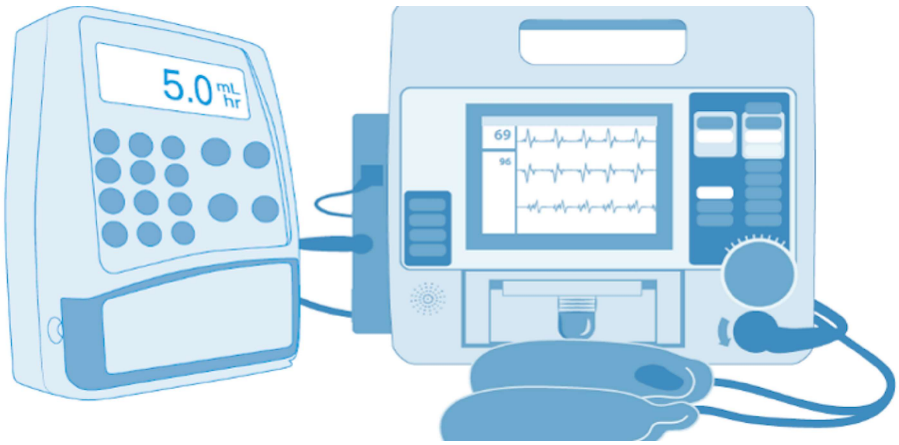
Choosing the right test tools for medical device maintenance

BY LEWIS LENNARD 27 JUNE 2022 14:00

Lewis Lennard, application engineer, Rigel Medical examines the ways to choose test tools for medical device maintenance.



Clinical/biomedical engineers are metrologists who use medical equipment to measure things. Understanding specification is key to choosing the correct test tool. Manufacturers recommend test tools, which, of course, should be understood. But if a medical equipment manufacturer is brand-specific toward a test instrument in a service manual, engineers should be aware of the underlying 'or equivalent' message.

Many Rigel Medical instruments are, indeed, in service manuals, but there should be a freedom of choice and to determine the requirements of the equipment under test to decide what the best options are. Evaluate; look at alternatives; demo equipment. That is the fun part of the job.

Maintenance of medical devices

The overall aim of medical equipment maintenance schedules is to inhibit medical device failures or inaccuracies from occurring. This is crucial in healthcare where severe failures could lead to serious injury or death and whereby prevention of patient

harm is of the upmost priority. Maintenance is essentially risk management of medical devices.

The simplest, short-term solution for a clinical engineering department is to develop preventive maintenance (PM) schedules strictly based on the Original Equipment Manufacturer (OEM) recommendations, because they state specific testing steps and recommended testing tools in their service manuals or individual PMs.

This can affect decision making during procurement of test tools. However, references to specific devices become irrelevant if the same technological measurement characteristics exist, as this will not adversely affect any maintenance schedule.

Alternatives to preventative maintenance

The same applies to alterations of some PM procedures. If there is documented evidence for an alternative maintenance schedule, where patient care is not adversely affected, then a department can implement their own methods and frequencies of testing. This is dependent on local legislation, but it has been the norm for a while in some countries.

During development of alternative methods, the risk, clinical need, cost, and resource must all be determined. Even a small healthcare facility will have an abundance of various medical devices, and for them to be maintained successfully, a thoroughly planned management system should be implemented.

Despite the initial cost and resource, developing alternative maintenance schedules, combined with carefully selected biomedical test tools can lead to improved efficiencies and use of staff time, whilst producing reliable data, mitigating risk, and ensuring medical device quality assurance.

Quality management in healthcare

Quality management systems (QMS) are policies and procedures developed to improve how an organisation functions to enhance customer satisfaction. The customer in healthcare is the patient, so the primary purpose is to make overall patient care better. ISO 13485 is designed to be used by organisations involved in the design, development, installation, and servicing of medical devices.

Healthcare technology management (HTM) professionals, such as clinical engineers and biomedical equipment technicians (BMETs), may not be responsible for these quality management systems, but they are responsible for providing quality improvement due to their expertise on the maintenance and the testing of medical devices. This way HTM professionals and risk managers work harmoniously to produce quality management procedures that benefit the healthcare organisation.

Accreditation and certification programmes are available for HTM departments to implement. When considering a QMS for a HTM department, it is important to understand that ISO 9001 forms a solid framework, but it's beneficial to include elements from ISO 13485, to have aspects more specific to medical devices.

Risk management in healthcare

ISO 14971 is an international risk management standard for medical devices, and it is mandatory in many countries. The standard emphasises on how to reduce risk of medical devices during the OEM stages of the product lifecycle.

