Making Informed Decisions When Testing Medical Equipment

Passionate about patient safety.

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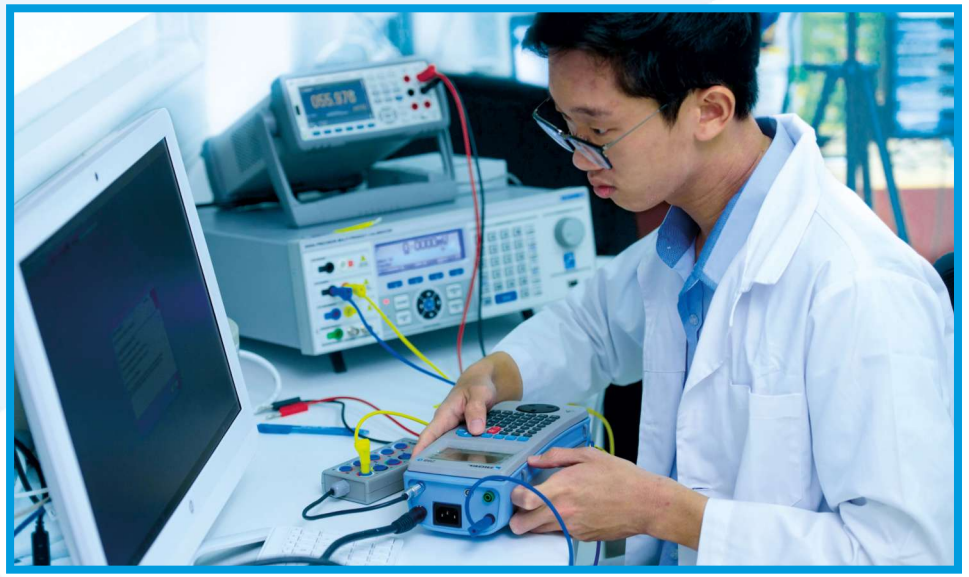
The ‘Equivalent’ Message

- Original equipment manufacturers (OEMs) recommend test tools, which needs to be understood
- Clinical/biomedical engineers are metrologists
- Understanding specification is key to choosing the correct test tool
- Engineers should be aware of the underlying ‘or equivalent’ message

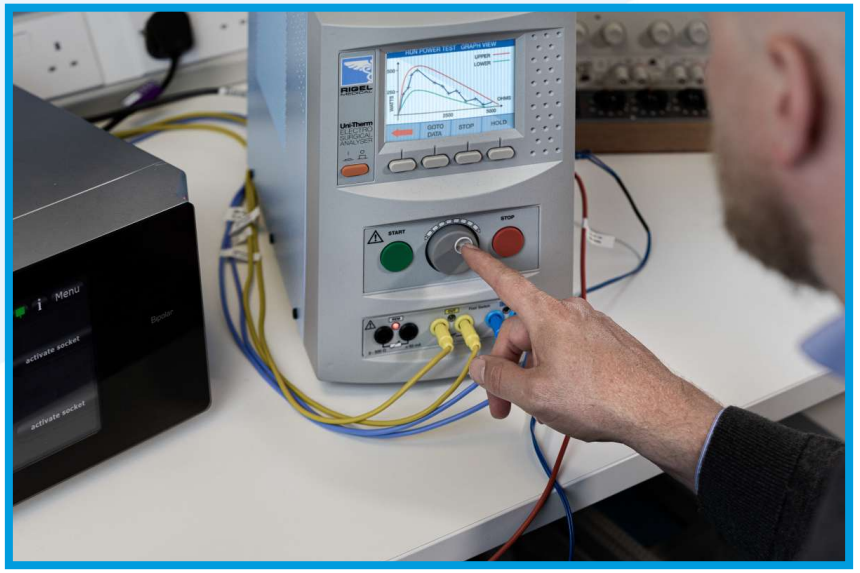


The ‘Equivalent’ Message

- There should be a freedom of choice
- To determine the requirements of the equipment under test to decide what the best options are:
  - Evaluate
  - Look at the alternatives
  - Trial demo equipment
  - Realise user preferences
- That is the fun part of the job!

