quality system standards as well as evidence of manufacturer accredited training to guarantee the standard of their work on specific equipment.

Again, it is the Health and Safety at Work Act 1974 which is relevant here with its requirement for employers to ensure employees are adequately trained, and particularly that all service staff have sufficient experience of the devices they repair and maintain.

The most effective guarantee of this (and the one that reduces potential risk) is manufacturer accredited training, although manufacturers are under no obligation to offer this to generic third-party service providers.

Looking at the three options in more detail, these are some of the key benefits that may be on offer:

Manufacturer's service organisation

- **Guarantees same build standard of work as original product**
- **Latest modifications, updates and upgrades included**
- **Guarantees access to authentic, approved spares**
- **Guarantees up-to-date, trained personnel**
- **Focused experts trained on a smaller range of medical device types**
- **It is in their interest to achieve a 'First-time-fix'**
- **May offer remote technical support**
- **May offer extended warranty periods**
- **May offer truly comprehensive service provision, including break down visits**
- **May offer discounted spares**
- **May be available for on-going end user training and support**
- **May offer free-of-charge loan equipment**
- **May manage scheduling / equipment availability with the end user department**
- **Offers short chain feedback route to the manufacturer**
- **Offers data for MDR vigilance and post-market surveillance activities, helping to further improve the usability and safety of the medical device**

Manufacturer's appointed service agent

Should perform within the same expectations outlined for the manufacturer's service organisation.

Generic third-party service provider

- **May offer reduced costs**
- **May offer reduced response times**
- **May offer all-in-one medical device type provision**
- **May offer on-site resource availability**

Further considerations on generic third-party service providers are however:

> **Reduced costs may be on a preventative service visit basis only, with return visits for corrective work charged as an additional cost**

> **Reduced response times may be based on the time in which they respond to assess a breakdown report, not the response time to repair the breakdown**

> **May not offer evidence of manufacturer's accredited training**

> **May not guarantee same build standard of work**

> **May not be versed in the latest modifications, updates and upgrades**

> **Multiple device type trained personnel may result in diluted expertise**

> **May not have access to authentic, approved spares**

> **May not offer remote technical support**

> **May not offer extended warranty periods**

> **May not offer truly comprehensive service provision, including break down visits**

> **May not offer discounted spares**

> **May not be available for on-going end user training and support**

> **May not offer free-of-charge loan equipment**

> **May not offer short chain feedback route to the manufacturer**

> **May not offer data to the manufacturer for MDR vigilance and post-market surveillance activities**

> **It may not be in their interest to discuss replacement of equipment past its stated life expectancy**

Manufacturer v generic third-party managed medical devices

After taking all of the above into consideration, it is clear there is no simple answer.

Whilst the continued availability of generic third-party service providers is no doubt critical to the function of the UK healthcare system in supporting biomedical engineering staff, there are many advantages to enlisting the support of the medical device manufacturer in terms of cost savings, the convenience of an all-in-one provider and the convenience of the procurement process.

A low upfront cost per piece of equipment offered by a generic third-party provider will seem attractive to a Trust, especially if an all-in-one medical device contract is also on offer – this can, on the surface, look simple and convenient. However, this can mask the true cost likely to accrue annually in 'hidden extras' such as breakdown call-outs, return visits for corrective work and heavily marked-up spares prices not included in the contracted price.

The key consideration is to remember you may not be comparing 'like with like'. Based on available data, here is an example of how a Manufacturer's comprehensive 'all in' cover could compare with a Third-party provider's costs, demonstrating how these 'hidden extras' can mount up:

	Manufacturer	Third-party	Manufacturer	Third-party
Quantity	**Annual PPM (each)**		**Annual PPM (total)**	
10	£150.00	£50.00	£1,500.00	£500.00

	Manufacturer	Third-party	Manufacturer	Third-party
Quantity	**Breakdown (per hour)**		**Breakdown (total)**	
10	£-	£50.00	£-	£500.00

	Manufacturer	Third-party	Manufacturer	Third-party
Quantity	**Spare 'A' (each)**		**Spare 'A' (total)**	
10	£-	£50.00	£-	£500.00

Manufacturer	Third-party
Total	
£1,500.00	£1,500.00

As this shows, the Manufacturer's 'all in' service may end up being no more expensive than the third-party provider. And in fact, this does not even take into account the costs associated with equipment downtime, as generic third-party service providers may be less likely to achieve a 'first visit fix', perhaps having to wait for vital spare parts to be delivered.