The risk manager in a HTM department will be responsible for implementing risk management processes for the post-production stages of a medical device’s lifecycle.

They do this by developing policies and procedures that help to measure, maintain, and reduce risk. A “risk-based-thinking” QMS uses continual risk analysis within the organisation to simultaneously maximise uptime whilst minimising risk.

The QMS and risk management standards that medical device manufacturers use are also important for a clinical engineer to understand, as it demonstrates how and why an OEM produces its specifications and PM schedules.

ISO 13485 for example, specifies the requirements that an OEM must follow to ensure their medical devices meet the applicable regulatory requirements. Part of this standard specifies that design verification must confirm that the end-product meets the design specification.

Simply put, the technical specifications of the medical device must meet the IEC 60601-1 electrical safety standards and the IEC 60601-2 performance and safety standards.

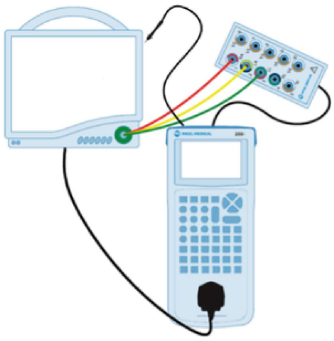
Performance and safety standards

Let’s take a section of the IEC 60601 series as an example - the output energy accuracy of a defibrillator. IEC 60601-2-4 establishes the requirements for cardiac defibrillators for manufacturers’ adherence. It specifies that the delivered energy from a defibrillator into a range of impedances must not vary by more than +/-3J or +/-15 %, whichever is greater, at any energy level. The manufacturer must design a product with a specification greater than or equal to this specification.

The product lifecycle of the defibrillator is passed onto the clinical engineer. A defibrillator analyser would be ideal for this as it covers all the recommended performance tests. This does not necessarily have to be the test tool recommended by the OEM, but it does have to test to the same parameters.

This is applicable when testing all medical devices in a HTM department. Any test tools would be satisfactory, and it’s ultimately a freedom of choice, if the risks are understood.

Importance of test tools



There are multiple factors that could affect the safety or accuracy of a device. Wear and tear in high stress environments, quality of the products, and manufacturing defects are all potential causes in healthcare. This is in addition to calibration drift, where all types of electronic measurement equipment will drift into inaccurate states over time.

The regular checks and tests recommended by the OEM ensure that the safety, accuracy, and precision are maintained throughout the product lifecycle to acceptable standards, protecting the patient. This is known as preventative maintenance and can be broken down into three main categories: scheduled maintenance, performance verification and safety testing.

This is where the importance of choosing the right biomedical test equipment becomes evident, because both safety testing and performance verification can be streamlined using the right tools.

Preventative maintenance

Many departments perform equipment maintenance based on OEM recommendations and will base their procedures and even their test tool purchases on them. This is regardless of the criticality of the device, which may not be the most efficient or effective system for a department that has limited resource.

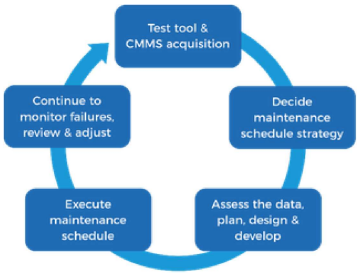
The reason this type of schedule-based maintenance is implemented is because it's the simplest form of preventive maintenance to execute and understand. It is a schedule based purely on manufacturer service processes. The alternative is to develop a risk-based or evidence-based maintenance schedule.

A bowtie analysis is ideal for the planning and design of a schedule. Healthcare departments rely on many controls to ensure patient safety. In a bow-tie analysis, preventative maintenance is a control that helps prevent adverse events from occurring. There must be an understanding on what these controls are, and if they fail, what impact that has.

For example, if a defibrillator has not been tested for its output energy levels, it is unlikely to be out of specification. Nevertheless, the risk is high.

Alternative equipment maintenance

There have been several studies that prove scheduled-based maintenance is prohibitively expensive and uses up excessive employee resource that is already scarce in most clinical engineering departments. As the sheer number of medical devices increases, medical device management will only become more resourceful.



The implementation of evidence-based, or risk-based maintenance is possible for non-critical medical devices by evaluating the reliability, which can increase departmental efficiencies and streamline PM schedules. However, the creation of alternative equipment maintenance (AEM) schedules requires initial resource, expertise, responsibility, and detailed documentation. It involves not only thorough planning and execution, but also a consistent review of the results and risks, where amendments can be made if required.

