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Webinar ▶ Wednesday

Jerry Zion presents:

Medical Device Quality Assurance Testing: Best Practices For Patient Risk Reduction

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Wednesday, June 28, 2017, 2:00pm ET

PRESENTER: JERRY ZION

Jerry Zion, Global Training Manager at Fluke Biomedical, is a renowned veteran in the medical device industry, and has more than 35 years of experience working in many capacities for hospitals and various medical device manufacturers. Jerry has spent the last decade at Fluke Biomedical as marketing manager, product manager, and pioneering the global training program. Jerry is an AAMI certified biomedical equipment technician, and holds a Bachelor of Science degree in Electrical Engineering Technology from Purdue University. Jerry also obtained a Master's in Management in Science and Technology from the Oregon Graduate Institute.

WEBINAR AGENDA: During this 60-minute presentation join Jerry Zion, Global Training Manager at Fluke Biomedical, as he discusses applying the Hypocratic Oath: "first, do no harm", Reducing patient risk using an effective quality management program; Sources of patient risk; Ensuring the clinical staff know how to get the most from their medical devices; Maintaining the medical device history record and compliance to GMP (repairs, inspections, etc.) as well as Keeping instrumentation current with Innovations in medical devices.

At the end of the session, participants will:
1) Understand the sources of patient risk.
2) Understand that human error is not managed using instrumentation or technology alone.
3) Understand how learning about the ways others have managed patient risk sources instructs/improves our own plans.
4) Understand the importance of maintaining the medical device history record is a responsibility the hospital Biomedical/Clinical Engineering Department cannot avoid under the USA FDA GMP 21 CFR requirements, even when repair, calibration services are outsourced.
5) Understand how establishing meaningful key performance indicators (kpis) and keeping daily visual management up to date helps us and visitors understand our role better, and our value in patient risk reduction.

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DON'T MISS THE WEBINAR WEDNESDAY'S Q&A

Our presenters will end today's webinar with a Q&A session. If you have a question, please submit it early by emailing webinar@mdpublishing.com.

All questions will be addressed at the end of today's presentation or the presenter will follow up with you offline.

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-Alero O.

"Webinar Wednesday's are an excellent resource for continuing education credits. We have found them to answer some of the questions we have had for specific equipment management, and the discussions on regulations and latest rules have been useful as well. Keep up the good work!"
- Leroy S.

Medical device quality assurance

Best practices for patient risk reduction

The Hypocratic Oath

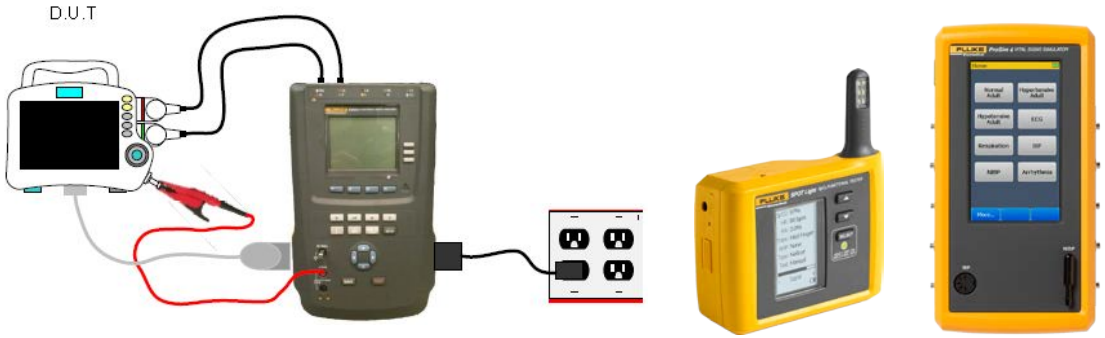
----first, do no harm----

The simple act of connecting a patient to a medical device exposes that patient to potential harm if the medical device fails. This is a risk that must be managed.

How do we do that?