The case for the patient stretcher / trolley

Certain medical devices may be deemed ‘low risk’ or simply ‘generic’, in terms of where they feature in the maintenance pecking order when, in fact, certain models play a key role in the daily function of a hospital or other medical facility.

Patient stretchers / trolleys may seem unimportant compared to a CPAP breathing machine or ventilator, but if their downtime means insufficient patient stretchers in circulation, the patient transfer flow around a healthcare facility could become backlogged – or even grind to a halt.

In the case of certain equipment there is also a strong case for manufacturer involvement in maintenance because they are continuously improving their device, which in the case of a stretcher, could be around better moving and handling and its impact on workplace injuries such as MSDs.

To innovate, a medical device manufacturer needs quantifiable first-hand data, and there is no better source for this than its own service organisation (or appointed service agent).

And then there is safety: in meeting the requirements of The Regulation on Medical Devices 2017/745, a manufacturer has to follow a post-market surveillance system to actively and systematically gather, record and analyse the data it collects on the quality, performance and safety of a device throughout its entire lifetime. This includes determining, implementing and monitoring any preventative and corrective actions – a system that is severely diluted and delayed if separated from the device and its end user. Consequences could be injury to practitioners and / or patients, or in a worst-case scenario, even the death of a patient. This might seem extreme – but as illustrated earlier, it can and has happened.

Summary

During the COVID-19 pandemic, and as the UK emerges from it, a huge burden of responsibility will be placed on hospital engineering departments to keep equipment available and functioning correctly to facilitate the increased level of patient throughput which will be required to reduce the waiting list backlog (believed to be around 5.1M people in February 2021).

As recognised by the Association of British Healthcare Industries (ABHI)[8], medical device manufacturers have the expertise – and the capacity – to support engineering departments, giving them the confidence of a trusted partner to manage the medical devices in their care.

References

Ref 1: https://resources.hse.gov.uk/convictions-history/breach/breach_details.asp?SF=BID&SV=4410571001

Ref 2: https://app.croneri.co.uk/law-and-guidance/case-reports/health-and-safety-executive-v-royal-berkshire-nhs-foundation-trust