One example of designing an AEM uses the method by *Fennigkoh and Smith*, which was proposed a few decades ago but is still in use today. It relies on three factors:

EM = CF + PR + RM

Where: **EM** = the equipment maintenance number, **CF** = the critical equipment *function,* **PR** = the *physical risk* to patients, and the **RM** = the required *maintenance.*

The higher the overall risk, the greater the EM number. This model permits clinical engineering departments to emit certain scheduled maintenance tasks for pieces or types of lower risk medical equipment and PM intervals are specified corresponding to a risk level of critical devices. This is only possible if these tasks can be emitted without impacting safe and reliable performance. There must be a detailed and documented evaluation on how this will not impact patient safety.

The hospital must continue to assess the risk of the alternative equipment maintenance schedule and provide data that it has assessed the maintenance track record. Medical device tests results help to optimise maintenance intervals.

Most clinical engineering departments employ CMS to track medical device history, which helps to identify and mitigate risk. Accurate and repeatable measurements that are recorded for performance and safety of medical devices ensures that the CMS data is consistent and true. The use of appropriate test equipment ensures test result data is stored properly and tests trends can be monitored over time. Traceability of measurements to national standards provides assurances that the recorded results are accurate and repeatable.

Metrology in maintenance

In clinical engineering departments, metrology is important to understand when testing medical devices and choosing the right biomedical test tools.

For example, BS 70000 in the UK, states the requirements for quality, safety, and competence in clinical engineering, also specifies an understanding of uncertainties, equipment implementation and traceability of measurements.

University hospitals have begun to adopt this standard, where clinical scientists are already forming their own internal test procedures and equipment maintenance systems. An understanding of these principles helps the clinical scientists evaluate the risk.

Testing, measurement and metrology

In any test and measurement setup, the measurement value of a device under test (DUT) is compared with those of a calibration standard of known accuracy. Performance testing of medical devices is referred to as calibration in some countries.

A standard could be a measurement or source device. An electrosurgical analyser measures the power readings of an ESU output. A patient simulator generates an ECG signal to test a patient monitor.

Best practise guidance for traceability, has a “10:1 ratio” for the calibration of measuring equipment. In other words, the measuring instrument should be 10 times as accurate as the device being measured. In practice however, this is unrealistic. A test accuracy ratio (TAR) of 4:1, or even 1:1, is considered acceptable if the risk is understood.

The accuracy of the delivered defibrillator energy compared to the measured accuracy of the tester or ‘known standard’ (the Rigel UniPulse 400) is a good example of this.

Specsmanship

Specifications or measurement results of one tester might be over-specified to establish an irrelevant advantage of one device over another, a practise sometimes referred to as specsmanship. An acceptable test accuracy ratio is the factor to consider when purchasing a test tool, so it’s important to not become absorbed in comparing like-for-like test equipment specifications.

Biomedical test equipment

An OEM may specify a recommended biomedical test device in their service manual or PM, but any alternative device with the same technological characteristics could be implemented. Specialised equipment is not a requirement. It can be substituted for standard test and measurement equipment that is still often found today in clinical engineering departments. It is the convenience that drives the need for specialised equipment.

Performing measurement tasks manually is much more challenging and highlights why the majority of HTM departments utilise specialist equipment. In fact, the world health organisation recommends utilisation of biomedical test equipment in their global medical equipment maintenance programme overview. This is because it effectively reduces clinical engineering resource, improves test accuracies and reading repeatability, when compared to traditional test and measurement methods.

The hospital will also be able to provide better evidence with accurate data when evaluating and testing their alternative equipment maintenance system. This further reduces the risks and improves overall efficiencies.

Conclusion

The demand for biomedical test equipment is clear and already widely understood, but how does a department decide on their purchase if a manufacturer has recommended a particular device?

Accuracy, precision, and function clearly need to be a considered and understood for any test and measurement device purchase. It is unnecessary to over-specify the ranges, limits, or functions. The parameters need to be appropriate for the application. Purchase descriptions could be over-specified due to a particular test tool being recommended in a service manual or PM, but this does not necessarily correlate with the specifications of the medical device.

In the same way a risk-based programme is developed instead of a preventive maintenance programme, alternative like-for-like biomedical test devices can be employed instead of recommended ones. There is no credible reason to not implement an accurate device.

An assessment should be made by the department to ensure that prospective test equipment is accurate and has measurement methods that are equal to the alternative within the medical device maintenance steps.

Best practise for the choice of test tool is ultimately down to user preference and what is fit for purpose of the required solution. The department can decide on factors as they would with any other product, such as budget, portability, simplicity, or the level of after-sales support and service a manufacturer offers.

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