Test Method Validation (TMV)

Good Automation

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About Good Automation

- We develop custom automated test equipment (ATE) for medical devices
- We consult on Quality Management System (QMS) and FDA compliance
- Our deliverables include:
  - ATE software development
  - ATE software validation plans/protocols
  - Test method validation
  - Process validation
- We have strong partnerships and capabilities in the following software platforms:
  - National Instruments (NI), including Certified LabVIEW Architects (CLA)
  - Keysight (formerly HP / Agilent)
  - Microsoft
- Successful customer deployments:

GE Healthcare · Johnson & Johnson · Medtronic · Cochlear · Abbott

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Test Method Validation

What are the **objective** and **purpose** of performing tests?

Test Method Validation

Objectives vary from test to test

- Determine if a design works for its expected input range
- Determine if a device has a part installed correctly
- Determine if a machine can perform its job
- Determine if a calculation is performed correctly

Test Method Validation

The entirety of the FDA regulations pertaining to medical devices boils down to this quote:

"…to ensure that finished devices will be safe and effective…" *CFR 21 Part 820.1*

This is also the **purpose** of testing!

Test Method Validation

Test Method Validation is the practice of gathering objective evidence that the test fulfills its part in ensuring safety and effectiveness.

In simpler terms, Test Method Validation **proves** your test method does what you say it does.

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Test Method Validation

So is test method validation only to satisfy the bureaucracy of the FDA?

NO!

Its primary purpose is

patient safety

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Requirement for Test Method Validation

- 21CFR820.70(i) “When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.”
- 21CFR820.72(a) “Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results.”

Risk

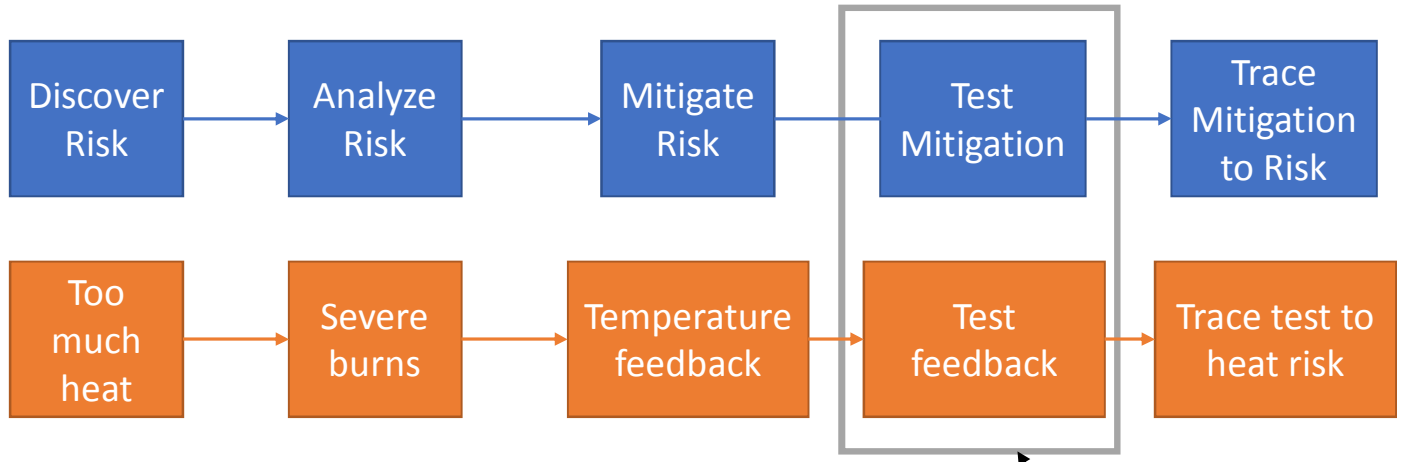
The FDA does not expect you to **guarantee** patient safety, but they do expect you to show a **low risk** of patient harm based on a **documented risk analysis** and **validated risk mitigation**.

Risk

The following slide shows a typical risk mitigation process.

- A risk of too much heat generated by a device is discovered. (or anticipated)
- The harm to patient is severe as the heat could result in burns
- A temperature feedback circuit is designed to turn device off if it gets too hot
- The feedback circuit is tested to ensure it is working

Risk



This is where validation comes into play

Test Method Validation

OK, so we found a problem, mitigated it, tested the mitigation to ensure it's safe… problem solved right?