Maintenance

- Objective - Inhibit medical device failures or inaccuracies from occurring
- Essentially Risk Management
- Simplest solution? PM schedules based strictly on OEM recommendations:
  - Specific testing steps and intervals
  - Recommended test tools
- References to specific devices are irrelevant if the same measurement characteristics exist
- Alterations to PM procedures



PM Alternatives?

- Must be documented evidence for an alternative equipment maintenance (AEM) schedule
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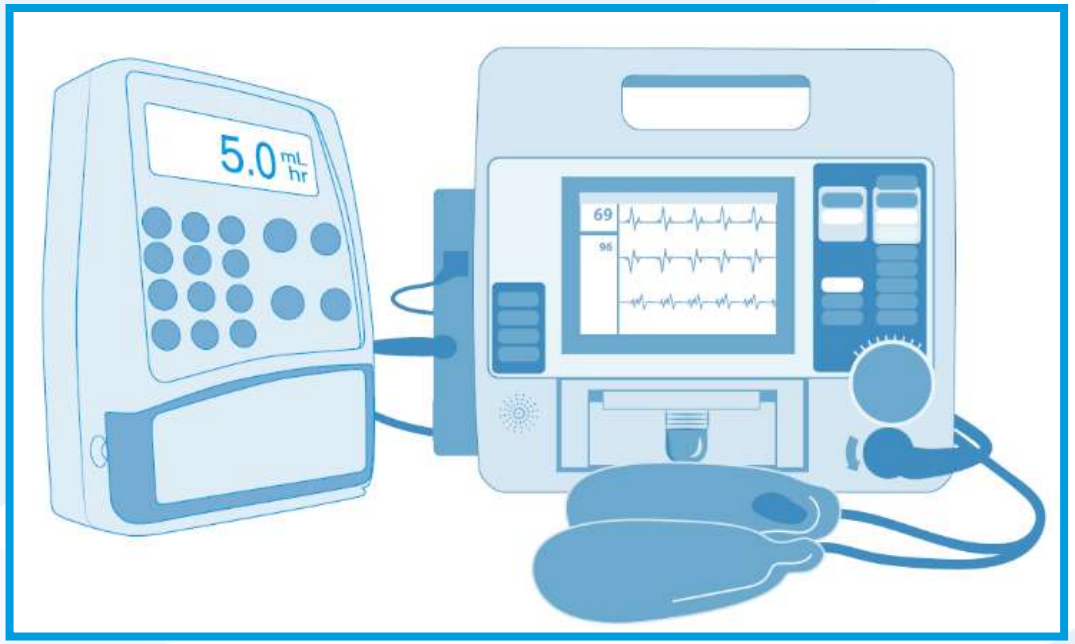
- If patient care is not adversely affected, then a department can implement own methods and frequencies of testing
- Depends on local legislation, but it is the norm in some countries



Development of AEM

- What needs to be considered
  - The HAZARD and RISK
  - The clinical need
  - The cost
  - The resource
- A thoroughly planned management system should be implemented for efficiency
- Developing an AEM
  - Better use of staff time
  - Reliable data
  - Mitigating risk
  - Quality assurance

Real World Examples

Defibrillators

PIP Test Equipment

To perform the PIP, use only the equipment listed in the Test Equipment Requirements table (Table 5.1 on page 102). Although the table lists specific test equipment by manufacturer, test equipment with equivalent specifications may be substituted.

NOTE: Using test equipment other than that specified in the Test Equipment Requirements table may provide test results that are different from those specified in this manual. It is the responsibility of the bio-medical personnel who maintain this device to determine test equipment equivalency.