Quality management program

1. Ensure the ongoing quality, safety and effectiveness of medical devices
2. Avoid medical device failures during critical medical procedures
3. Improve clinical effectiveness
4. Reduce total cost of device ownership
5. Uphold staff morale and professionalism through positive patient experience
6. Reduce patient risk and improve patient confidence
7. Comply with regulations and OEM recommendations



Medical device management plan: clinical factors

Device function

- What function does the equipment perform in a clinical environment?
  - Highest risk → life-support devices
  - Lower risk → with non-invasive, diagnostic devices

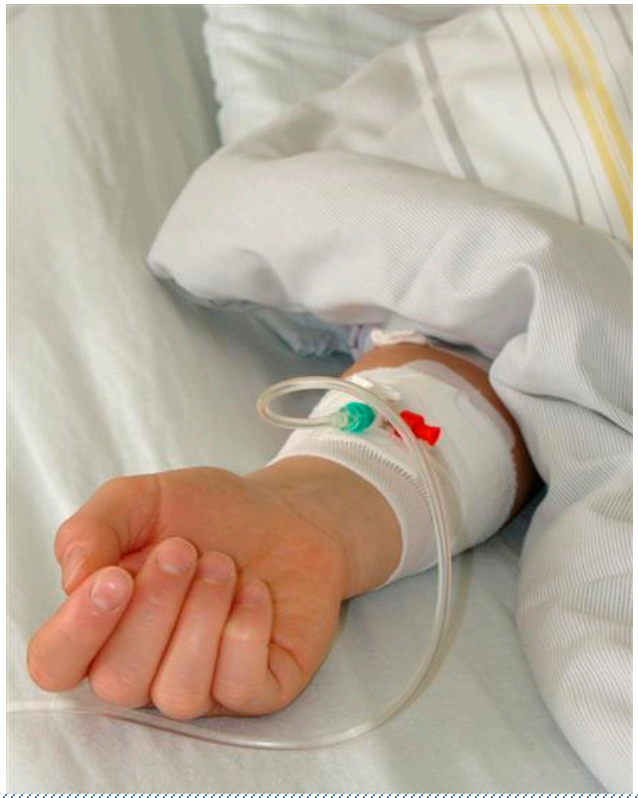
Risk of misuse or failure

- What are the possible consequences to the patient of a device malfunction or misapplication?
  - Range from “no significant risk” to death

Mission criticality

- What is the impact on overall hospital patient care or patient flow when the medical device in question is not available?
  - Critical, important, non-critical

Patient risk reduction

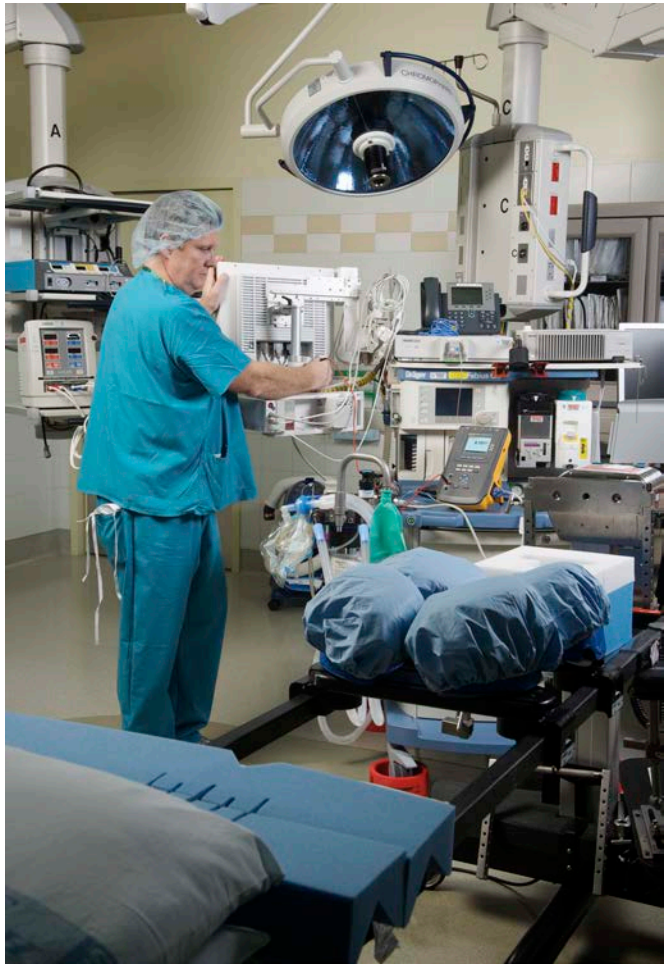


How do we ensure the continuous safety and effectiveness of medical devices in an systematic, repeatable way?