Ref 3: https://www.legislation.gov.uk/uksi/1998/2306/contents/made

Ref 4: https://www.hse.gov.uk/legislation/hswa.htm

Ref 5: https://www.legislation.gov.uk/uksi/1999/3242/contents/made

Ref 6: https://apps.who.int/gho/data/view.main.BIOENGHWF8v

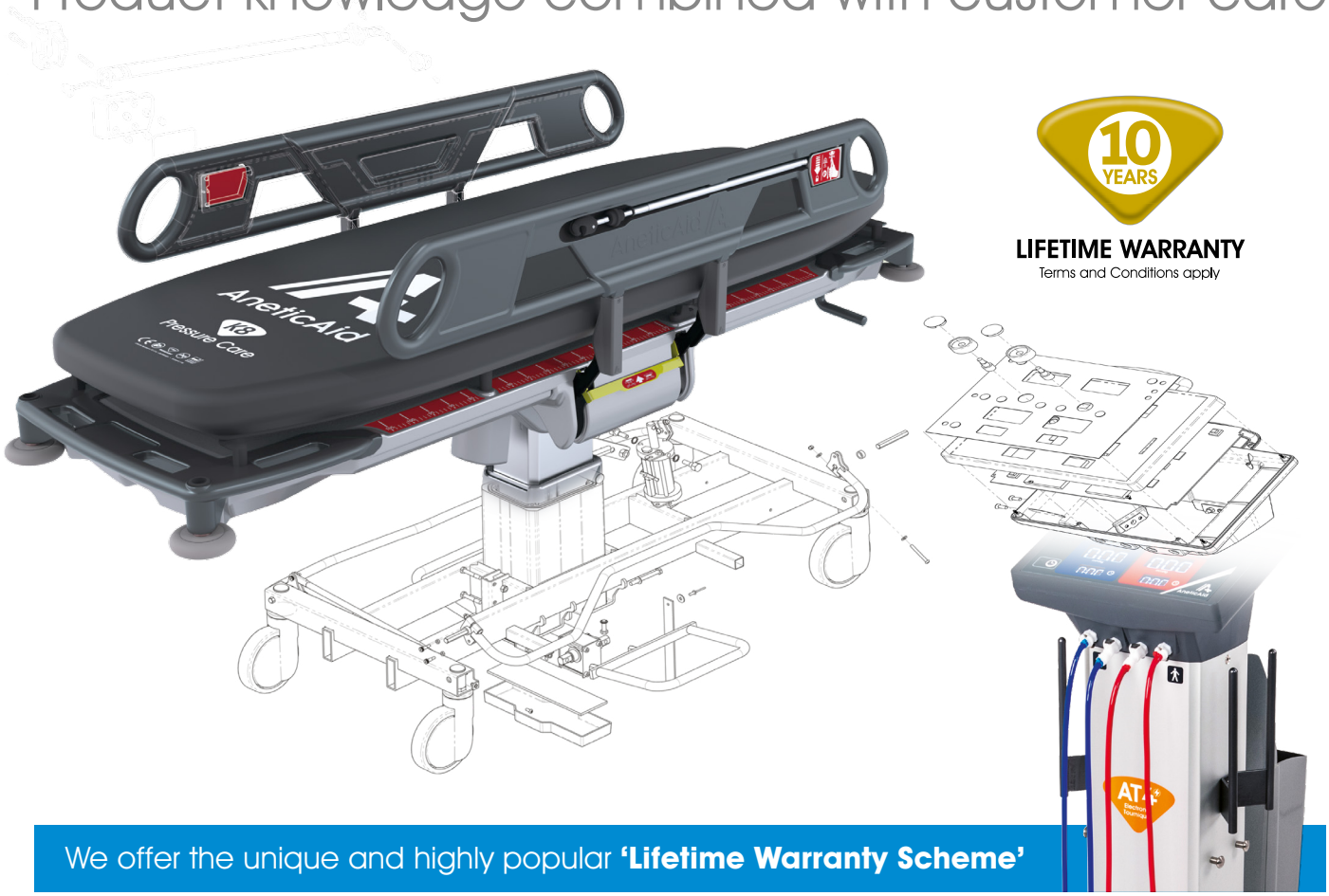
Ref 7: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf

Ref 8: https://www.abhi.org.uk/multimedia/docs/industry-recommendations/abhi-industry-recommendations.pdf

AneticCare®

Service & Maintenance

Product knowledge combined with customer care



We offer the unique and highly popular **'Lifetime Warranty Scheme'**

Safety and peace of mind – all our service plans are fully compliant with MHRA 'Managing Medical Devices' and CQC guidelines

Monitoring and auditing – to ensure timely, preventative action to optimise performance throughout a product's life

Cost savings – we offer simple, structured pricing plans

Ease of administration – we liaise with your clinical team, planning service schedules to minimise equipment downtime

Expertise – as a UK Designer / Manufacturer we use only original parts, fitted by our own locally-based and fully-trained engineers for a swift 'fix first time' policy

Training – we provide free, certified end-user training programmes on all equipment

For more information on any of our products or service contracts, call:

sales@aneticaid.com **+44 (0)1943 878647** aneticaid.com

Innovative **Medical** Technology - **Practically Applied**

Anetic Aid Ltd, Sapper Jordan Rossi Business Park, Otley Road, Baildon BD17 7AX, UK

AneticAid®