NOTE: SpO2 monitor/probe accuracy can not be accessed using functional test equipment. Unlike many other types of medical electrical equipment, SpO2 (pulse oximeter) equipment is not designed to be calibrated after it leaves the factory. Currently there are no accepted method of verifying the correct calibration of a SpO2 (pulse oximeter) monitor/probe combination other than testing on human beings. Source: EN ISO 9919:2009 - 6.8.3 aa) 1) 2) and Annex FF.

a. Some energy meters are not accurate for biphasic waveforms; contact your defibrillator analyzer's manufacturer for more information.

*Equivalent equipment is required to meet the specifications listed in the specification column.

The following test equipment, or equivalent, is required to conduct the PIP.

Table 5.1—Test Equipment

Equipment	Specifications or Description	Manufacturer or Part Number
Defibrillator analyzer with external noninvasive pacer measurements[a]	Energy range: 0 to 450 J Load resistance: 50 Ω ±1% Accuracy: +/- 2%, non-inductive Waveforms: Simultaneous 12-lead output Rates: 30 bpm, 120 bpm, with rate accuracy of ± 1% Amplitude: 1 mV ± 5%, based on Lead II ECG performance: Amplitudes of Lead II and Leads V1-V6 are equivalent. Lead I = 70% amplitude of Lead II. Sine wave: 10 Hz @ 1 mV ± 2%, based on Lead II	[redacted]
Patient simulator	Simultaneous 12-lead output Rates: 30 bpm, 120 bpm, with rate accuracy of ± 1% Amplitude: 1 mV ± 5%, based on Lead II ECG performance: Amplitudes of Lead II and Leads V1-V6 are equivalent. Lead I = 50% amplitude of Lead II. Sine wave: 10 Hz @ 1 mV ± 2%, based on Lead II Blood pressure accuracy: ± 1% full scale, ± 1 mmHg	[redacted]
Safety analyzer	90 V ac rms to 264 V ac rms mains voltage Current range: 0-1999 µA Current accuracy: 5% of reading or 1 digit (whichever is greater) Insulation resistance test: 0.5 M ohm to 20 M ohm and 20 M ohm to 100Mohm Accuracy +/- 2% of reading + 0.2 Mohm +/- 7.5% of reading + 0.2 Mohm	[redacted]

Ventilators

A.3.2 Electrical Safety Tester

Electrical Safety Testing is required according to IEC-60601-1. A RIGEL 288, or similar equipment is required.

All tests can be performed using commercially available safety analyzer test equipment.

Patient Monitors

Hi-Pot Test Tools?

Commercially available general-purpose/medical test equipment

Item	Manufacturer part number/specification
Power supply	Variable, 0-28 VDC, 0.100A (minimum), with voltage and current indicators (for 1mA current measurement)
Digital pressure meter	[redacted] or equivalent
AC withstand voltage (hi-pot) tester	Associated Research 3605 or equivalent
Hi-Pot Return Test Probe	Associated Research 38082 Return Retractor
Hi-Pot High Voltage Test Probe	Associated Research 38083 Safe-T Probe (High Voltage Test Gun)
ECG Simulator	[redacted] or Equivalent
SpO_2 simulator (to test the monitor and SpO_2 sensor)	[redacted] or equivalent
Masimo SpO_2	
Functional tester, Masimo SET (to test the monitor only)	Masimo SET Tester 1795
Cable, Masimo SET, DB9-LNCS (4', 10', or 14')	LNC-04-WA 4' LNCS cable or LNC-10-WA 10' LNCS cable or LNC-14-WA 14' LNCS cable
Adapter cable, Masimo	1645, MAC-1 SpO2 adapter cable (LNOP-to-LNCS)
Nellcor SpO_2	
Functional tester (to test the monitor only)	Nellcor SRC-MAX
Extension cable (required for SRC-MAX)	Nellcor DEC-8
Syringe, 60-ml, Slip-tip, Luer	[redacted] or equivalent

IBP Performance Test

Tool required:

- [redacted] patient simulator, [redacted], or other equivalent device
- Dedicated IBP adapter cable (300B, P/N 00-002199-00) (use P/N 00-002198-00, if the simulator is [redacted])

Electrosurgical Generators

Recommended Test Equipment

- Digital voltmeter—[redacted], or equivalent
- True RMS voltmeter—[redacted], or equivalent
- Oscilloscope—[redacted], or equivalent
- Leakage current tester—Use UL load device or commercially available leakage tester
- Leakage table—per IEC 601-2-2, Figure 104
- 100, 200, 300, 500 ohm, all 250 watt, 1% tolerance, noninductive ([redacted] or equivalent).