Medical device technology should:

1. Help sustain high quality of care provided to each patient
2. Facilitate faster/easier diagnoses to improve patient care/outcomes
3. Be safe to use at all times for both patients and staff
4. Maintain functionality and effectiveness throughout the life of the device

Quality assurance: maintenance factors



Manufacturer maintenance requirements

- Recommendations based on device type, design, and the components inside
- Compliance with standards

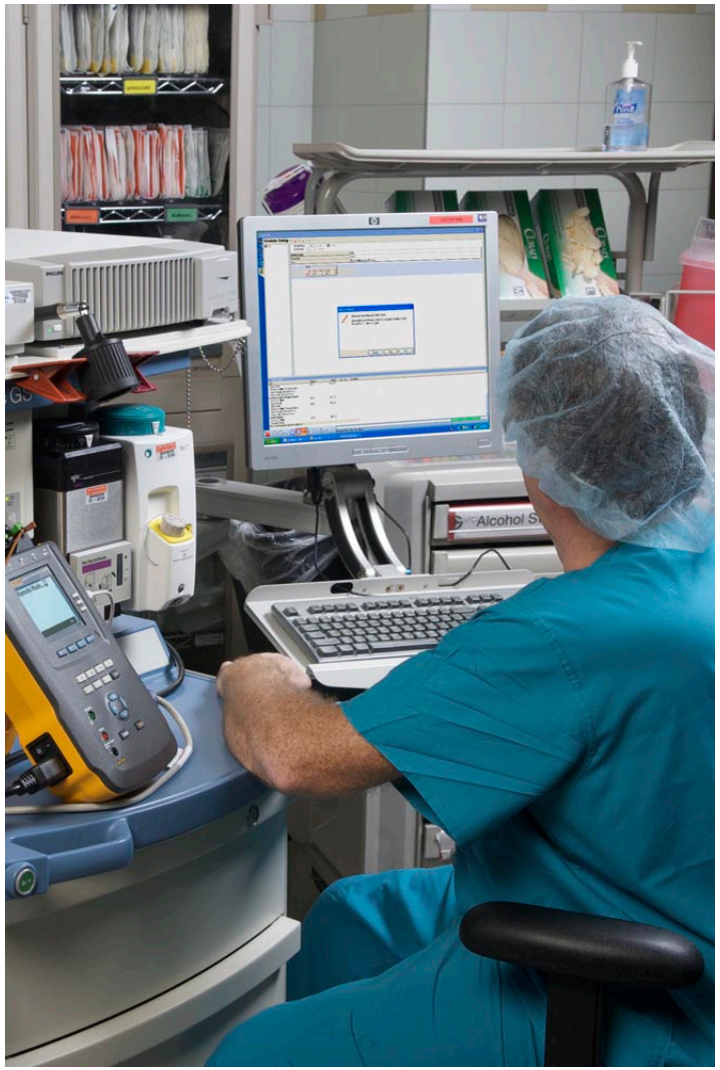
Equipment maintenance history

- How prone to failure is this device or group of devices?
- Maintenance sensitivity: device failures more likely in the absence of scheduled maintenance and testing