No.

Current Good Manufacturing Practices, and the FDA, requires you to show that the test fails **every** bad unit and **only** passes good units.

Like any engineering effort, validation can be broken down into simple steps.

Test Method Validation

- Is the measurement system suitable?
  - Measurement system analysis (error stack-up)
  - Calibration methods
  - Gauge Repeatability & Reproducibility (Gauge R&R) Study
- Are other test conditions vital to the purpose being met?
  - “Measure voltage” vs “Measure voltage when…”
  - These conditions need verification tests: Is the “test right?”
- Combined “output package” demonstrated that the test method is accurate, repeatable, and correct- **objective evidence** that test covers risk

Direct Measurements

- Direct measurements are valid if the measurement pathway is suitable to take the measurement
  - Measuring a voltage
    - See specifications of meter
    - Confirm assumptions are met (calibration, temperature, sample time, etc.)
    - If assumptions are not met, confirm that they do not introduce unacceptable error
  - Measuring a voltage level produced by a transducer to get a physical quantity
    - Analyze errors of all of the components in the pathway
    - Combine errors appropriately

Accuracy vs Resolution

Accuracy: Offset from the **actual value**

Resolution: Smallest change in value the measurement equipment can discern

Resolution

The clock on the top has a one hour resolution.

It can be used to indicate if you are on-time for a meeting or if its time to go to lunch.

The clock on the bottom has a one minute resolution.

It can be used to indicate you have two minutes until your meeting starts.

Resolution

Neither clock is suitable for timing test operations because that requires sub-second resolution.

Plus…

Neither clock is supplied with annual calibration records so their accuracy is unknown.

Accuracy & Resolution

A stopwatch, on the other hand can be used to time events in small increments and can be calibrated annually.

Indirect Measurements

Indirect: requires additional analysis, depending on type of indirect measurement

Example:

Measuring average speed over a specified distance (1 mile pace for a horse)

- Measure a distance traveled
- Measure a time elapsed
- Calculate distance / time

Indirect Measurements

- Seems simple enough, but consider:
  - The measured distance has an accuracy error that will factor into our calculation
  - The measured time has an accuracy error that will factor into our calculation
  - AND an additional confounding error is introduced
    - if the track is too short (error in distance), the jockey can run the horse faster for longer, as he sees the finish line approach
    - Therefore, the speed is faster than it should be for a “1 mile” pace
  - Don’t forget about where those measurements were rounded along the way

Other Considerations

- How does rounding affect our calculations?
- Complex measurements will require additional validation activity
- Automated processes (software) will require additional validation activity

Test Method Validation

- Level and type of effort depend heavily on situation for test
  - Design verification/validation vs Production line: different types of risks
  - Severity of risks mitigated by the test
  - Direct vs Indirect
  - Complex software setup vs simple manual reading
- If the test covers multiple risks… use the most severe

Measurement System Analysis (MSA)

- Meter is only as good as…
  - Error source between device and transducer (friction, electrical noise)
  - Error from transducer (inaccuracy, nonrepeatability, hysteresis)
  - Error added during signal conditioning (nonlinearity, delay)
  - Error in measurement card (ADC, settling time)
  - Error in SW algorithms (truncation/rounding, filtering artifacts)
- Many of these do NOT come from a datasheet!

Measurement System Analysis (MSA)

- How do different errors combine?
  - Example- Tare removes offset errors but adds more random error
- What is my confidence interval?
  - Compare/interface with statistical quality metrics, define calibration references
- Error stack-up analysis
  - How do I infer distribution from a datasheet?

Don’t skimp on measurements

One expensive instrument can cost less than several false failures

Measurement System Analysis- (MSA)

- Top-Down:
  - Before you buy hardware to make sure it's the right hardware
  - Leave room in "error budget" for unexpected error sources
- Risk-Based:
  - Balance the cost of improved accuracy against the cost of Type I failures
  - Based on limiting Type II failures to an acceptable risk level
- Compliance:
  - Demonstrates equipment suitability
  - Part of 21CFR820.72(a)

Software

We may just be getting started. If your tester is automated, the software for that tester needs a validation of its own.

See *Software Validation.pptx* for details.