Risk & Quality Management in Healthcare

Quality Management

- Quality management systems (QMS) are based on documented:
  - Policies
  - Processes
  - Procedures
- Purpose to make overall patient care better
- ISO 13485 – For design, development, installation, and servicing of medical devices -Suitable HTM departments?
- ISO 9001 forms a solid framework for any organisation, but its beneficial to include elements from ISO 13485, to have aspects more specific to medical devices

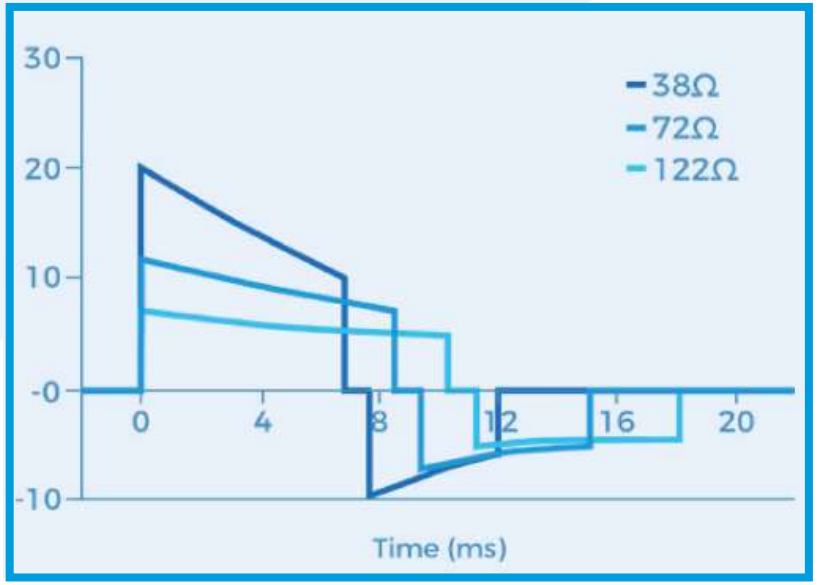
"ISO 9001 is implemented by over one million companies and organizations in over 170 countries" (ISO

Risk Management

- ISO 14971 is a risk management standard for medical devices – widely used
- Emphasises how to reduce risk of medical devices during design and manufacture
- In a HTM department, policies and procedures must be developed to measure, maintain and reduce risk
- A "risk-based-thinking" QMS uses continual risk analysis
- Done right can maximise uptime whilst minimising risk

Performance and Safety Standards Example

- Does the device meet the IEC 60601-1 and IEC 60601-2 performance and safety standards?
- For example, the output energy accuracy of a defibrillator (IEC 60601-2-4)
  - *"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 with this requirement in mind
- This applies to all steps and a device