Organization and keeping track

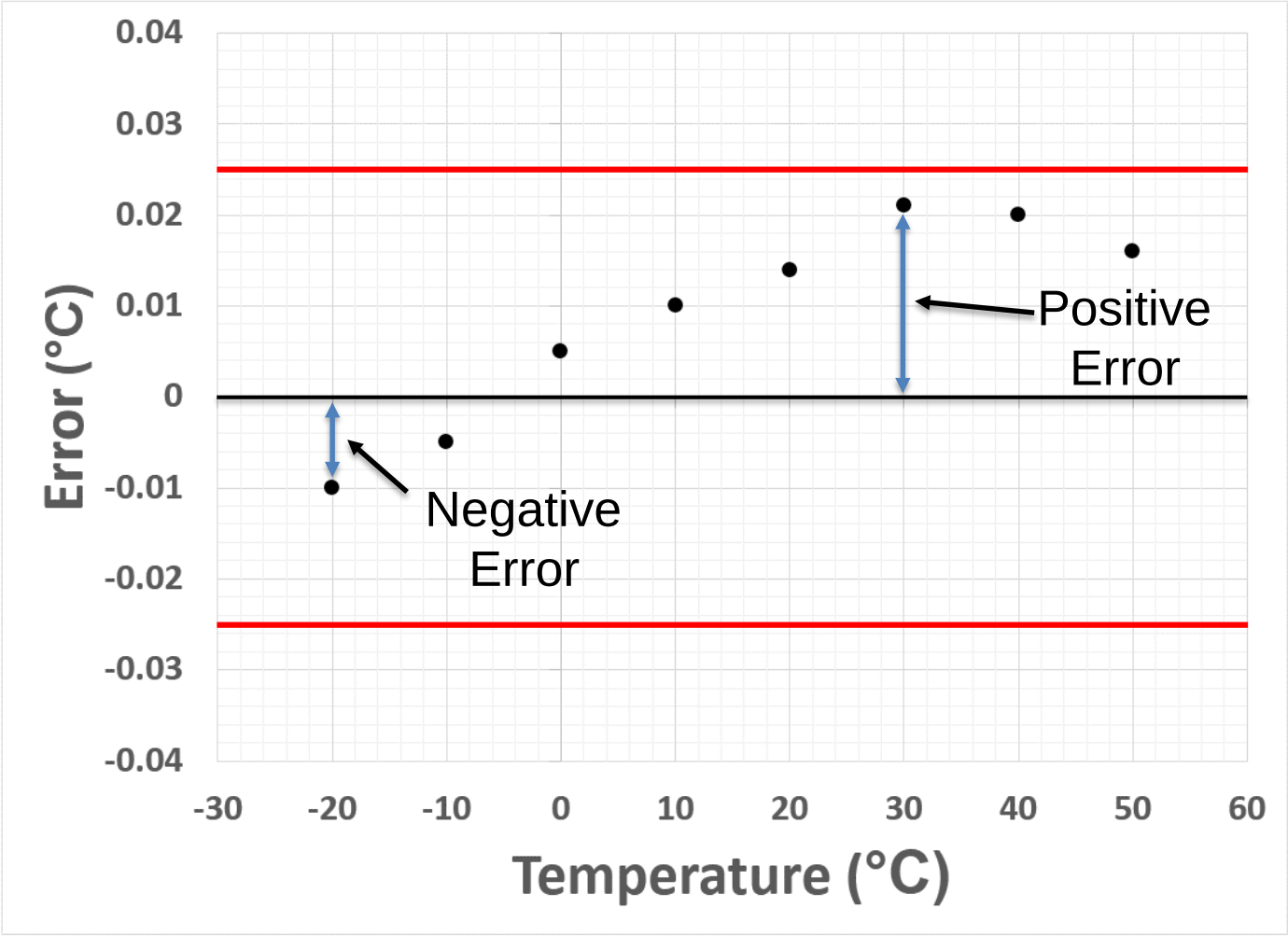
- Computerized maintenance management systems (CMMS)
  - Many providers worldwide
  - Some in-house-designed (Microsoft Access, etc.)
    - Keep track of medical device inventory
    - Help schedule and assign inspection work
    - Keep medical device history (repairs, inspections, etc.)
- Risk management databases
  - ECRI Institute Health Devices Alerts
  - ASHE Inspection system

All USA hospitals have Clinical Engineering services and most use a CMMS to track/organize/analyze and plan with quality assurance data