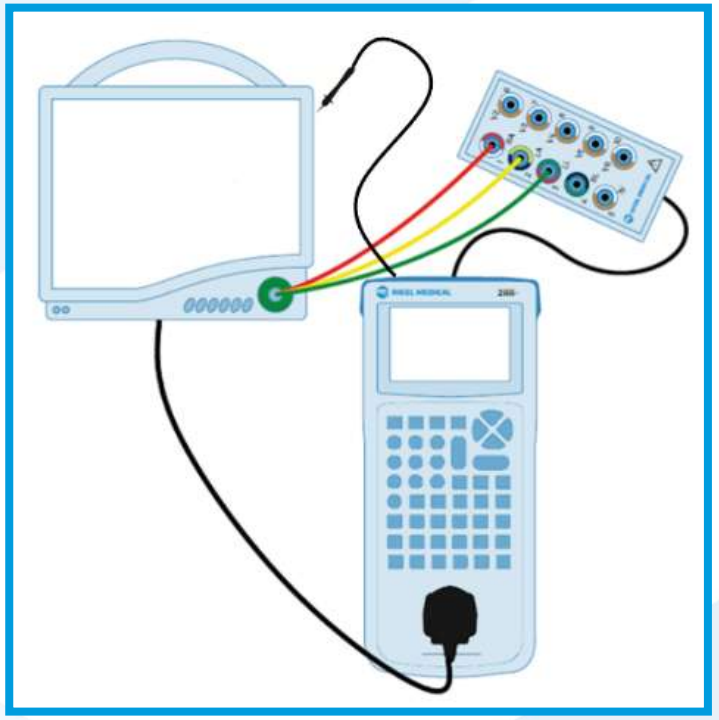
Maintenance Testing

- Standards DO NOT define specialist test equipment
- Dedicated analysers are ideal as they cover all the recommended 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

The Importance of Testing and Maintenanc

Is the Medical Device Accurate and Safe?

- There are multiple factors that could affect the safety or accuracy of a device in healthcare
  - Wear and tear in high stress environments
  - Quality of the products
  - Manufacturing defects
- This is in addition to usual calibration drift
- 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!



Testing and Performance Verification

- These regular checks can be broken down into three main categories:
  - Scheduled maintenance
  - Performance verification
  - Safety testing
- This is where the importance of choosing the right biomedical test equipment becomes evident
- Both safety testing and performance verification can be streamlined using the right tools

How to Development an Alternative Maintenance Procedure

Preventative Maintenance

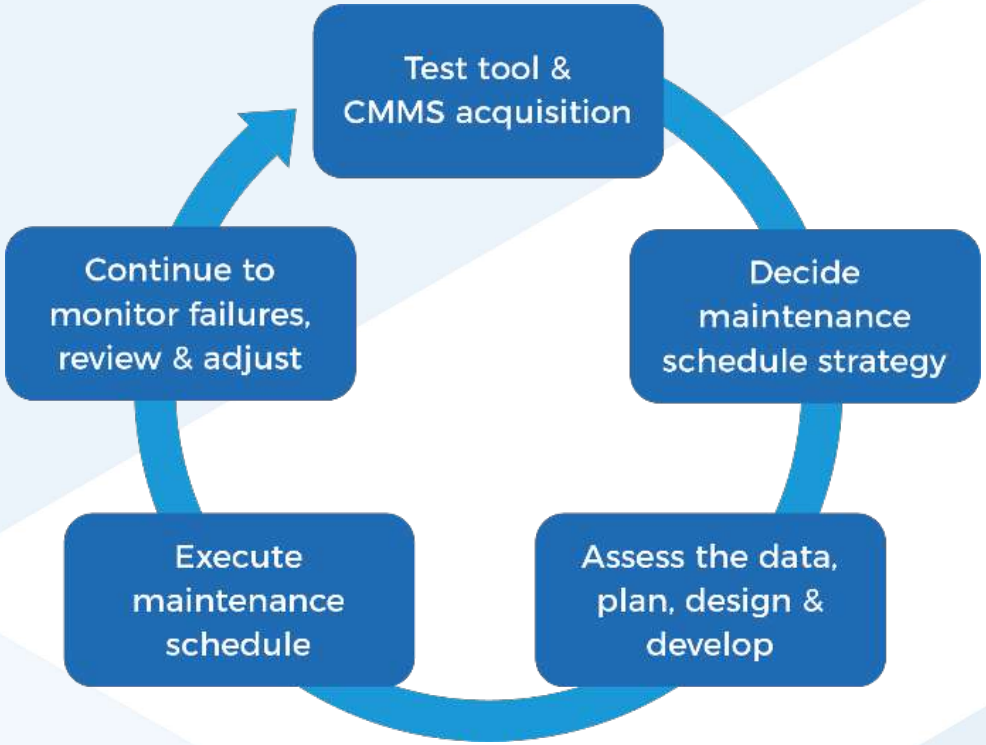
- Many departments perform maintenance based on OEM recommendations – base their procedures and even test tool purchases on them
- It is the simplest maintenance schedule to execute
- Based purely on manufacturer service processes – **schedule**-based
- The alternative is to develop a **risk** or **evidence**-based maintenance schedule

Alternative Equipment Maintenance (AEM)

- Scheduled-based maintenance is expensive and uses excessive employee resource – scarce in most clinical engineering departments
- Benefits of alternative maintenance
  - Increase departmental efficiencies
  - Streamline PM schedules
  - Constantly reviews the results and risks
- Disadvantages alternative maintenance
  - Initial resource and expertise
  - Responsibility and detailed documentation
  - Thorough planning and execution requi

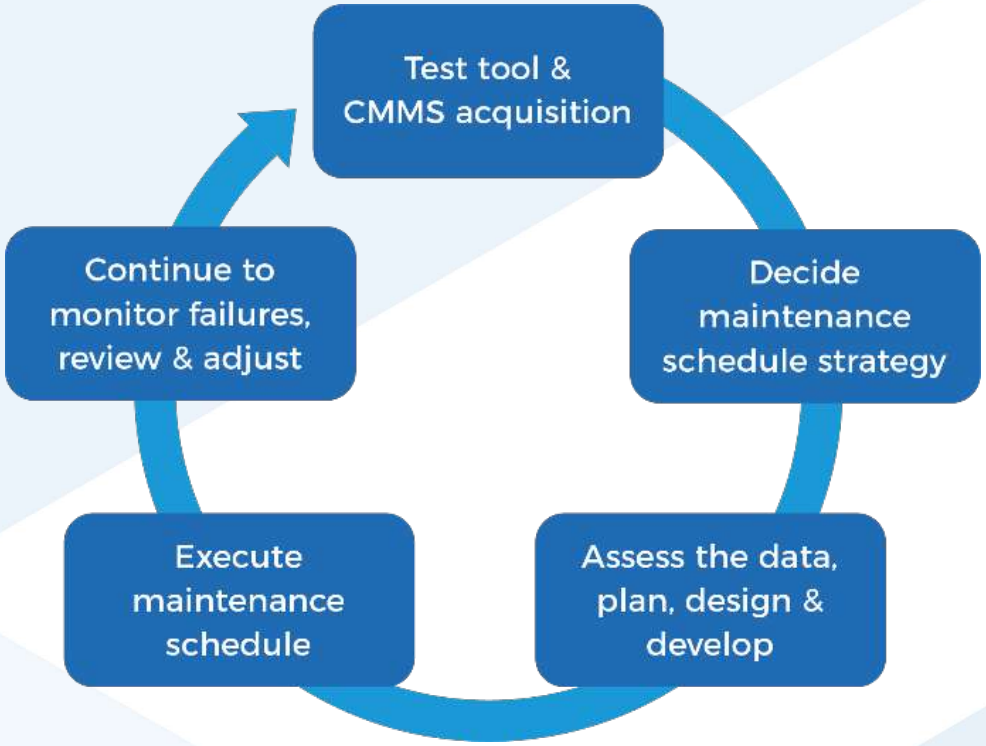
Developing an AEM

- Only emit scheduled maintenance tasks for lower risk medical equipment
- PM intervals are specified corresponding to a risk level of critical devices
- Tasks can only be emitted without impacting safe and reliable performance
- Must continue to assess the risk of the schedule and provide data that it has assessed the maintenance track record