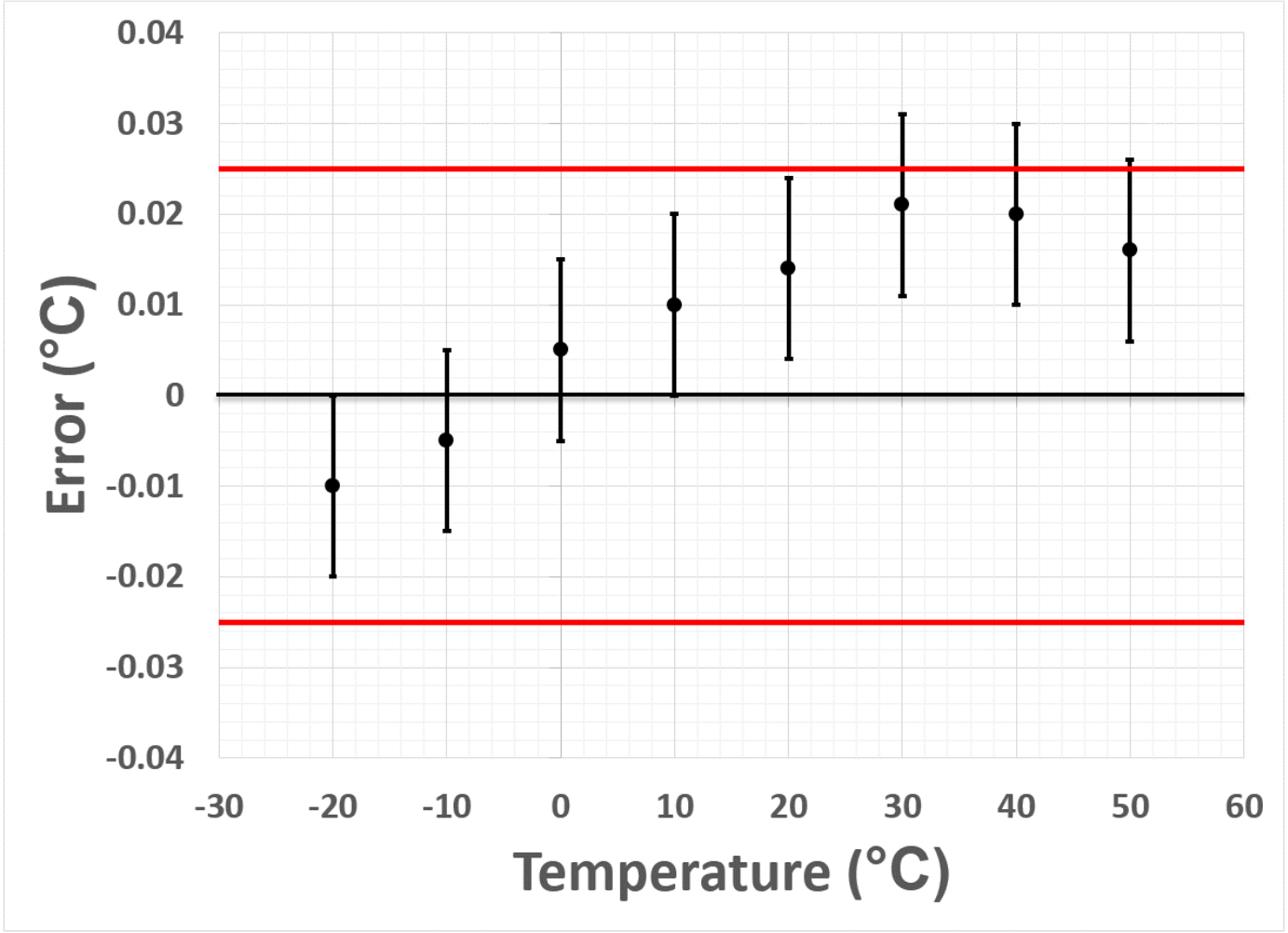


Accuracy vs Precision

What is Measurement Error?

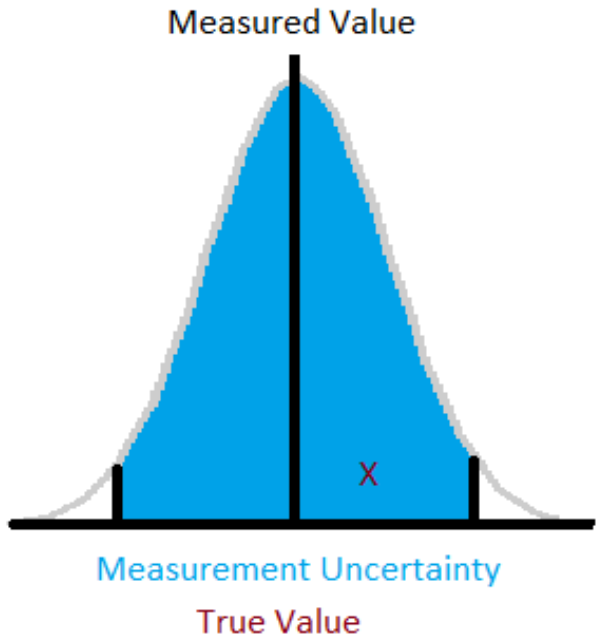


What is Measurement Error?