Asset Management and Test Tools

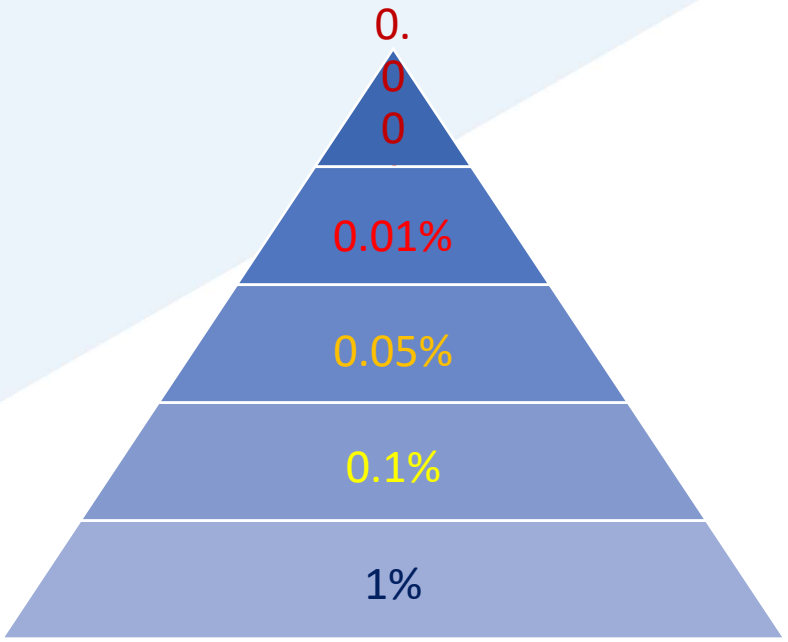
- CMMS track medical device history, which helps to identify and mitigate risk
- Medical device tests results help to optimise maintenance intervals
- Accurate and repeatable measurements ensures that the data is true
- Automatic test results mean that data is stored properly, and tests trends can be monitored over time



Testing, Measurement and Metrology

Measurement Standards

- The measurement value of a device under test (DUT) is compared with those of a calibration standard of known accuracy
- A standard could be a measurement or source device
- A test accuracy ratio (TAR) of 4:1, or even 1:1, is considered acceptable if the risk is understood
- For example: The accuracy of the delivered defibrillator energy compared to the measured accuracy of the tester or ‘known standard’ (the Rigel UniPulse 400)



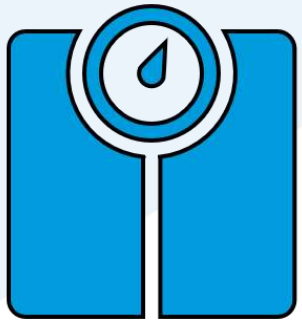
Specsmanship

- 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
- It's important to not become absorbed in comparing like-for-like test equipment specifications

The Biomed's Choice

Alternative Test Tools

- A recommended biomedical test device may be in a service manual or PM
- Any device with the same technological characteristics can be implemented
- With the right approach, a better choice will be made by customising a purchase to your organisation
- Hospitals will be able to provide better evidence with accurate data when evaluating and testing their alternative equipment maintenance system



The Biomed's Choice

- The demand for biomedical test equipment is widely understood, but how does a department decide on their purchase?
- Accuracy, precision, and function need to understood
- Needless to **over-specify** the ranges, limits, or functions…
  - Parameters need to be appropriate for the application
- Purchase descriptions or tenders may be over-specified due to a particular test tool being recommended in a service manual or PM
- This does not necessarily correlate with the specifications of the medical device
- Alternative like-for-like biomedical test devices can be employed instead of recommended ones – AEMs and service manuals are proof of that

The Biomed's Choice

- An assessment by the department ensures that measurement methods are equal to the alternative within maintenance steps
- Choice is ultimately down to user preference and what is fit for purpose
- A department can decide as they would with any product
- Budget, portability, simplicity, the level of after-sales support, or even a particular service a manufacturer offers

Please circle a number at the end of each question.					
Question	Not at all likely				Extremely likely
How would you rate the biomedical test tools for ease of use?	1	2	3	4	5
How would you rate the biomedical test tools for data storage and transfer?	1	2	3	4	5
How would you rate the biomedical test tools for portability?	1	2	3	4	5
How would you rate the biomedical test tools for streamlining your workflow?	1	2	3	4	5
How likely would you recommend this biomedical test tool purchase for our workshop / department?	1	2	3	4	5

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