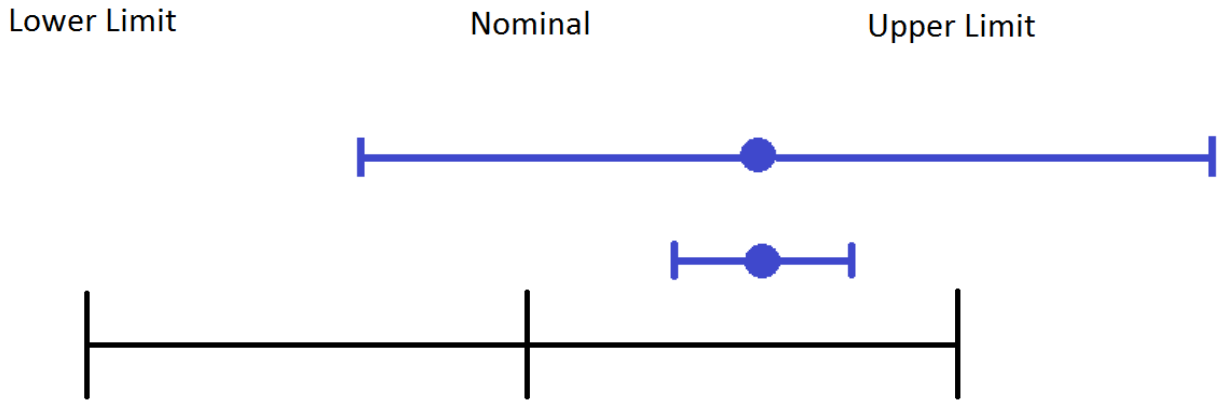


What is Uncertainty?

- A number that characterizes the dispersion of values attributed to a measurand, based on the information at hand
- An interval about the measured value that we are reasonably confident that the true value lies within
- How confident? Depends on what level you need
  - For most Calibration Labs, it is expressed at about 95%



Measurement Quality



- Measurement Decision Risk
- If your uncertainty is large compared to the specified requirement, how confident are you in your declaration of In Tolerance or Out of Tolerance?

What is Traceability?

Traceability *noun* | tra·cea·bil·ity | \trā-sə-'bi-lə-tē\

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

JCGM 200:2012 International vocabulary of metrology – Basic and general concepts and associated terms (VIM) 3RD edition

What is Traceability?

- Step-by-step transfer process
- Multiple steps extending to the SI
- Each transfer increases the uncertainty

Traceability – Unbroken Chain

Josephson Junction Array at Fluke, EVT USA

0.02 µV/V

DVMP

0.1 µV/V

0.5 µV/V

8 µV/V

50 µV/V

ESA 615 Production Cell

0.1%

Summary

- Metrology underpins our technology and affects patient risk
- Maintain traceability
  - Measurements not traceable? They are not VALID!
- Measurements matter
- Don’t know where to start?
  - See bipm.org
  - See FlukeBiomedical.com

Keeping up with the pace of change

- Innovations in medical devices change the way independent evidence of safety and effectiveness for clinical use is assessed
  - Example: CT scanners with increasing number of “slices” to improve resolution of images and accuracy of diagnosis
- Test instruments and systems change to accommodate innovation and new functionality, streamline data collection and analysis
  - Example: Defibrillator testing
    - Innovation: Impedance sensing functionality to ensure the energy selected is the energy delivered
    - Required change: Use of multiple test loads during testing, including the IEC/AAMI/ANSI 50 ohm test load

Assessing effectiveness

- Quantifiable outcomes:
  - Benchmarked schedule of preventive maintenance results in completion of X% of the plan (e.g., 96% PMs completed)
  - Medical device up-time/availability for use improves by X% (e.g., 25% improvement in up-time)
  - Cost of repair decreased by X% (e.g., 30% reduction in cost of repair)
  - “Spare” inventory of medical devices reduced by X% because main-line medical device inventory is more available (e.g., 30% reduction in medical device “spares” due to improvement in up-time)
- Key performance indicators (KPI’s) of performance/benefit of the medical device maintenance team
- CMMS database helps capture/analyze these metrics and helps to report quantified measures of success against plan and/or benchmark

Benchmarking

1. Growing pressures to reduce cost through efficiency and effectiveness

2. Medical device quality assurance can quantify, measure and drive efficiency and effectiveness

3. Benchmarking helps determine progress
   - Prove efficiency and effectiveness while still allowing for and evidence-based approach
   - Show the value delivered by investment in these efforts

AAMI Benchmarking resources

AAMI's Benchmarking Solution

Developed by clinical engineering experts, ABS provides detailed benchmarking information on all the important topics:

- Budgeting levels for maintenance, office expense, training, computers/software, and more
- Staffing levels allocated to management, repair, and other responsibilities
- Cost of maintenance contracts
- Hours spent on maintenance and repair
- Personnel qualifications and responsibilities
- Reporting structures
- Number of devices maintained by a CE program
- Percentage of scheduled inspections that identify a need for corrective maintenance

Designing and Developing CE Department *BI&T* November/ December 2011

How to Use Financial Benchmarks *BI&T* September/October 2011

Staffing Metrics: A Case Study *BI&T* July/August 2011

Benchmarking Basics: Cautions and Precautions *BI&T* May/June 2011

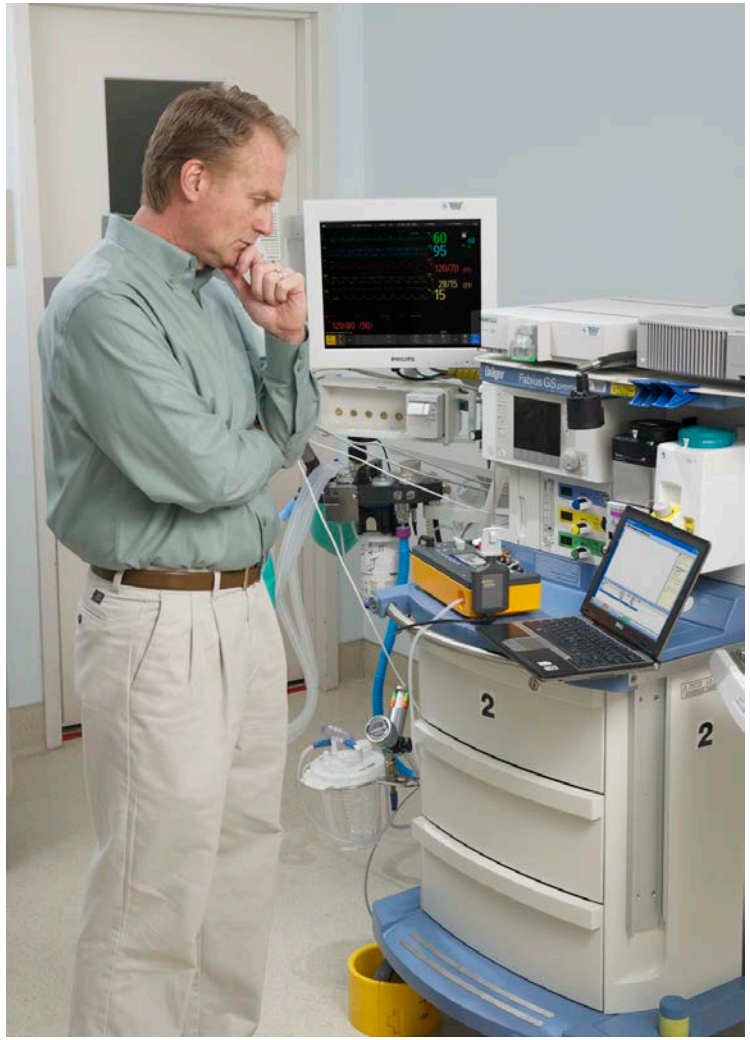
Benchmarking for More, *24x7 Magazine* April 2011

AAMI's Benchmarking Solution Enhanced with New Features *AAMI News*, Sept. 2010

Analysis of Cost of Service Ratio and Other Metrics *BI&T*, July/Aug 2010

It’s up to you---

- How well do you understand the goals and objectives of your MDQA program?
- How do you want the medical device to work if you, or someone you love is the next patient to be connected to it?
- Evidence is still a preeminent guide to determine test frequency and scope (*where allowed)



Opportunity for global collaboration

The growing global dedication to medical device quality assurance represents opportunity for global leadership through mentoring

- Medical device safety and performance standards (regulation)
- Clinical Engineering departments and their medical device management plans and experiences
- Interest and partnership in medical device quality assessment and reporting in other countries

Questions?

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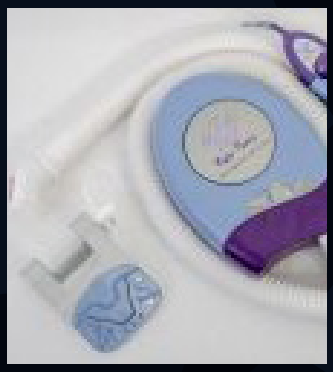

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